ELEVEN BIOTHERAPEUTICS, INC.

FORM 10-Q
(Quarterly Report)

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2016

OR

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

For the transition period from _____ to _____

Commission File No. 001-36296

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 October 31, 2016 : 24,238,369

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future product research or development, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "goals," "estimate," "expect," "intend," "may," "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

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

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

Our product candidates are investigational biologics undergoing clinical development and have not been approved by the U.S. Food and Drug Administration, or FDA, or Health Canada, or submitted to the FDA or Health Canada, for approval. Our product candidates have not been, nor may they ever be, approved by any regulatory agency nor marketed anywhere in the world.

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

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

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 30,716	$ 36,079
Restricted cash	94	—
Prepaid expenses and other current assets	952	232
Due from related party	50	—
Total current assets	31,812	36,311
Property and equipment, net	894	407
Restricted cash	10	94
Intangible assets	36,200	—
Goodwill	10,312	—
Other assets	350	13
Total assets	$ 79,578	$ 36,825
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,761	$ 1,246
Accrued expenses	2,492	1,794
Due to related party	697	—
Notes payable, current portion	—	4,134
Deferred revenue	1,250	406
Other current liabilities	65	—
Total current liabilities	6,265	7,580
Other liabilities	—	423
Notes payable, net of current portion	—	9,763
Due to related parties, net of current portion	117	—
Warrant liability	77	115
Deferred tax liability	9,774	—
Contingent consideration	21,900	—
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized at September 30, 2016 and December 31, 2015 and no shares issued and outstanding at September 30, 2016 and December 31, 2015	—	—
Common stock, $0.001 par value per share; 200,000,000 shares authorized at September 30, 2016 and December 31, 2015 and 24,155,161 and 19,619,124 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	24	20
Additional paid-in capital	161,201	144,126
Accumulated deficit	(119,780)	(125,202)
Total stockholders' equity	41,445	18,944
Total liabilities and stockholders' equity	$ 79,578	$ 36,825

See accompanying notes.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue	$ 28,650	$ 67	$ 29,156	$ 425
Operating expenses:				
Research and development	2,754	6,745	10,684	18,252
General and administrative	6,366	2,681	11,984	7,531
Total operating expenses	9,120	9,426	22,668	25,783
Income (loss) from operations	19,530	(9,359)	6,488	(25,358)
Other income (expense):				
Other income (loss), net	(43)	73	96	3,207
Loss on extinguishment of debt	—	—	(915)	—
Interest expense	—	(407)	(247)	(972)
Total other income (expense), net	(43)	(334)	(1,066)	2,235
Net income (loss) and comprehensive income (loss)	$ 19,487	$ (9,693)	$ 5,422	$ (23,123)
Net income (loss) per share — basic	$ 0.95	$ (0.50)	$ 0.27	$ (1.23)
Weighted-average number of common shares used in net income (loss) per share — basic	20,495	19,345	20,004	18,806
Net income (loss) per share — diluted	$ 0.91	$ (0.50)	$ 0.26	$ (1.23)
Weighted-average number of common shares used in net income (loss) per share — diluted	21,423	19,345	20,796	18,806

See accompanying notes.

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

	Nine Months Ended September 30,	
	2016	2015
Operating activities		
Net income (loss)	$ 5,422	$ (23,123)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	111	292
Non-cash interest expense	26	67
Stock-based compensation expense	3,351	1,895
Change in fair value of warrant liability	(38)	(3,186)
Loss on extinguishment of debt	221	—
Gain on sale of equipment	(14)	—
Changes in operating assets and liabilities, excluding impact of acquisition:		
Prepaid expenses and other assets	62	(311)
Restricted cash	(10)	—
Accounts payable	(648)	(179)
Accrued expenses and other liabilities	(1,189)	(568)
Deferred revenue	844	(35)
Net cash provided by (used in) operating activities	8,138	(25,148)
Investing activities		
Cash acquired in the acquisition	136	—
Sales (purchases) of property and equipment, net	283	(286)
Net cash provided by (used in) investing activities	419	(286)
Financing activities		
Proceeds from issuance of common stock and common stock warrants, net of offering costs	—	12,675
Payments on notes payable	(14,124)	—
Proceeds from notes payable	—	5,000
Proceeds from exercise of common stock options and warrants	204	62
Net cash (used in) provided by financing activities	(13,920)	17,737
Net decrease in cash and cash equivalents	(5,363)	(7,697)
Cash and cash equivalents at beginning of period	36,079	54,059
Cash and cash equivalents at end of period	$ 30,716	$ 46,362
Supplemental non-cash investing and financing activities		
Common stock issued in connection with the acquisition (Note 3)	$ 13,525	$ —
Fair value of assets and liabilities acquired in the acquisition (Note 3):		
Fair value of assets acquired in the acquisition, excluding cash and cash equivalents	$ 48,568	$ —
Fair value of liabilities assumed in the acquisition	$ 13,279	$ —
Issuance of warrants for common stock	$ —	$ 328
Supplemental cash flow information		
Cash paid for interest	$ 663	$ 644

See accompanying notes.

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

1. Organization and Basis of Presentation

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

On September 20, 2016, the Company entered into a Share Purchase Agreement with Viventia Bio Inc., a corporation incorporated under the laws of the Province of Ontario, Canada (“Viventia”), the shareholders of Viventia named therein (the “Selling Shareholders”) and, solely in its capacity as seller representative, Clairmark Investments Ltd., a corporation incorporated under the laws of the Province of Ontario, Canada (“Clairmark”) (the “Share Purchase Agreement”), pursuant to which the Company agreed to and simultaneously completed the acquisition of all of the outstanding capital stock of Viventia from the Selling Shareholders (the “Acquisition”). In connection with the closing of the Acquisition, the Company issued 4,013,431 shares of its common stock to the Selling Shareholders, which represented approximately 19.9% of the voting power of the Company as of immediately prior to the issuance of such shares of the Company's common stock.

In addition, under the Share Purchase Agreement, the Company will be obligated to pay to the Selling Shareholders certain post closing contingent cash payments upon the achievement of specified milestones and based upon net sales, in each case subject to the terms and conditions set forth in the Share Purchase Agreement, including: (i) a one-time milestone payment of $12.5 million payable upon the first sale of Vicinium ™ or any variant or derivative thereof, other than Proxinium ™ (the “Purchased Product”), in the United States; (ii) a one-time milestone payment of $7.0 million payable upon the first sale of the Purchased Product in any one of certain specified European countries; (iii) a one-time milestone payment of $3.0 million payable upon the first sale of the Purchased Product in Japan; and (iv) and quarterly earn-out payments equal to two percent (2%) of net sales of the Purchased Product during specified earn-out periods. Such earn-out payments are payable with respect to net sales in a country beginning on the date of the first sale in such country and ending on the earlier of (i) December 31, 2033 and (ii) fifteen years after the date of such sale, subject to early termination in certain circumstances if a biosimilar product is on the market in the applicable country. Under the Share Purchase Agreement, the Company, its affiliates, licensees and subcontractors are required to use commercially reasonable efforts, for first seven years following the closing of the Acquisition, to achieve marketing authorizations throughout the world and, during the applicable earn-out period, to commercialize the Purchased Product in the United States, France, Germany, Italy, Spain, United Kingdom, Japan, China and Canada. Certain of these payments are payable to individuals or affiliates of individuals that became employees or members of the Board of Directors of the Company (the "Board").

Each of the Company, Viventia and the Selling Shareholders has agreed to customary representations, warranties and covenants in the Share Purchase Agreement. The Share Purchase Agreement also includes indemnification obligations in favor of the Company from the Selling Shareholders, including for breaches of representations, warranties, covenants and agreements made by Viventia and the Selling Shareholders in the Share Purchase Agreement. In connection with the closing of the Acquisition, the Company deposited 401,343 shares of its common stock (representing approximately 10% of the Company's common stock portion of the aggregate closing consideration owed to the Selling Shareholders pursuant to the Share Purchase Agreement) into an escrow fund for the purposes of securing the indemnification obligations of the Selling Shareholders to the Company for any and all losses for which the Company is entitled to indemnification pursuant to the Share Purchase Agreement. The Share Purchase Agreement also includes indemnification obligations in favor of the Selling Shareholders from the Company, including for breaches of representations, warranties, covenants and agreements made by the Company in the Share Purchase Agreement.

As a result of the Acquisition, Viventia became a wholly owned subsidiary of the Company (See Note 3).

License Transaction

On June 10, 2016, the Company entered into a License Agreement (the “License Agreement”) with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (collectively, “Roche”), which became effective on August 16, 2016. Under the License Agreement, the Company granted Roche an exclusive, worldwide license, including the right to sublicense, to its patent rights and know-how related to the Company’s monoclonal antibody EBI-031 or any other IL-6 antagonist anti-IL-6 monoclonal

antibody, to make, have made, use, have used, register, have registered, sell, have sold, offer for sale, import and export any product containing such an antibody or any companion diagnostic used to predict or monitor response to treatment with such a product (collectively, the “Licensed Intellectual Property”).

Under the License Agreement, Roche is required to continue developing EBI-031 and any other product made from the Licensed Intellectual Property that contains an IL-6 antagonist anti-IL-6 monoclonal antibody (a “Licensed Product”) at its cost.

Financial Terms

The Company received an upfront license fee of $7.5 million from Roche and Roche agreed to pay up to an additional $262.5 million upon the achievement of specified regulatory, development and commercial milestones with respect to up to two unrelated indications. Specifically, an aggregate amount of up to $197.5 million is payable to the Company for the achievement of specified milestones with respect to the first indication: $72.5 million in development milestones, $50.0 million in regulatory milestones and $75.0 million in commercialization milestones. Additional amounts of up to $65.0 million are payable upon the achievement of specified development and regulatory milestones in a second indication.

The first development milestone payment for the first indication was paid in the amount of $22.5 million as a result of the IND application for EBI-031 becoming effective on or before September 15, 2016.

In addition, the Company is entitled to receive royalty payments in accordance with a tiered royalty rate scale, with rates ranging from 7.5% to 15% for net sales of potential future products containing EBI-031 and up to 50% of these rates for net sales of potential future products containing other IL-6 compounds, with each of the royalties subject to reduction under certain circumstances and to the buy-out options of Roche further described below.

Buy-Out Options

The License Agreement provides for two “option periods” during which Roche may elect to make a one-time payment to the Company and, in turn, terminate its diligence, milestone and royalty payment obligations under the License Agreement. Specifically, (i) Roche may exercise a buy-out option following the first dosing (“Initiation”) in the first Phase II study for a Licensed Product until the day before Initiation of the first Phase III study for a Licensed Product, in which case Roche is required to pay the Company $135 million within 30 days after Roche's exercise of such buy-out option and receipt of an invoice from the Company, or (ii) Roche may exercise a buy-out option following the day after Initiation of the first Phase III study for a Licensed Product until the day before the acceptance for review by the FDA or other regulatory authority of a biologics license application (“BLA”) or similar application for marketing approval for a Licensed Product in either the United States or in the European Union, in which case Roche is required to pay the Company, within 30 days after Roche’s exercise of such buy-out option and receipt of an invoice from the Company, $265 million , which amount would be reduced to $220 million if none of the Company’s patent rights containing a composition of matter claim covering any compound or Licensed Product has issued in the European Union.

Termination

The Company or Roche may each terminate the License Agreement if the other party breaches any of its material obligations under the License Agreement and does not cure such breach within a specified cure period. Roche may terminate the License Agreement following effectiveness by providing advance written notice to the Company or by providing written notice if the Company is debarred, disqualified, suspended, excluded, or otherwise declared ineligible from certain federal or state agencies or programs. The Company may terminate the License Agreement if, prior to the first filing of a BLA for a Licensed Product, there is a period of 12 months where Roche is not conducting sufficient development activities with respect to the products made from the Licensed Intellectual Property.

Following the Acquisition, the Company continues to retain its rights to its early stage product candidates in its pipeline existing prior to the Acquisition, rights to its AMP-Rx proprietary protein engineering platform that it had used to discover and develop innovative protein therapeutics to treat diseases of the eye and rights under the License Agreement with Roche. However, the Company expects that its primary business following the Acquisition will consist of the business conducted by Viventia immediately prior to the Acquisition.

Liquidity

The Company has financed its operations to date primarily through private placements of its common stock and preferred stock and convertible bridge notes, venture debt borrowings, its initial public offering ("IPO"), sales effected in an "at the market"

offering through its agent, Cowen and Company, LLC, and the License Agreement, and as of September 30, 2016 , the Company had cash and cash equivalents totaling approximately $30.7 million , net working capital of $25.5 million and an accumulated deficit of $119.8 million .

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

The Company believes that its cash and cash equivalents of $30.7 million as of September 30, 2016 , will be sufficient to fund the Company's current operating plan into 2018. If the Company is unable to obtain adequate financing or engage in another strategic transaction on acceptable terms and when needed, the Company will be required to implement further cost reduction strategies. These factors and the factors described above continue to raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

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

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 consolidated 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, 2015 (the "2015 10-K").

The condensed consolidated financial statements as of September 30, 2016 and for the three and nine months ended September 30, 2016 and 2015 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 September 30, 2016 , the statements of operations and comprehensive income (loss) for the three and nine months ended September 30, 2016 and 2015 and the statement of cash flows for the nine months ended September 30, 2016 and 2015. The results for the three and nine months ended September 30, 2016 are not necessarily indicative of results to be expected for the year ending December 31, 2016, or any other future annual or interim periods.

License Revenue

Revenues from license arrangements are recognized when persuasive evidence of an arrangement exists, delivery of goods or services has occurred including title to the product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer has been reasonably assured, all performance obligations have been met, and any associated reductions of revenue can be reasonably estimated. The Company licenses certain rights to its product candidates to third parties. Activities under licensing agreements are evaluated to determine if they represent a multiple element arrangement. The Company identifies the deliverables included within the agreement and evaluates which deliverables represent separate units of accounting. The Company accounts for those components as separate units of accounting if the following two criteria are met:

- the delivered item or items have stand-alone value to the customer; and
- delivery or performance of the undelivered item(s) is considered probable and substantially in the control of the Company, and the arrangement includes a general right of return relative to the delivered item(s).

Factors considered in this determination include, among other things, whether any other vendors sell the items separately and if the licensee could use the delivered item for its intended purpose without the receipt of the remaining deliverables. The consideration that is fixed or determinable is allocated to the separate units of accounting based on the relative selling prices of each deliverable. The consideration allocated to each unit of accounting is recognized as the related goods and services are delivered. The amount allocable to the delivered units of accounting is limited to the amount that is not contingent upon the delivery of additional items or meeting other specified performance conditions.

The Company determines the selling price on the basis of vendor-specific objective evidence, or VSOE, third party evidence, or best estimate of selling price. VSOE is the price charged for a deliverable when it is sold separately. Third party evidence is the price that the Company or vendors charge for a similar deliverable when sold separately. Best estimate is the price at which the Company would sell the deliverable if the deliverable were sold by the Company regularly on a stand-alone basis.

When multiple deliverables are combined and accounted for as a single unit of accounting, the Company bases its revenue recognition on the last element to be delivered using the straight-line or proportional performance method depending on the Company's ability to estimate the timing of the delivery of the performance obligation. Amounts received or recorded as receivable prior to satisfying the associated revenue recognition criteria are recorded as deferred revenue in the condensed consolidated balance sheets. Amounts not expected to be recognized within one year following the balance sheet date are classified as non-current deferred revenue.

If a future milestone payment under a license agreement is contingent upon the achievement of a substantive milestone, license revenue is recognized in its entirety in the period in which the milestone is achieved. Nonsubstantive milestone payments that are paid based on the passage of time or as a result of the licensee's performance are allocated to the units of accounting within the arrangement and recognized as revenue when those deliverables are satisfied. A milestone is substantive if:

- it can only be achieved based in whole or in part on either the Company's performance or the occurrence of a specific outcome resulting from the Company's performance;
- there is substantive uncertainty at the date an arrangement is entered into that the event will be achieved; and
- it would result in additional payments being due to the Company.

Options are considered substantive if, at the inception of the arrangement, the Company is at risk as to whether the licensee will choose to exercise the option. Factors that the Company considers in evaluating whether an option is substantive include the overall objective of the arrangement, the benefit the licensee might obtain from the arrangement without exercising the option, the cost to exercise the option and the likelihood that the option will be exercised. For arrangements under which an option is considered substantive, the Company does not consider the item underlying the option to be a deliverable at the inception of the arrangement and the associated option fees are not included in allocable arrangement consideration, assuming the option is not priced at a significant and incremental discount. Conversely, for arrangements under which an option is not considered substantive or if an option is priced at a significant and incremental discount, the Company would consider the item underlying the option to be a deliverable at the inception of the arrangement and a corresponding amount would be included in allocable arrangement consideration.

Commercial milestone and royalty payments received under license agreements are recognized as license revenue when they are earned.

Business Combinations

The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination by assessing whether or not the Company has acquired inputs and processes that have the ability to create outputs. If determined to be a business combination, the Company accounts for business acquisitions under the acquisition method of accounting as indicated in the Financial Accounting Standards Board ("FASB") issued Accounting Standards Codification ("ASC") Topic 805, *Business Combinations* , ("ASC 805") which requires the acquiring entity in a business combination to recognize the fair value of all assets acquired and liabilities assumed and establishes the acquisition date as the fair value measurement point. Accordingly, the Company recognizes assets acquired and liabilities assumed in business combinations, including contingent assets and liabilities, and non-controlling interest in the acquiree based on the fair value estimates as of the date of acquisition. In accordance with ASC 805, the Company recognizes and measures goodwill as of the acquisition date, as the excess of the fair value of the consideration paid over the fair value of the identified net assets acquired.

The consideration for the Company's business acquisitions includes future payments that are contingent upon the occurrence of a particular event or events. The obligations for such contingent consideration payments are recorded at fair value on the acquisition date. The contingent consideration obligations are then evaluated each reporting period. Changes in the fair value of contingent consideration obligations, other than changes due to payments, are recognized as a gain or loss on fair value remeasurement of contingent consideration in the condensed consolidated statements of operations.

Indefinite-Lived Intangible Assets

In accordance with ASC Topic 350, *Intangibles — Goodwill and Other* ("ASC 350"), during the period that an asset is considered indefinite-lived, such as in-process research and development ("IPR&D"), it will not be amortized. Acquired IPR&D represents the fair value assigned to research and development assets that have not reached technological feasibility. The value assigned to acquired IPR&D is determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting revenue from the projects, and discounting the net cash flows to present value. The revenue and costs projections used to value acquired IPR&D are, as applicable, reduced based on the probability of success of developing a new drug. Additionally, the projections consider the relevant market sizes and growth factors, expected trends in technology, and the nature and expected timing of new product introductions by the Company and its competitors. The rates utilized to discount the net cash flows to their present value are commensurate with the stage of development of the projects and uncertainties in the economic estimates used in the projections. Upon the acquisition of IPR&D, the Company completes an assessment of whether its acquisition constitutes the purchase of a single asset or a group of assets. Multiple factors are considered in this assessment, including the nature of the technology acquired, the presence or absence of separate cash flows, the development process and stage of completion, quantitative significance and the rationale for entering into the transaction. Indefinite-lived assets are maintained on the Company's condensed consolidated balance sheet until either the project underlying it is completed or the asset becomes impaired. Indefinite-lived assets are tested for impairment on an annual basis, or whenever events or changes in circumstances indicate the reduction in the fair value of the IPR&D asset is below its respective carrying amount. If the Company determines that an impairment has occurred, a write-down of the carrying value and an impairment charge to operating expenses in the period the determination is made is recorded. When development of an IPR&D asset is complete the associated asset would be deemed finite-lived and would then be amortized based on its respective estimated useful life at that point.

Goodwill

Goodwill represents the difference between the purchase price and the fair value of the identifiable tangible and intangible net assets when accounted for using the purchase method of accounting. Goodwill is not amortized, but is reviewed for impairment. The Company tests its goodwill for impairment annually, or whenever events or changes in circumstances indicate an impairment may have occurred, by comparing its carrying value to its implied fair value in accordance with ASC 350. Impairment may result from, among other things, deterioration in the performance of the acquired asset, adverse market conditions, adverse changes in applicable laws or regulations and a variety of other circumstances. If the Company determines that an impairment has occurred, a write-down of the carrying value and an impairment charge to operating expenses in the period the determination is made is recorded. In evaluating the carrying value of goodwill, the Company must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the acquired assets. Changes in strategy or market conditions could significantly impact those judgments in the future and require an adjustment to the recorded balances.

Net income (loss) per share

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

The following common stock equivalents, using the treasury-stock method, were included in the calculation of diluted net income (loss) per share for the periods indicated.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Stock options	891,341	—	776,580	—
Unvested restricted stock	—	—	—	—
Restricted stock units	37,063	—	15,156	—
Common stock warrants	—	—	—	—
	928,404	—	791,736	—

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Stock options	1,732,954	1,932,489	1,829,193	1,932,489
Unvested restricted stock	26,580	48,767	26,580	48,767
Restricted stock units	—	221,400	—	221,400
Common stock warrants	926,840	926,840	926,840	926,840
	2,686,374	3,129,496	2,782,613	3,129,496

There have been no other material changes to the significant accounting policies previously disclosed in the 2015 10-K.

Recent Accounting Pronouncements

In the second quarter of 2014, the FASB issued guidance applicable to revenue recognition that will be effective for the Company for the year ending December 31, 2018. The new guidance must be adopted using either a full retrospective approach for all periods presented or a modified retrospective approach. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. 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 ending after December 15, 2016 and for interim periods after 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 further disclosure in its financial statements once adopted.

In November 2015, the FASB issued Accounting Standard Update No. 2015-17, *Balance Sheet Classification of Deferred Taxes* ("ASU 2015-17"). ASU 2015-17 requires companies to classify all deferred tax assets and liabilities as noncurrent on the balance sheet instead of separating deferred taxes into current and noncurrent amounts. The guidance is effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted. The guidance may be adopted on either a prospective or retrospective basis. The Company does not expect the adoption of this guidance to have a material effect on the Company's financial statements.

In February 2016, the FASB issued Accounting Standard Update No. 2016-02, *Leases* (Topic 842) ("ASU 2016-02"). ASU 2016-02 addresses the financial reporting of leasing transactions. Under current guidance for lessees, leases are only included on the balance sheet if certain criteria, classifying the agreement as a capital lease, are met. This update will require the recognition of a right-of-use asset and a corresponding lease liability, discounted to the present value, for all leases that extend beyond 12 months. For operating leases, the asset and liability will be expensed over the lease term on a straight-line basis, with all cash flows included in the operating section of the statement of cash flows. For finance leases, interest on the lease liability will be recognized separately from the amortization of the right-of-use asset in the statement of operations and the repayment of the principal portion of the lease liability will be classified as a financing activity while the interest component will be included in the operating section of the statement of cash flows. This guidance is effective for annual and interim

reporting periods beginning after December 15, 2018. Early adoption is permitted. The Company has not yet completed the analysis of how adopting this guidance will affect its financial statements.

In March 2016, the FASB issued Accounting Standard Update No. 2016-09, *Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"). ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. Some of the areas of simplification apply only to nonpublic entities. For public business entities, the amendments in ASU 2016-09 are effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. For all other entities, the amendments are effective for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018. Early adoption is permitted for any entity in any interim or annual period for which financial statements haven't been issued or made available for issuance. If an entity early adopts the amendments in an interim period, any adjustments must be reflected as of the beginning of the fiscal year that includes that interim period. An entity that elects early adoption must adopt all of the amendments in the same period. The Company has not yet completed the analysis of how adopting this guidance will affect its financial statements.

3. Business Combination

On September 20, 2016, the Company entered into a Share Purchase Agreement pursuant to which the Company agreed to and simultaneously completed the Acquisition (See Note 1). In connection with the closing of the Acquisition, the Company issued 4,013,431 shares of its common stock to the Selling Shareholders, which represented approximately 19.9% of the voting power of the Company as of immediately prior to the issuance of such shares of the Company's common stock. A portion of these total shares, equal to 401,343 shares, were placed in escrow and are still in escrow as of September 30, 2016.

The Company concluded that the transaction included inputs and processes that have the ability to create outputs and accordingly accounted for the transaction as a business combination in accordance with ASC 805. As such, the assets acquired and liabilities assumed were recorded at fair value, with the remaining purchase price recorded as goodwill.

The purchase price consisted of the issuance of the 4,013,431 shares of the Company's common stock to the Selling Shareholders. In addition, under the Share Purchase Agreement, the Company will be obligated to pay to the Selling Shareholders certain post closing contingent cash payments upon the achievement of specified milestones and based upon net sales (See Note 1). Certain of these payments are payable to individuals or affiliates of individuals that became employees or members of the Board.

The Company valued the shares issued at approximately $13.5 million , based on the closing price of the Company's common stock on the acquisition date. The contingent consideration was preliminarily valued at approximately $21.9 million , using a probability-adjusted, discounted cash flow estimate as of the acquisition date. The total fair value of consideration for the acquisition was approximately $35.4 million .

As of September 30, 2016, purchase accounting for the Acquisition is preliminary and subject to completion upon obtaining the necessary remaining information, including (1) the valuation of the consideration transferred, including contingent consideration and whether any consideration is compensatory, (2) the identification and valuation of assets acquired and liabilities assumed, including intangible assets, fixed assets, and related goodwill, (3) the finalization of the opening balance sheet, including certain accruals and prepaid expenses, and (4) the related tax impacts of the Acquisition. The Company has preliminarily valued the acquired assets and liabilities based on their estimated fair value. These estimates are subject to change as additional information becomes available. The preliminary fair values included in the balance sheet as of September 30, 2016 are based on the best estimates of the Company. Any adjustments to the preliminary fair values will be made as such information becomes available, but no later than September 19, 2017. The following table presents the preliminary allocation of the purchase consideration for the transaction as of September 20, 2016 (the "Acquisition Date"), including the contingent consideration (in thousands):

Cash and cash equivalents	$	136
Prepaid expenses and other assets		1,189
Property and equipment		867
In-process research and development - Vicinium		35,400
In-process research and development - Proxinium		800
Goodwill		10,312
Accounts payable		(1,163)
Accrued expenses		(1,530)
Other liabilities		(812)
Deferred tax liability		(9,774)
	$	35,425

The preliminary fair value of the Vicinium IPR&D was determined using a risk-adjusted discounted cash flow approach, which includes probability adjustments for projected revenues and operating expenses based on the success rates assigned to each stage of development; as well as a discount rate of 17.4% applied to the projected cash flows. The remaining estimated cost of development for this asset is approximately $48.0 million , with an expected completion date of no earlier than 2019. The Company believes the assumptions are representative of those a market participant would use in estimating fair value.

The preliminary fair value of the Proxinium IPR&D was determined using a risk-adjusted discounted cash flow approach, which includes probability adjustments for projected revenues and operating expenses based on the success rates assigned to each stage of development; as well as a discount rate of 17.4% applied to the projected cash flows. The remaining estimated cost of development for this asset is approximately $27.0 million , with an expected completion date of no earlier than 2020. The Company believes the assumptions are representative of those a market participant would use in estimating fair value.

The deferred tax liability of $9.8 million primarily relates to the potential future impairments or amortization associated with IPR&D intangible assets, which is not deductible for tax purposes, and which can not be used as a source of income to realize deferred tax assets. As a result, the Company recorded the deferred tax liability with an offset to goodwill.

The amount allocated to the IPR&D is considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. As of September 30, 2016, there was no impairment related to the IPR&D.

The Company allocated the excess of the purchase price over the identifiable intangible assets to goodwill. Such goodwill is not deductible for tax purposes and represents the value placed on expected synergies and deferred tax liabilities recognized in connection with the acquisition. As of September 30, 2016, there was no impairment of goodwill. All goodwill has been assigned to the Company’s single reporting unit.

These fair value measurements were based on significant inputs not observable in the market and thus represent Level 3 fair value measurements.

As of September 30, 2016, the estimated fair value of the Company’s contingent consideration liability did not change, compared to the Acquisition Date.

The operating results of Viventia for the period from September 20, 2016 to September 30, 2016, which includes $0 revenue and an operating loss of $0.5 million , have been included in the Company’s condensed consolidated financial statements as of and for the three and nine months ended September 30, 2016.

The Company incurred a total of $2.5 million in transaction costs in connection with the transaction, excluding Viventia transaction costs, which were included in selling, general and administrative expense within the condensed consolidated statement of operations and other comprehensive income (loss) for the three and nine months ended September 30, 2016.

The Company’s financial results for the nine months ended September 30, 2016 are inclusive of Viventia financial results since the Acquisition Date. The unaudited estimated pro forma results presented below include the effects of the Acquisition as if it had been consummated as of the beginning of each period. The pro forma results include the direct expenses of Viventia as well as the additional depreciation expense as a result of the increase in the fair value of the fixed assets. The pro forma results exclude the costs of the transaction, severance and stock-based compensation expenses, the Viventia forgiveness of debt and the related interest expense in connection with the Acquisition. In addition, the pro forma results do not include any anticipated

synergies or other expected benefits of the Acquisition. Accordingly, the unaudited estimated pro forma financial information below is not necessarily indicative of either future results of operations or results that might have been achieved had the Acquisition been consummated as of the beginning of each period.

	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Revenue	$ 29,156	$ 425
Net income (loss)	$ 566	$ (31,367)

4. License Agreement with Roche

On June 10, 2016, the Company entered into the License Agreement with Roche, which became effective on August 16, 2016. Under the License Agreement, the Company granted Roche an exclusive, worldwide license, including the right to sublicense the Licensed Intellectual Property (See Note 1).

The Company's License Agreement with Roche contains the following deliverables 1) an exclusive, worldwide license, including the right to sublicense, its patent and know-how related to the Company's monoclonal antibody EBI-031 or any other IL-6 antagonist anti-IL-6 monoclonal antibody; 2) IND regulatory clearance activities; 3) conduct a tissue cross-reactivity study; 4) transfer pre-clinical inventory and 5) perform de minimus post-effective date services.

The Company has determined that the License Agreement contains four units of accounting. The de minimis post-effective date services were not determined to be substantive, and thus were not considered units of accounting. The $29.9 million of allocable arrangement consideration was allocated to each of the units of accounting using the relative selling price method based on the Company's best estimate of selling price of each of the units of accounting. The best estimate of selling price of the license was calculated using a discounted cash flow model that included the following key assumptions: the development timeline, revenue forecast, discount rate and probability of success. The best estimate of selling price of the remaining deliverables was based on estimated costs plus a reasonable margin.

The Company recognizes arrangement consideration allocated to each unit of accounting when all of the revenue recognition criteria in ASC 605-25 are satisfied for that particular unit of accounting. As of September 30, 2016, the basic revenue recognition criteria has been met for all units of accounting except for the transfer of pre-clinical inventory. Accordingly, the Company recognized $28.7 million in revenue related to the License Agreement for the three and nine months ended September 30, 2016 under the License Agreement. The $1.3 million of revenue allocated to the transfer of pre-clinical inventory will be recognized upon delivery of the inventory to Roche.

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

5. Fair Value of Financial Instruments

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

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

The following table summarizes the assets measured at fair value on a recurring basis at September 30, 2016 (in thousands):

Description	Total	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	$ 30,716	$ 30,716	$ —	$ —
Total	$ 30,716	$ 30,716	$ —	$ —

Description	Total	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Liabilities:				
Warrant liability	$ 77	$ —	$ —	$ 77
Contingent consideration	21,900	—	—	21,900
Total	$ 21,977	$ —	$ —	$ 21,977

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

Description	Total	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	$ 36,079	$ 36,079	$ —	$ —
Total	$ 36,079	$ 36,079	$ —	$ —

Description	Total	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Liabilities:				
Warrant liability	$ 115	$ —	$ —	$ 115
Total	$ 115	$ —	$ —	$ 115

Warrant Liability

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

	September 30, 2016	December 31, 2015
Risk-free interest rate	0.59%	1.06%
Expected dividend yield	—%	—%
Expected term (in years)	1.17	1.92
Expected volatility	87.59%	70.67%

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

Beginning balance, January 1, 2016	$ 115
Change in fair value	(38)
Ending balance, September 30, 2016	$ 77

The change in the fair value of the warrant liability is primarily influenced by the price of the underlying common stock.

Contingent consideration

On September 20, 2014, the Company acquired Viventia. The Company may be required to make certain post closing contingent cash payments upon the achievement of certain specified milestones and based upon net sales in future contingent cash payments to the Selling Shareholders of Viventia, including: (i) a one-time milestone payment of $12.5 million payable upon the first sale of the Purchased Product in the United States; (ii) a one-time milestone payment of $7.0 million payable upon the first sale of the Purchased Product in any one of certain specified European countries; (iii) a one-time milestone payment of $3.0 million payable upon the first sale of the Purchased Product in Japan; and (iv) and quarterly earn-out payments equal to two percent (2%) of net sales of the Purchased Product during specified earn-out periods. Such earn-out payments are payable with respect to net sales in a country beginning on the date of the first sale in such country and ending on the earlier of (i) December 31, 2033 and (ii) fifteen years after the date of such sale, subject to early termination in certain circumstances if a biosimilar product is on the market in the applicable country. Certain of these payments are payable to individuals or affiliates of individuals that became employees or members of the Board.

In connection with the Acquisition, the Company recorded contingent consideration pertaining to the amounts potentially payable to Viventia's selling shareholders pursuant to the Stock Purchase Agreement. Contingent consideration is measured at fair value and is based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The valuation of contingent consideration uses assumptions the Company believes would be made by a market participant. The Company assesses these estimates on an on-going basis as additional data impacting the assumptions is obtained. Future changes in the fair value of contingent consideration related to updated assumptions and estimates are recognized within the condensed consolidated statements of operations and comprehensive income (loss).

Contingent consideration may change significantly as development progresses and additional data are obtained, impacting the Company’s assumptions regarding probabilities of successful achievement of related milestones used to estimate the fair value of the liability and the timing in which they are expected to be achieved. In evaluating the fair value information, considerable judgment is required to interpret the market data used to develop the estimates. The estimates of fair value may not be indicative of the amounts that could be realized in a current market exchange. Accordingly, the use of different market assumptions and/or different valuation techniques could result in materially different fair value estimates.

The significant unobservable inputs used in the measurement of fair value of the Company’s contingent consideration are probabilities of successful achievement of clinical and commercial milestones, the period in which these milestones are expected to be achieved ranging from 2019 to 2033 and discount rates ranging from 4.4% to 9.8% . Significant increases or decreases in any of the probabilities of success would result in a significantly higher or lower fair value measurement, respectively. Significant increases or decreases in these other inputs would result in a significantly lower or higher fair value measurement, respectively.

The following table sets forth a summary of changes in the fair value of the Company’s contingent consideration obligations, which include Level 3 inputs (in thousands):

Beginning balance, September 20, 2016	$	21,900
Change in fair value		—
Ending balance, September 30, 2016	$	21,900

There have been no changes to the valuation methods utilized during the three and nine months ended September 30, 2016 . The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of assets or liabilities between levels during the three and nine months ended September 30, 2016 .

6. Collaboration Agreement

On May 28, 2013 , the Company entered into the collaboration and license agreement (the "Collaboration and License Agreement") with ThromboGenics N.V. ("ThromboGenics"). Under the Collaboration and License Agreement, the Company and ThromboGenics collaborated to seek to identify protein or peptide therapeutics that directly modulate any of a specified set of targets in a novel pathway in retinal disease. In connection with the Collaboration and License Agreement, ThromboGenics paid the Company an upfront technology licensing fee of $1.75 million and paid the Company to perform activities under the Collaboration and License Agreement at a set rate per full-time equivalent person working on collaboration activities. The

initial research term concluded in November 2015, however it was amended at that time to extend the performance period into 2016. The Collaboration and License Agreement provides for potential future payments to the Company upon achievement of specified pre-clinical, clinical and regulatory milestones with respect to collaboration products and royalties on sales of collaboration products by ThromboGenics, its affiliates or sublicensees. However, as there have not been any collaboration products identified whose modulation of any of the targets has been confirmed in the course of the research conducted under the Collaboration and License Agreement, none of these milestones or royalties are expected to be payable. On August 1, 2016, the Company received notice from ThromboGenics of ThromboGenics's termination, effective as of October 31, 2016, of the Collaboration and License Agreement.

The Company accounts for this agreement pursuant to ASC Topic 605-25, *Revenue Recognition - Multiple Element Arrangements* , or ASC 605-25. The Company was 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. Subsequent to the amendment in November 2015, the Company is recognizing revenue on a straight-line basis over the remaining performance period. For the three and nine months ended September 30, 2016 , the Company recognized $0.0 million and $0.4 million included in revenue in the condensed consolidated statement of operations. No further amounts are expected to be recognized in the future. The costs incurred by the Company related to the research activities are recorded as research and development expense in the condensed consolidated statement of operations and comprehensive income (loss).

7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
Development costs	$ 1,156	$ 931
Employee compensation	855	573
Professional fees	355	194
Interest	—	88
Other	126	8
	$ 2,492	$ 1,794

8. Commitments and Contingencies

License Agreements

The Company is a party to or assignee of License agreements that may require it to make future payments relating to license fees, sublicense fees, milestone fees, and royalties on future sales of licensed products.

The following outlines the license agreements the Company believes it will owe payments to if its product candidates reach certain milestones and begin to generate revenue.

License agreement with The University of Zurich

The Company has an exclusive license agreement with the University of Zurich ("Zurich"), which grants the Company an exclusive license, with the right to sublicense, under certain patents to make, use and sell under certain patents primarily directed to the Company's targeting agent, including EpCAM chimera, and related immunoconjugates and methods of use and manufacture of the same. The Company is obligated to pay $750,000 in milestone payments for its first product, in the event it reaches the applicable clinical development milestones. As part of the consideration, the Company is also obligated to pay a 4% royalty on the net product sales, for any products that are covered by the applicable Zurich patent rights. The Company has the right to reduce the amount of royalties owed to Zurich if the total royalty rate owed by the Company to Zurich and any other third party is 10% or greater, provided that the royalty rate may not be less than 2% of net sales. The obligation to pay royalties in a particular country expires upon the expiration, lapse or abandonment of the last of the licensed patent rights that covers the manufacture, use or sale of a product and there is no obligation to pay royalties in a country if there is no patent rights that cover the manufacture, use or sale of a product.

License agreement with Merck KGaA

The Company holds an exclusive license agreement with Merck KG&A ("Merck") pursuant to which the Company was granted an exclusive license, with the right to sublicense, under certain patents and technology relating to aspects of VB6-845d, to make, use, sell and import VB6-845d or any products that would otherwise infringe such patents in the field of therapeutic or diagnostic purposes in humans. Under the agreement, the Company may be obligated to make milestone payments in respect of certain stages of regulatory approval reached by a product candidate generated by this technology or covered by a licensed patent, as well as royalties calculated with respect to net sales of these products.

The license remains in force on a country-by-country basis and product-by-product basis, and expires until the longer of (i) the expiration of the last to expire patent within the licensed patent rights that covers a licensed product and (ii) 10 years from the first commercial sale of a licensed product in such country; provided that no royalty is payable for more than 15 years from the first commercial launch of a licensed product anywhere in the world.

9. Share-Based Payments

In December 2013, the Company's 2014 Stock Incentive Plan (the "2014 Plan") was adopted by the Board and approved by the Company's stockholders in January 2014. Pursuant to the terms of the plan, the number of shares authorized for issuance automatically increases on the first day of each fiscal year. On January 1, 2016 and 2015, the number of shares reserved for issuance under the 2014 Plan increased by 786,431 and 722,331 shares, respectively. As of September 30, 2016 , the total number of shares of common stock available for issuance under the 2014 Plan was 713,021 .

On September 20, 2016, in connection with the Acquisition, the Company granted stock options to purchase 650,000 shares of the Company's common stock. The grants were made in the form of inducement equity awards outside the 2014 Plan in accordance with NASDAQ Listing Rule 5635(c)(4).

These stock options were granted with an effective grant date of September 20, 2016 and an exercise price of $3.37 per share (the closing price per share of the Company's common stock on September 20, 2016) as an inducement to each recipient in connection with his employment. The inducement equity awards were approved and recommended by the Company's Compensation Committee, approved by the Board and were made as an inducement material to each recipient's acceptance of employment with the Company in accordance with NASDAQ Listing Rule 5635(c)(4).

Each of the inducement grants expires on the day preceding the ten th anniversary of the grant date and vests over four years , with 25% of the original number of shares subject to the option vesting on the one year anniversary of the date of grant of the option and an additional 6.25% of the shares subject to the option vesting at the end of each successive three -month period following the one -year anniversary of the date of grant of the option, subject to the recipient's continued service with the Company through the applicable vesting dates.

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

Stock-Based Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Stock options	$ 1,932	$ 475	$ 2,825	$ 1,708
Restricted stock	50	55	155	88
Restricted stock units	156	99	354	99
Employee stock purchase plan	6	—	17	—
	$ 2,144	$ 629	$ 3,351	$ 1,895

At September 30, 2016 , there was $2.4 million of total unrecognized compensation expense, net of estimated forfeitures, related to non-vested stock options, unvested restricted stock, restricted stock units (each with service-based vesting provisions), and shares issued pursuant to the Company's 2014 Employee Stock Purchase Plan (the "2014 ESPP"). This unrecognized compensation expense is expected to be recognized over a weighted-average period of 2.81 years .

The Company has granted stock options to the founders and officers 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 pre-clinical 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. The Compensation Committee of the Company determined that the Company had achieved milestone events on July 9, 2016 and September 20, 2016. As of September 30, 2016 , there was no unrecognized compensation expense remaining related to performance based awards.

Stock Options

A summary of the stock option activity is presented below:

	Shares	Weighted-Average Exercise Price
Outstanding at December 31, 2015	1,803,574	$ 6.28
Granted	1,747,495	1.69
Exercised	(341,526)	0.49
Cancelled or forfeited	(494,787)	3.30
Outstanding at September 30, 2016	2,714,756	$ 4.60
Exercisable at September 30, 2016	1,606,002	$ 5.18
Vested and expected to vest at September 30, 2016 (1)	2,530,001	$ 4.69

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

Restricted Stock

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

	Restricted Stock	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2015	41,657	$ 11.05
Vested	(15,077)	10.38
Unvested at September 30, 2016	26,580	$ 11.43

Restricted Stock Units

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

	Restricted Stock Units	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2015	150,932	$ 2.85
Vested	(131,166)	2.83
Cancelled	(13,100)	2.76
Unvested at September 30, 2016	6,666	$ 3.43

Employee Stock Purchase Plan

On January 21, 2014, the Board adopted its 2014 ESPP, which was subsequently approved by its stockholders and became effective upon the closing of the Company's IPO on February 6, 2014. The 2014 ESPP authorizes the initial issuance of up to a total of 157,480 shares of the Company's common stock to participating employees. The first offering period under the 2014

ESPP opened on September 15, 2015 and closed on March 14, 2016. On March 14, 2016, the Company issued and sold 20,760 shares of its common stock pursuant to the 2014 ESPP at a purchase price of $0.31 per share. The second offering period under the 2014 ESPP opened on March 15, 2016 and closed on September 14, 2016. On September 14, 2016 the Company issued and sold 68,111 shares of its common stock pursuant to the 2014 ESPP at a purchase price of $0.42 per share. The third offering period under the 2014 ESPP opened on September 15, 2016. The Company has estimated the number of shares to be issued at the end of the third offering and recognized expense over the requisite service period.

Acceleration of Equity Awards

In connection with the closing of the Acquisition, certain officers of the Company were terminated and entered into separation agreements with the Company. Under the separation agreements, the Company accelerated in full the vesting of all of their outstanding equity awards consistent with their existing employment agreements. As a result of the acceleration, the Company recognized $1.7 million of compensation expense. In addition, the Company provided that all stock options granted to Dr. Celniker under the Company's 2009 Plan shall continue to be exercisable based on her continued service as a non-employee member of the Board. As a result of this modification, the Company recorded $0.1 million of compensation expense.

10. Indebtedness

Term Loan

On March 1, 2016, the Company prepaid all outstanding amounts owed to Silicon Valley Bank ("SVB") under the Loan and Security Agreement, dates May 27, 2010, as amended September 4, 2012, November 25, 2014, and December 4, 2015 (the "Loan Agreement"). These obligations included the outstanding principal and interest of $13.8 million and a prepayment penalty of $0.2 million . In addition, the Company was required to pay a final payment equal to 6% of the amounts borrowed under the Loan Agreement, or $0.9 million , of which $0.4 million was accrued as of March 1, 2016. In addition, as a result of the prepayment, the Company wrote off the unamortized debt issuance costs and debt discount of $0.2 million . In connection with the prepayment, the Company has recorded a loss on extinguishment of debt of $ 0.9 million , which is included in other expense on the condensed consolidated statement of operations and comprehensive income (loss) for the nine months ending September 30, 2016 .

11. Reduction in Workforce

On June 16, 2016, the Board approved a strategic restructuring of the Company to eliminate a portion of the Company's workforce in order to preserve the Company's resources as it determined its future strategic plans. As of June 30, 2016 the Company estimated total restructuring costs of approximately $0.6 million , which included severance, benefits and related costs in accordance with the Company's severance benefit plan. On September 20, 2016, in connection with the Acquisition, the Company eliminated additional positions and recorded additional restructuring charges of $1.3 million . The Company recorded total restructuring charges of $1.3 million and $1.9 million in the condensed consolidated statement of operations and comprehensive income and loss for the three and nine months ending September 30, 2016 , respectively.

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

Balance as of January 1, 2016	$	—
Charges		582
Payments		—
Balance as of June 30, 2016		582
Additions		1,338
Payments		(1,411)
Balance as of September 30, 2016	$	509

12. Related Party Transactions

The Company leases a manufacturing, laboratory, and office facility in Winnipeg, Manitoba, from an affiliate of a director of the Company, under a five year renewable lease through September 2020. Rent expense was $9,000 for the period beginning September 20, 2016 (the acquisition date) through September 30, 2016.

The Company leases an office facility in Toronto, Ontario from an affiliate of a director of the Company. The lease is on a month-to-month basis unless terminated by either party by giving the requisite notice. Rent expense for this facility was $1,000 for the period beginning September 20, 2016 (the acquisition date) through September 30, 2016.

The Company pays fees, under an intellectual property license agreement, to Protoden, a company indirectly owned by a director of the Company, Clairmark Investments Ltd., under an intellectual property licensing agreement. Pursuant to the agreement, the Company has an exclusive, perpetual, irrevocable and non-royalty bearing license, with the right to sublicense, under certain patents and technology to make, use and sell products that utilize such patents and technology. The annual fee is $100,000 . Upon expiration of the term, the licenses granted to the Company will require no further payments to Protoden. As of September 30, 2016, $3,000 was owed to this related party and included in the current portion of due to related party on the accompanying consolidated balance sheet.

In connection with the forgiveness of certain debt held by Viventia immediately preceding the Acquisition, the Company irrevocably assigned and set over the right to receive up to $814,000 in the form of research and development investment tax credits to and in favour of Clairmark Investments Ltd., an affiliate of a director of the Company. As of September 30, 2016, $697,000 is included in the current portion of due to related party and $117,000 is included in the non-current portion of due to related party on the accompanying consolidated balance sheet.

13. Subsequent Events

On October 14, 2016, the Company and ARE-MA Region No. 38, LLC (the “Landlord”) entered into an Agreement for Termination of Lease and Voluntary Surrender of Premises (the “Termination Agreement”) under which they terminated by mutual consent the Lease Agreement by and between the Company and the Landlord entered into January 14, 2010, as amended (the “Lease Agreement”), regarding the Company’s corporate headquarters at 215 First Street, Suite 400, Cambridge, MA 02142.

The Lease Agreement was previously scheduled to expire on April 30, 2018. Pursuant to the Termination Agreement, the Lease Agreement expiration date was accelerated to October 10, 2016. The Company did not incur any termination penalties in connection with the Termination Agreement. The Company has elected to terminate the Lease Agreement as it plans to move its corporate headquarters to 245 First Street, Suite 1800 Cambridge, MA 02142.

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, 2015 (the "2015 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 biologics oncology company primarily focused on designing, engineering and developing targeted protein therapeutics, or TPTs. Our TPTs are single-protein therapeutics composed of targeting moieties genetically fused via linker domains to cytotoxic protein payloads that are produced through our proprietary one-step manufacturing process. We target tumor cell surface antigens that allow for rapid internalization into the targeted cancer cell and have limited expression on normal cells. We have designed our TPTs to overcome the fundamental efficacy and safety challenges inherent in existing antibody drug conjugates, or ADCs, where a payload is chemically attached to a targeting antibody.

Our most advanced product candidate is Vicinium ™, which is a locally-administered TPT. In the third quarter of 2015, Viventia commenced in the United States and Canada a Phase 3 clinical trial of Vicinium intended for the treatment of subjects with high-grade non-muscle invasive bladder cancer, or NMIBC. Our second most advanced product candidate is Proxinium ™, a locally-administered TPT intended for the treatment of squamous cell carcinoma of the head and neck, or SCCHN. We intend to enter into discussions with the FDA relating to our proposed Phase 2 clinical trial design. This Phase 2 clinical trial will explore the potential of Proxinium in combination with a checkpoint inhibitor for the treatment of SCCHN and is planned to commence enrollment in the first half of 2017. We are also developing cancer therapies for systemic administration utilizing our TPT platform and our proprietary payload deBouganin. We may explore additional therapeutic indications for Vicinium and Proxinium.

Our locally-administered TPTs contain a targeting moiety that is designed to bind to epithelial cell adhesion molecule, or EpCAM, which is a surface protein over expressed in many cancers. This targeting moiety is genetically fused to a truncated form of exotoxin A, or ETA, which is an immunogenic cytotoxic protein payload that is produced by the bacterial species, Pseudomonas. The TPT-EpCAM complex is subsequently internalized into the cell and, once inside the cell, the TPT is cleaved by a cellular enzyme to release the cytotoxic protein payload, thus enabling cancer cell-killing. We believe that our TPTs designed for local administration may not only directly kill cancer cells through targeted delivery of a cytotoxic protein payload, but also potentiate an anti-cancer therapeutic immune response. This immune response is from the release of tumor antigens and the immunologically active setting created by the nature of the cytotoxic protein payloads.

Our early pipeline product candidate, VB6-845d, is being developed for systemic administration as a treatment for multiple types of EpCAM-positive solid tumors. VB6-845d is a TPT consisting of an EpCAM targeting Fab genetically linked to deBouganin, a novel plant derived cytotoxic payload that we have optimized for minimal immunogenic potential.

License Agreement with Roche

On June 10, 2016, we entered into a License Agreement, which we refer to as the License Agreement, with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., or collectively, Roche. Under the License Agreement, we granted Roche an exclusive, worldwide license, including the right to sublicense, to our patent rights and know-how related to our monoclonal antibody EBI-031 or any other IL-6 antagonist anti-IL-6 monoclonal antibody, to make, have made, use, have used, register, have registered, sell, have sold, offer for sale, import and export any product containing such an antibody or any companion diagnostic used to predict or monitor response to treatment with such a product, or collectively, Licensed Intellectual Property.

Pursuant to the terms of the License Agreement, Roche is required to continue developing EBI-031 and any other product made from the Licensed Intellectual Property that contains an IL-6 antagonist anti-IL-6 monoclonal antibody, or Licensed Product, at its cost, except that we are responsible, at our cost, for any tissue cross-reactivity studies of EBI-031 that we initiated before the achievement of IND Clearance.

Roche paid an upfront license fee of $7.5 million and $22.5 million as a result of the IND application for EBI-031 becoming effective on or before September 15, 2016. Roche has also agreed to pay up to an additional $240.0 million upon the achievement of specified regulatory, development and commercial milestones with respect to up to two unrelated indications. Specifically, an aggregate amount of up to $175.0 million is payable to us for the achievement of specified milestones with respect to the first indication: consisting of $50.0 million in development milestones, $50.0 million in regulatory milestones

and $75.0 million in commercialization milestones. Additional amounts of up to $65.0 million are payable upon the achievement of specified development and regulatory milestones in a second indication.

In addition, we are entitled to receive royalty payments in accordance with a tiered royalty rate scale, with rates ranging from 7.5% to 15% for net sales of potential future products containing EBI-031 and up to 50% of these rates for net sales of potential future products containing other IL-6 compounds, with each of the royalties subject to reduction under certain circumstances and to the buy-out options of Roche.

We were incorporated and commenced active operations in early 2008, and our operations to date have been limited to organizing and staffing our company, acquiring rights to intellectual property, business planning, raising capital, developing our technology, identifying potential product candidates, undertaking pre-clinical studies and conducting clinical trials. To date, we have financed our operations primarily through private placements of our common stock and preferred stock and convertible bridge notes, venture debt borrowings and our initial public offering, or IPO, sales effected in an "at the market" offering through our agent, Cowen and Company, LLC, or Cowen, from a license agreement and, to a lesser extent, from a collaboration. We have devoted substantially all of our financial resources and efforts to research and development activities. 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.

Liquidity

Since inception, we have incurred significant operating losses and expect to continue to incur operating losses for the foreseeable future. We had net income of $5.4 million for the nine months ended September 30, 2016 due to the $28.7 million of revenue from the License Agreement, however we have incurred net losses of $33.5 million for the year ended December 31, 2015, $34.2 million for the year ended December 31, 2014 and $18.0 million for the year ended December 31, 2013. As of September 30, 2016 , we had an accumulated deficit of $119.8 million .

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

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

- the initiation, progress, timing, costs and results of pre-clinical studies and clinical trials for our product candidates or any other future product candidates;
- the scope, progress, results and costs of pre-clinical development and laboratory testing of our pre-clinical product candidates;
- our ability to establish collaborations on favorable terms, if at all, particularly manufacturing, marketing and distribution arrangements for our product candidates;
- the costs and timing of the implementation of commercial-scale manufacturing activities;
- the costs and timing of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval;

- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- our obligation to make milestone, royalty and other payments to third party licensors under our licensing agreements;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- the outcome, timing and cost of regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities, including Health Canada, to require that we perform more studies than those that we currently expect;
- our ability to achieve certain future regulatory, development and commercialization milestones under our license agreement with F. Hoffmann-La Roche Ltd. and Hoffmann La-Roche Inc.;
- the effect of competing technological and market developments; and
- the revenue, if any, received from commercial sales of any product candidates for which we receive regulatory approval.

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

We believe that our cash and cash equivalents of $30.7 million as of September 30, 2016 will be sufficient to fund our current operating plan into 2018.

Financial Operations Overview

Revenue

To date, we have not generated any revenues from the sale of products. Substantially all of our revenue to date has been derived from a license agreement and, to a lesser extent, from a collaboration. We do not expect to generate significant product revenue unless and until we obtain marketing approval for, and commercialize our product candidates.

On June 10, 2016, we entered into a License Agreement, which we refer to as the License Agreement, with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., or collectively, Roche. Under the License Agreement, we granted Roche an exclusive, worldwide license, including the right to sublicense, to our patent rights and know-how related to our monoclonal antibody EBI-031 or any other IL-6 antagonist anti-IL-6 monoclonal antibody, to make, have made, use, have used, register, have registered, sell, have sold, offer for sale, import and export any product containing such an antibody or any companion diagnostic used to predict or monitor response to treatment with such a product, or collectively, Licensed Intellectual Property.

Pursuant to the terms of the License Agreement, Roche is required to continue developing EBI-031 and any other product made from the Licensed Intellectual Property that contains an IL-6 antagonist anti-IL-6 monoclonal antibody, or Licensed Product, at its cost.

Roche paid an up-front license fee of $7.5 million and $22.5 million as a result of the IND application for EBI-031 becoming effective on or before September 15, 2016. Roche has also agreed to pay up to an additional $240.0 million upon the achievement of specified regulatory, development and commercial milestones with respect to up to two unrelated indications. Specifically, an aggregate amount of up to $175.0 million is payable to us for the achievement of specified milestones with respect to the first indication: consisting of $50.0 million in development milestones, $50.0 million in regulatory milestones and $75.0 million in commercialization milestones. Additional amounts of up to $65.0 million are payable upon the achievement of specified development and regulatory milestones in a second indication.

In addition, we are entitled to receive royalty payments in accordance with a tiered royalty rate scale, with rates ranging from 7.5% to 15% for net sales of potential future products containing EBI-031 and up to 50% of these rates for net sales of potential future products containing other IL-6 compounds, with each of the royalties subject to reduction under certain circumstances and to the buy-out options of Roche.

We also have generated revenue 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 collaborated to seek to identify protein or peptide therapeutics that directly modulate any of a specified set of targets in a novel pathway in retinal disease. In connection with the agreement, ThromboGenics paid us an upfront technology licensing fee of $1.75 million and paid us to perform activities under the agreement at a set rate per full-time equivalent person working on collaboration activities. The initial research term concluded in November 2015, however it was amended at that time to extend the performance period into 2016. The agreement provides for potential future payments to us upon achievement of specified pre-clinical, clinical and regulatory milestones with respect to collaboration products and royalties on sales of collaboration products by ThromboGenics, its affiliates or sublicensees. However, as there have not been any collaboration products identified whose modulation of any of the targets has been confirmed in the course of the research conducted under the agreement, none of these milestones or royalties are expected to be payable. On August 1, 2016, we received notice from ThromboGenics of ThromboGenics's termination, effective as of October 31, 2016, of the agreement.

Research and Development Expenses

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

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

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

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

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

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

We allocate direct research and development expenses, consisting principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical trials, and costs related to manufacturing or purchasing clinical trial materials, to specific product programs. We do not allocate employee and contractor-related costs, costs associated with our platform and facility expenses, including depreciation or other indirect costs, to specific product programs because these costs are deployed across multiple product programs under research and development and, as such, are separately classified. The table below provides research and development expenses incurred for our isunakinra and EBI-031 product programs and other expenses by category. Following the acquisition of Viventia, our research and

development expenses for Vicinium and Proxinium will materially increase during subsequent periods. We did not allocate research and development expenses to any other specific product program during the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(in thousands)			
Programs:				
Isunakinra (1)	$ 34	$ 3,968	$ 1,564	$ 11,391
EBI-031 (2)	230	1,185	2,982	2,011
Vicinium (3)	164	—	164	—
Total program expenses	428	5,153	4,710	13,402
Personnel and other expenses:				
Employee and contractor-related expenses	2,085	1,217	4,985	3,552
Platform-related lab expenses	45	126	284	466
Facility expenses	170	138	480	375
Other expenses	26	111	225	457
Total personnel and other expenses	2,326	1,592	5,974	4,850
Total research and development expenses	$ 2,754	$ 6,745	$ 10,684	$ 18,252

(1) Our development activities for Isunakinra are no longer ongoing as of September 30, 2016.
(2) Roche is required to continue developing EBI-031 at its costs as of August 16, 2016.
(3) Our development activities for Vicinium will increase significantly during subsequent periods.

General and Administrative Expenses

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

Other Income (Expense), Net

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

Business Combinations

On September 20, 2016, we completed our acquisition of Viventia for total consideration of $35.4 million, consisting of common stock consideration of $13.5 million and contingent consideration with an estimated fair value of $21.9 million. Future changes in our estimates of contingent consideration may impact research and development expense in future periods. The estimated fair value of the contingent consideration is based upon significant assumptions regarding probabilities of successful achievement of related milestones, the estimated timing in which the milestones are achieved and discount rates. The estimated fair value could materially differ from actual values or fair values determined using different assumptions.

This transaction was accounted for as a business combination under the acquisition method of accounting. Accordingly, the tangible assets and identifiable intangible assets acquired and liabilities assumed were recorded at fair value as of the date of acquisition, with the remaining purchase price recorded as goodwill. The estimated fair values of acquired assets and assumed liabilities were determined using the methods discussed in the following paragraphs and require significant judgment and estimates, which could materially differ from actual values and fair values determined using different methods or assumptions.

The purchase price allocation was initially prepared on a preliminary basis and is subject to change as additional information becomes available concerning (1) the valuation of the consideration transferred, including contingent consideration and whether any consideration is compensatory, (2) the identification and valuation of assets acquired and liabilities assumed, including intangible assets, fixed assets and related goodwill, (3) the finalization of the opening balance sheet, including certain accruals and prepaid expenses, and (4) the related tax impacts of the acquisition. Any adjustments to the purchase price allocations are made as soon as practicable but no later than one year from the acquisition date.

Goodwill

Goodwill represents the excess of the purchase price over the fair value of the net assets acquired when accounted for using the acquisition method of accounting for business combinations. Goodwill is not amortized but is evaluated for impairment within our single reporting unit on an annual basis or more frequently if an event occurs or circumstances change that would more-likely-than-not reduce the fair value of the reporting unit below its carrying amount. We have not recognized any impairment charges related to goodwill.

Intangible Assets

Intangible assets consist of in-process research and development, or IPR&D, with indefinite lives. During the period that an asset is considered indefinite-lived, it will not be amortized. Indefinite-lived assets are tested for impairment on an annual basis, or whenever events or changes in circumstances indicate the reduction in the fair value of the IPR&D asset is below its respective carrying amount. If we determine that an impairment has occurred, a write-down of the carrying value and an impairment charge to operating expenses in the period the determination is made is recorded. When development of an IPR&D asset is complete the associated asset would be deemed finite-lived and would then be amortized based on its respective estimated useful life at that point.

Contingent Consideration

Each reporting period, we revalue the contingent consideration obligations associated with business combinations to their fair value and record increases in their fair value as contingent consideration expense and decreases in the fair value as contingent consideration income. Changes in contingent consideration result from changes in the assumptions regarding probabilities of successful achievement of related milestones, the estimated timing in which the milestones are achieved and the discount rate used to estimate the fair value of the liability. Contingent consideration may change significantly as development of our clinical programs in certain indications progress and additional data are obtained, impacting our assumptions. The assumptions used in estimating fair value require significant judgment. The use of different assumptions and judgments could result in a materially different estimate of fair value.

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Results of Operations

Comparison of the Three Months Ended September 30, 2016 and 2015

	Three Months Ended September 30,		
	2016	2015	Change
		(in thousands)	
Revenue	$ 28,650	$ 67	$ 28,583
Operating expenses:			
Research and development	2,754	6,745	(3,991)
General and administrative	6,366	2,681	3,685
Total operating expenses	9,120	9,426	(306)
Income (loss) from operations	19,530	(9,359)	28,889
Other income (expense), net	(43)	(334)	291
Net income (loss)	$ 19,487	$ (9,693)	$ 29,180

Revenue . Revenue was $28.7 million for the three months ended September 30, 2016 compared to $0.1 million the three months ended September 30, 2015 . The increase was primarily due to the fees received from Roche under the License Agreement.

Research and development expenses . Research and development expenses were $2.8 million for the three months ended September 30, 2016 compared to $6.7 million for the three months ended September 30, 2015 . The decrease of $4.0 million was primarily due to a decrease of $3.9 million of isunakinra-related development expenses, which development activities are no longer ongoing, as well as decreases in EBI-031 related development expenses of $1.0 million due to the License Agreement with Roche. These decreases were partially offset by increases in employee and contractor-related expenses, including stock-based compensation and severance, which were $2.1 million for the three months ended September 30, 2016 compared to $1.2 million for the three months ended September 30, 2015.

General and administrative expenses . General and administrative expenses were $6.4 million for the three months ended September 30, 2016 compared to $2.7 million for the three months ended September 30, 2015 . The increase of $3.7 million was primarily due to increased severance, retention and stock-based compensation expenses and professional fees related to our review of strategic alternatives and the acquisition of Viventia.

Other income, net . Other income, net was $0.0 million for the three months ended September 30, 2016 compared to $(0.3) million for the three months ended September 30, 2015 . The decrease of $0.3 million was primarily due to the decrease in interest expense of $0.4 million for the three months ended September 30, 2016 compared to the three months ended September 30, 2015 .

Comparison of the Nine Months Ended September 30, 2016 and 2015

	Nine Months Ended September 30,		
	2016	2015	Change
		(in thousands)	
Revenue	$ 29,156	$ 425	$ 28,731
Operating expenses:			
Research and development	10,684	18,252	(7,568)
General and administrative	11,984	7,531	4,453
Total operating expenses	22,668	25,783	(3,115)
Loss from operations	6,488	(25,358)	31,846
Other income (expense), net	(1,066)	2,235	(3,301)
Net income (loss)	$ 5,422	$ (23,123)	$ 28,545

Revenue . Revenue was $29.2 million for the nine months ended September 30, 2016 compared to $0.4 million for the nine months ended September 30, 2015 . The increase was primarily due to the fees received from Roche under the License Agreement.

Research and development expenses . Research and development expenses were $10.7 million for the nine months ended September 30, 2016 compared to $18.3 million for the nine months ended September 30, 2015 . The decrease of $7.6 million was primarily due to a decrease of $9.8 million of isunakinra-related development expenses, which was partially offset by increases in EBI-031 related development expenses of $1.0 million . In addition, employee and contractor-related expenses, including stock-based compensation and severance, were $5.0 million for the nine months ended September 30, 2016 compared to $3.6 million for the nine months ended September 30, 2015.

General and administrative expenses . General and administrative expenses were $12.0 million for the nine months ended September 30, 2016 compared to $7.5 million for the nine months ended September 30, 2015 . The increase of $4.5 million was primarily due to increased severance, retention and stock-based compensation expenses and professional fees related to the License Agreement with Roche, our review of strategic alternatives and the acquisition of Viventia.

Other income (expense), net . Other income (expense), net was $(1.1) million for the nine months ended September 30, 2016 compared to $2.2 million for the nine months ended September 30, 2015 . The change of $(3.3) million was due to the decrease of the change in the fair value of our warrant liability from $3.2 million in 2015 to $0.0 million in 2016. In addition, there was a loss on extinguishment of debt in 2016 of $0.9 million associated with the prepayment of the loan with SVB. These changes were partially offset by a decrease in interest expense from $1.0 million in 2015 to $0.2 million in 2016.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, we have incurred significant operating losses and expect to continue to incur operating losses for the foreseeable future. Substantially all of our revenue to date has been from the License Agreement and, to a lesser extent, from a collaboration agreement. 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, sales effected in an "at the market" offering through our agent, Cowen, a license agreement and, to a lesser extent, from a collaboration.

In June 2016, we entered into the License Agreement with Roche and received an up-front license fee of $7.5 million and up to an additional $262.5 million upon the achievement of specified regulatory, development and commercial milestones with respect to up to two unrelated indications. Specifically, an aggregate amount of up to $197.5 million is payable to us for the achievement of specified milestones with respect to the first indication: consisting of $72.5 million in development milestones, $50.0 million in regulatory milestones and $75.0 million in commercialization milestones.

The first development milestone payment was equal to $22.5 million as a result of the IND for EBI-031 becoming effective on or before September 15, 2016. Additional amounts of up to $65.0 million are payable upon the achievement of specified development and regulatory milestones in a second indication.

In addition, we are entitled to receive royalty payments in accordance with a tiered royalty rate scale, with rates ranging from 7.5% to 15% for net sales of potential future products containing EBI-031 and at up to 50% of these rates for net sales of potential future products containing other IL-6 compounds, with each of the royalties subject to reduction under certain circumstances and to the buy-out options of Roche.

Cash Flows

As of September 30, 2016 , we had cash and cash equivalents of $30.7 million . Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation.

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

	Nine Months Ended September 30,	
	2016	2015
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ 8,138	$ (25,148)
Investing activities	419	(286)
Financing activities	(13,920)	17,737
Net decrease in cash and cash equivalents	$ (5,363)	$ (7,697)

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

Net cash used in operating activities was $25.1 million for the nine months ended September 30, 2015 , and consisted primarily of a net loss of $23.1 million adjusted for non-cash items, including stock-based compensation expense of $1.9 million , depreciation expense of $0.3 million , a change of $(3.2) million in the fair value of the warrant liability and a net change in operating assets and liabilities of $(1.1) million .

Investing activities . Net cash provided by (used in) investing activities consists of sales and purchases of property and equipment. For the nine months ended September 30, 2016 , we sold $0.3 million of property and equipment. We also acquired $0.1 million of cash from the acquisition of Viventia. For the nine months ended September 30, 2015 , we purchased $0.3 million of property and equipment.

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

Net cash provided by financing activities for the nine months ended September 30, 2015 was $17.7 million and consisted primarily of net proceeds of $12.7 million from the issuance of common stock in connection with sales effected in an "at the market" offering through our agent , Cowen, and $5.0 million from additional borrowings under our loan with SVB.

Funding Requirements

We will incur substantial expenses if and as we:

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

We believe that our cash and cash equivalents of $30.7 million as of September 30, 2016 will be sufficient to fund our current operating plan into 2018. 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 initiation, progress, timing, costs and results of pre-clinical studies and clinical trials for our product candidates or any other future product candidates;
- the scope, progress, results and costs of pre-clinical development and laboratory testing of our pre-clinical product candidates;
- our ability to establish collaborations on favorable terms, if at all, particularly manufacturing, marketing and distribution arrangements for our product candidates;
- the costs and timing of the implementation of commercial-scale manufacturing activities;
- the costs and timing of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- our obligation to make milestone, royalty and other payments to third party licensors under our licensing agreements;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- the outcome, timing and cost of regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities, including Health Canada, to require that we perform more studies than those that we currently expect;
- our ability to achieve certain future regulatory, development and commercialization milestones under the License Agreement with Roche;
- the effect of competing technological and market developments; and
- the revenue, if any, received from commercial sales of any product candidates for which we receive regulatory approval.

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

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of September 30, 2016 :

	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years
			(in thousands)		
Operating lease obligations(1)	$ 1,185	$ 296	$ 593	$ 296	$ —
License maintenance fees(2)	1,374	180	360	360	474
Total fixed contractual obligations	$ 2,559	$ 476	$ 953	$ 656	$ 474

(1) We lease our manufacturing facility located in Winnipeg, Manitoba Canada, which consists of an approximately 31,400 square foot manufacturing, laboratory, warehouse and office facility, under a five year renewable lease through September 2020. The monthly rent for this office space is approximately $25,000 per month.

(2) We have entered into various license agreements that, upon successful clinical development, contingently trigger payments upon achievement of certain milestones, royalties and other such payments. See ‘‘—License Agreements’’ below. Because the achievement of these milestones are uncertain, the amounts have not been included.

We enter into agreements in the normal course of business with CROs for clinical trials and with vendors for pre-clinical studies, license agreements and other services and products for operating purposes which are cancelable by us, upon prior written notice. We have an agreement with a CRO that may be terminated at any time with 30 days’ notice; however, upon termination, we would be required to pay all costs incurred by the CRO up to the termination date, plus an additional fee, which
is calculated as an amount equal to either (a) 5% of the unearned fees for services as provided in the budget if we have paid 50% or more of the total fees for services as specified in the work order or (b) 3% of the amount of fees we have paid for services as of the date of termination if we have paid less than 50% of the total fees for services as specified in the work order. As of September 30, 2016, we incurred with this CRO $2.8 million in fees for services, which is less than 50% of the total fees for services as specified in the current work order with this CRO. Therefore, as of September 30, 2016, we would have been required to pay a termination fee of 3% of the amount of fees as of the date of termination of this agreement, which would have equaled $84,000 as of September 30, 2016. Amounts owed to such CRO were not included in the ‘‘Contractual Obligations and Commitments’’ table above as it was considered a contingent payment as of September 30, 2016.

We also leased our corporate headquarters located at 215 First Street Cambridge, Massachusetts, which consisted of approximately 11,200 square foot of laboratory and office space. On October 14, 2016, we terminated our lease and relocated our corporate offices to 245 First Street Cambridge, Massachusetts. We also lease office space in Philadelphia, PA, where we occupy office space under a lease that was executed in September 2015. The initial term of the lease expired in August 2016, after which the lease continues on a month-to-month basis unless terminated by either party by giving the requisite notice. The monthly rent for this office space is approximately $5,000 per month. We also occupy office space in Toronto, with rent of approximately $2,000 per month, on a month-to-month lease, which can be terminated by either party by giving 30 days written notice. These payments are not included in this table of contractual obligations.

Under the Share Purchase Agreement, we are obligated to pay to the Selling Shareholders certain post closing contingent cash payments upon the achievement of specified milestones and based upon net sales, in each case subject to the terms and conditions set forth in the Share Purchase Agreement, including: (i) a one-time milestone payment of $12.5 million payable upon the first sale of Vicinium ™ or any variant or derivative thereof, other than Proxinium ™ (the “Purchased Product”), in the United States; (ii) a one-time milestone payment of $7.0 million payable upon the first sale of the Purchased Product in any one of certain specified European countries; (iii) a one-time milestone payment of $3.0 million payable upon the first sale of the Purchased Product in Japan; and (iv) and quarterly earn-out payments equal to two percent (2%) of net sales of the Purchased Product during specified earn-out periods. Such earn-out payments are payable with respect to net sales in a country beginning on the date of the first sale in such country and ending on the earlier of (i) December 31, 2033 and (ii) fifteen years after the date of such sale, subject to early termination in certain circumstances if a biosimilar product is on the market in the applicable country. Because the achievement of these milestones are uncertain, the amounts have not been included.

License Agreements

License Agreement with the University of Zurich

We have a license agreement with Zurich, which grants us exclusive license rights, with the right to sublicense, to make, have made, use and sell under certain patents primarily directed to our targeting agent, including EpCAM chimera and related immunoconjugates and methods of use and manufacture of the same. These patents cover some key aspects of our product candidates Vicinium and Proxinium.

Under the terms of the agreement, we may be obligated to pay $0.8 million in milestone payments, for the first product candidate that achieves applicable clinical development milestones. Based on current clinical status, we anticipate that these milestones may be triggered by Vicinium’s clinical development pathway. As part of the consideration, we will also be obligated to pay up to a 4% royalty on the net product sales for products covered by or manufactured using a method covered by a valid claim in the Zurich patent rights. We have the right to reduce the amount of royalties owed to Zurich if the total royalty rate owed by us to Zurich and any other third party is 10% or greater, provided that the royalty rate may not be less than 2% of net sales. The obligation to pay royalties in a particular country expires upon the expiration or termination of the last of the Zurich patent rights that covers the manufacture, use or sale of a product. There is no obligation to pay royalties in a country if there is no valid claim that covers the product or a method of manufacturing the product.

License Agreement with Merck KGaA

We have a license agreement with Merck, which grants us an exclusive license, with the right to sublicense, under certain patents and technology relating to the de-immunization of our cytotoxin Bouganin for therapeutic and *in vivo* diagnostic purposes in humans. The de-immunized cytotoxin is known as deBouganin and has been incorporated in to our product candidates, VB6-845d. We have the worldwide exclusive right, with the right to sublicense, under the licensed patents and technology to, among other things, make, have made, use or sell products incorporating deBouganin.

Under the agreement, we may be obligated to make milestone payments in respect of certain stages of regulatory approval reached by a product candidate generated by this technology or covered by a licensed patent, as well as royalties calculated with respect to net sales of these products.

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.

Foreign Currency Risk

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

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures as of September 30, 2016 . The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e)) under Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time period specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of the Company's disclosure controls and procedures as of September 30, 2016 , the Company's Chief Executive Officer and Chief Financial 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, other than those related to business combination and accounting for significant non-routine transactions.

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 and expect to continue to incur operating losses for the foreseeable future. We had net income of $5.4 million for the nine months ended September 30, 2016 due to the $28.7 million of revenue from the License Agreement, however we have incurred net losses of $33.5 million for the year ended December 31, 2015, $34.2 million for the year ended December 31, 2014 and $18.0 million for the year ended December 31, 2013. As of September 30, 2016 , we had an accumulated deficit of $119.8 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, sales effected in an "at the market" offering through our agent, Cowen and Company, LLC, through our License Agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., or collectively, Roche and, to a lesser extent, from a collaboration. Substantially 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 activities. 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 will incur substantial expenses if and as we:

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

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, the European Medicine Agency, or EMA, or Health Canada to perform studies in addition to those currently expected; or
- if there are any delays in enrollment of subjects in, or completing our clinical trials or the development of any product candidates that we may develop.

Our ability to become and remain profitable depends on our ability to generate revenue.We have not commercialized any of our product candidates. We do not expect to generate significant revenue unless and until we obtain marketing approval for, and

commercialize, Vicinium, Proxinium or our other product candidates that we may develop, in-license or acquire in the future. This would require us to be successful in a range of challenging activities, including:

- successfully completing development activities, including clinical trial design and enrollment of a sufficient number of subjects in our clinical trials and completion of the necessary clinical trials;
- completing and submitting biologics license applications, or BLAs, to the FDA and obtaining regulatory approval for indications for which there is a commercial market;
- completing and submitting applications to, and obtaining regulatory approval from, foreign regulatory authorities, including Health Canada and the EMA;
- establishing sales, marketing and distribution capabilities, either ourselves or through collaborations or other arrangements with third parties, to effectively market and sell our product candidates;
- achieving an adequate level of market acceptance of our product candidates;
- successfully commercializing any product candidates, if approved;
- protecting our rights to our intellectual property portfolio;
- ensuring the manufacture of commercial quantities of our product candidates;
- finding suitable partners to help us develop certain of our product candidates and market, sell and/or distribute any of our products that receive regulatory approval in other markets; and
- obtaining adequate pricing, coverage and reimbursement from third parties, including government and private payors.

We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

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 are devoting substantial financial resources to our ongoing and planned activities including functions associated with operating as a public company. We expect to continue to spend substantial amounts of funds in connection with our ongoing activities, particularly as we continue our Phase 3 clinical trial for Vicinium, initiate our Phase 2 clinical trial for Proxinium, and continue research and development activities. 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 initiation, progress, timing, costs and results of clinical trials for our product candidates or any other future product candidates;
- the scope, progress, results and costs of pre-clinical development and laboratory testing of our pre-clinical product candidates;
- our ability to establish collaborations on favorable terms, if at all, particularly manufacturing, marketing and distribution arrangements for our product candidates;
- the costs and timing of the implementation of commercial-scale manufacturing activities;
- the costs and timing of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;

- our obligation to make milestone, royalty and other payments to third party licensors under our licensing agreements;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- the outcome, timing and cost of regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities, including Health Canada, to require that we perform more studies than those that we currently expect;
- the effect of competing technological and market developments; and
- the revenue, if any, received from commercial sales of any product candidates for which we receive regulatory approval.

We believe that our cash and cash equivalents of $30.7 million as of September 30, 2016 will be sufficient to fund our current operating plan into 2018. 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.

Identifying potential product candidates and conducting pre-clinical 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 any products that we successfully develop, none of which we expect to be commercially available for many years, if at all. In addition, if approved, any 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.

Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in our Annual Report on Form 10-K.

Our report from our independent registered public accounting firm for the year ended December 31, 2015 includes an explanatory paragraph stating that our losses from operations and required additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. While we believe our license agreement with Roche will provide us with sufficient funding for at least the next twelve months, given our planned expenditures for the next several years, we and our independent registered public accounting firm may conclude, in connection with the preparation of our financial statements for the year ended December 31, 2016 that there is still a substantial doubt regarding our ability to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or a part of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all.

Future sales and issuances of shares of our common stock or rights to purchase shares of our common stock, including pursuant to our 2014 Stock Incentive Plan and 2009 Stock Incentive Plan, could result in additional dilution of the percentage ownership of 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 the amounts payable under the License Agreement with Roche. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights as holders of our common stock. 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. Additionally, since April 2015, we have issued and sold 1,446,781 shares of our common stock in "at the market" offerings, which resulted in dilution to our existing stockholders. Further, in September 2016 we acquired Viventia

in an all-stock transaction pursuant to which we issued 4,013,431 shares of our common stock to the selling stockholders of Viventia, which resulted in further dilution to our existing stockholders.

We have also adopted the 2014 Stock Incentive Plan, or the 2014 Plan, to enable us and our subsidiaries to recruit and retain highly qualified employees, directors and consultants, provide those individuals with an incentive for productivity, and provide those individuals with an opportunity to share in our growth and value. As of September 30, 2016, we had 713,021 shares of common stock available for issuance under 2014 Plan. Future equity incentive grants and issuances of shares of common stock under the 2014 Plan may have an adverse effect on the market price of shares of our common stock.

Further, 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.

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 pre-clinical studies and conducting clinical trials. All of our product candidates which we are currently pursuing are still in clinical or pre-clinical development. We have not yet demonstrated our ability to successfully complete clinical development of any product candidate, 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.

Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. The ultimate impact on us and our general infrastructure of being in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a fire or other natural disaster.

The anticipated benefits of the Viventia acquisition may not be fully realized and may take longer to realize than expected.

The Viventia acquisition involved the integration of Viventia’s operations, product candidates and technology with our existing operations and programs, and there are uncertainties inherent in such integration. We have devoted and will continue to devote significant management attention and resources to the Viventia integration and to the further development of Viventia's product candidates and other development programs. Delays, unexpected difficulties in the integration process or failure to retain key management personnel could adversely affect our business, financial results and financial condition. Even if we were able to conduct the integration successfully, we may not realize the full achievement of the benefits of the Viventia acquisition within a reasonable period of time.

In addition, we may have not yet discovered during the due diligence process all factors regarding Viventia that could produce unintended and unexpected consequences for us. Undiscovered factors could cause us to incur potentially material financial liabilities, and prevent us from achieving the expected benefits from the acquisition within our desired time frames, if at all.

Risks Related to the Discovery and Development of Our Product Candidates

We are dependent on our lead product candidates, Vicinium ™ and Proxinium ™. If we are unable to obtain marketing approval for or successfully commercialize either of these lead product candidates, either alone or through a collaboration, or experience significant delays in doing so, our business could be materially harmed.

We currently have no products approved for sale and have invested a significant portion of our efforts and financial resources in the development of Vicinium for the treatment of patients with high-grade non-muscular invasive bladder cancer, or NMIBC, and of Proxinium for the treatment of patients with squamous cell carcinoma of the head and neck, or SCCHN. Our prospects are substantially dependent on our ability to obtain marketing approval for and successfully commercialize Vicinium and Proxinium. The success of these two lead product candidates will depend, among other things, on our ability to design and successfully complete clinical trials for each product candidate. The clinical trial process is uncertain, and failure of one or more clinical trials can occur at any stage of testing. For example, in 2009, Viventia put its development of Vicinium on hold due to the uncertainty of the standard of care for bladder cancer, and in 2008, Viventia terminated its Phase 3 clinical trial of Proxinium due to enrollment and retention reasons that we believe were specific to emerging markets. While we plan to move both of these programs forward, and believe that we will not have enrollment and retention problems with our Phase 2 clinical trial for Proxinium in the United States and Canada, the general clinical development of product candidates involves a lengthy and expensive process with an uncertain outcome. We are also in the early stages of development of EBI-031. We submitted an investigational new drug, or IND, application for EBI-031 for the treatment of DME and uveitis in June 2016, which received IND Clearance from the FDA on July 7, 2016, and enables initiation of clinical development of this product candidate.

In addition to the successful completion of clinical trials, the success of Vicinium, Proxinium and EBI-031 will also depend on several other factors, including the following:

- receipt of marketing approvals from the FDA, Health Canada or comparable foreign regulatory authorities;
- performance of our future collaborators, if any;
- extent of any required post-marketing approval commitments to applicable regulatory authorities;
- obtaining and maintaining patent, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protection of our rights in our intellectual property portfolio;
- launch of commercial sales, if and when marking approval is received;
- demonstration of an acceptable safety profile prior to and following any marketing approval;
- marketplace acceptance, if and when approved, by patients, the medical community and third party payors;
- establishing and maintaining pricing sufficient to realize a meaningful return on our investment; and
- competition with other therapies.

If we (or, in the case of EBI-031, Roche) are unable to develop, receive marketing approval for, or successfully commercialize Vicinium, Proxinium or EBI-031, or experience delays as a result of any of these factors or otherwise, our business could be materially harmed.

If clinical trials of any product candidate that we develop fail to demonstrate safety and efficacy to the satisfaction of the FDA, Health Canada, 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 any product candidate.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete pre-clinical 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 pre-clinical 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, pre-clinical and clinical data are often susceptible to varying interpretations and

analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. For example, in May 2015, we announced top-line results from our Phase 3 clinical trial of our product candidate isunakinra in patients with moderate to severe dry eye disease. In this trial, there was no statistically significant difference between the isunakinra treated group and the vehicle control group on the co-primary endpoints. In addition, there were no statistically significant differences between the isunakinra treated group and the vehicle treated group on any secondary endpoints. Additionally, in January 2016, we announced top-line results from our Phase 3 clinical trial of isunakinra in patients with severe allergic conjunctivitis. In this trial, there was no statistically significant difference between the isunakinra treated group and the vehicle control group on the primary endpoint of ocular itching or on any secondary endpoints.

Many compounds that initially showed promise in early-stage testing for treating cancer have later been found to not be effective treatments or may cause side effects that prevented further development of the compound. The therapeutic efficacy of our product candidates is unproven in humans, and we may not be able to successfully develop and commercialize our product candidates.

Our product candidates are novel and their potential benefit is unproven. Our ability to generate revenues from our product candidates, which we do not expect will occur in the short term, if ever, will depend heavily on the successful development, approval and commercialization, if achieved. For example, our product candidates may not prove to be effective treatments for the cancer targets they are being designed to act against and may not demonstrate in clinical trial subjects any or all of the pharmacological data points that may have been demonstrated in pre-clinical studies and clinical trials. Our product candidates may interact with human biological systems in unforeseen, ineffective or harmful ways. If our product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in early-stage testing for treating cancer have later been found to not be effective treatments or may cause side effects that prevented further development of the compound. As a result of these and other risks described herein that are inherent in the development of novel therapeutic agents, we may never successfully develop, enter into or maintain third party licensing or collaboration transactions with respect to, or successfully commercialize our product candidates, in which case we will not achieve profitability and the value of our shares of common stock may decline.

We may expend our limited resources to pursue development of a particular product candidate or indication and fail to capitalize on product candidates or indications that have a greater likelihood of clinical success or commercial potential.

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 likelihood of clinical success or commercial potential. For example, we previously invested a significant portion of our efforts and financial resources in the development of isunakinra for the treatment of patients with dry eye disease and allergic conjunctivitis. Notwithstanding this significant investment, based on the results from our completed Phase 3 clinical trials in dry eye disease and allergic conjunctivitis, we do not plan to pursue further development of isunakinra.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on research and development programs and product candidates for specific indications may not yield any commercially viable products. In addition, 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.

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 any 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 subjects 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 or fail to reach agreement with the FDA or a comparable foreign regulatory authority, including Health Canada, on a trial design that we are able to execute;
- 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 or other reviewing entities, including comparable foreign regulatory authorities such as Health Canada, 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;
- we may receive feedback from the FDA, data safety monitoring boards, or DSMBs, or a comparable foreign regulatory authority, including Health Canada, or results from earlier stage or concurrent pre-clinical studies and clinical trials, that might require modification to the protocol for the clinical trial or performance of additional studies before the clinical trials may continue;
- the FDA, a comparable foreign regulatory authority, including Health Canada, or we, may decide to, or a DSMB may recommend to, suspend or terminate clinical trials at any time for safety issues or for any other reason;
- 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;
- 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;
- lack of adequate funding to continue a clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical trials or increased expenses associated with the services of our contract research organizations, or CROs, and other third parties; and
- changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their activities, we have limited influence over their actual performance. Any delays in completing our clinical trials will increase our costs, slow down our development and regulatory submission process for our product candidates and jeopardize our ability to obtain regulatory approval, commence commercial sales and generate revenues, if our product candidates are ultimately approved.

Further, conducting clinical trials in foreign countries, as we have done historically for Vicinium and Proxinium and as we may decide to do in the future, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled subjects in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

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 pre-clinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant pre-clinical 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 subjects 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 our product candidates that we may develop if we are unable to locate and enroll a sufficient number of eligible subjects to participate in these trials as required by the FDA or similar regulatory authorities outside the United States, including Health Canada. We have previously experienced difficulties with clinical trial enrollment and retention, which led to the early termination of our Phase 3 trial of Proxinium in 2007, and we may experience difficulties in subject enrollment in our clinical trials in the future for a variety of reasons.

Subject enrollment is affected by a number of factors, including:

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;
- the size of the subject population required for analysis of the clinical trial's primary endpoints;
- the design of the clinical trial;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the subject referral practices of physicians;
- any ongoing clinical trials conducted by competitors for the same indication;
- the risk that subjects enrolled in clinical trials will drop out of the clinical trials before completion;
- the ability to monitor subjects adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective subjects.

Further, our ability to successfully initiate, enroll and complete a clinical trial in any foreign country, should we decide to do so, is subject to numerous risks unique to conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with CROs and physicians;
- different standards for the conduct of clinical trials;
- absence in some countries of established groups with sufficient regulatory expertise for review of the protocols associated with our product candidates;
- our inability to locate qualified local consultants, physicians and partners; and
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatments.

In addition, our clinical trials will compete with other clinical trials for other product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of subjects available to us, because some subjects who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of subjects who are available for our clinical trials in such clinical trial site. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential subjects and their doctors may be inclined to use conventional therapies, such as chemotherapy, rather than enroll subjects in any of our future clinical trials.

Our inability to enroll a sufficient number of subjects 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.

Our product candidates may cause undesirable side effects, serious adverse events or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any marketing approval.

Undesirable side effects or serious adverse events caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt respective clinical trials and could result in a restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities, including Health Canada. For example, even though each of our product candidates that have been administered to humans in earlier-stage clinical trials have generally been well-tolerated by subjects, in some cases there were side effects and serious adverse events, some of which were severe.

High-grade NMIBC (Vicinium)

There were no Grade 4 or Grade 5 serious adverse events that were considered by the clinical investigator to be related to Vicinium. However, there was one Grade 5 serious adverse event, or death, which was determined by the clinical investigator to be unrelated to Vicinium. The most common treatment-related Grade 3 serious adverse events were an abnormally frequent passage of small amounts of urine, blood in the urine and painful urination, the majority of which were considered to be mild or moderate in severity. No subjects discontinued treatment due to a Vicinium-related adverse event during the Phase 1 and Phase 2 clinical trials.

SCCHN (Proxinium)

There were no Grade 5 serious adverse events that were considered by the clinical investigator to be related to Proxinium. The Grade 3 and Grade 4 serious adverse events that were reported in the clinical trials of Proxinium and were considered to be possibly, probably or definitely related to treatment consisted of abnormal tumor growth, anorexia, cancer pain, decrease in red blood cells, difficulty swallowing, elevated calcium levels, facial pain, fatigue, high blood sugar, influenza-like illness, injection site pain, liver function abnormalities, low albumin level, low sodium concentration, nausea, rash, swelling, tumor hemorrhage and tumor necrosis. Seven subjects died during the clinical trials of Proxinium, but none of the deaths were deemed to be related to Proxinium. Eleven subjects discontinued treatment due to liver function test abnormalities; however, the serum levels were transient and they eventually returned to baseline without any evidence of liver damage. Four subjects withdrew from the clinical trials. Three of the four subjects withdrew at their request and one of the four subjects withdrew at the request of the investigator.

Multiple types of EpCAM-positive solid tumors (VB6-845d)

There were no Grade 5 serious adverse events that were considered by the clinical investigator to be related to VB6-845, which is the prior version of VB6-845d. The Grade 3 and Grade 4 serious adverse events that were considered to be possibly, probably or definitely related to treatment consisted of an infusion related reaction and an infusion site reaction.

As a result of these side effects and serious adverse events or further safety or toxicity issues that we may experience in our clinical trials in the future, we may not receive regulatory approval for any of our product candidates, which could prevent us from ever generating revenues or achieving profitability. Results of our clinical trials could reveal an unacceptably high severity and prevalence of side effects or serious adverse events. In such an event, our clinical trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities, including Health Canada, could order us to cease further development or deny approval of any of our product candidates for any or all targeted indications. The clinical trial drug-related side effects or serious adverse events could affect clinical trial subject recruitment or the ability of enrolled subjects to complete the clinical trial or result in potential product liability claims.

We have no clinical safety data on human exposure to EBI-031 or any of our other pre-clinical product candidates. 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.

Additionally, if our product candidates receive marketing approval, and we or others later identify undesirable side effects or serious adverse events caused by our product candidates, a number of potentially significant negative consequences could result, including:

- we may be forced to suspend marketing of our product candidates;

- regulatory authorities may withdraw their approvals of our product candidates;
- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of our product candidates;
- we may be required to conduct post-marketing studies;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates, if approved.

We will need to obtain FDA approval of any proposed names for our product candidates, and any failure or delay associated with such naming approval may adversely impact our business.

We have not yet submitted our proposed proprietary names, Vicinium and Proxinium, to the FDA or any foreign regulatory authority, including Health Canada, for provisional approval. Any proprietary name we propose to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA reviews any proposed product name, including an evaluation of potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. If the FDA objects to any proposed proprietary product name, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may apply for and could possibly obtain provisional approval of our proprietary names by the FDA prior to submission of our BLAs. However, this approval is conditional upon a further and final review by the FDA at the time of BLA review.

We may attempt to secure approval from the FDA or comparable non-U.S. regulatory authorities through the use of accelerated registration pathways. If unable to obtain approval under an accelerated pathway, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.

We may seek an accelerated approval development pathway for certain indications for our product candidates, including Vicinium in BCG refractory high-grade NMIBC. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, or FDCA, and the FDA's implementing regulations, the FDA may grant accelerated approval to a product designed to treat a serious or life-threatening condition that provides meaningful therapeutic advantage over available therapies and demonstrates an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

If we choose to pursue accelerated approval, we intend to seek feedback from the FDA or will otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that the FDA will agree that our proposed primary endpoint of a pivotal study is an appropriate surrogate endpoint. There also can be no assurance that, after our evaluation of the feedback from the FDA or other factors, we will decide to pursue or submit a BLA for accelerated approval or any other form of expedited development, review or approval. Furthermore, if we submit an application for accelerated approval, there can be no assurance that such application will be accepted or that approval will be granted on a timely basis, or at all. For example, if another company receives full approval from the FDA to market a product for treatment of BCG refractory high-grade NMIBC, our ability to seek and obtain accelerated approval for Vicinium in the same indication may be materially adversely affected. The FDA or foreign regulatory authorities also could require us to conduct further studies prior to considering our application or granting approval of any type. We might not be able to fulfill the FDA's requirements in a timely manner, which would cause delays, or approval might not be granted because our submission is deemed incomplete by the FDA. A failure to obtain accelerated approval or any other form of expedited development, review or approval for a product candidate would result in a longer time period to commercialize such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Moreover, even if we receive accelerated approval from the FDA, we will be subject to rigorous postmarketing requirements, including the completion of confirmatory postmarket clinical trial(s) to verify the clinical benefit of the product, and submission to the FDA of all promotional materials 30-120 days prior to their dissemination. The FDA could seek to withdraw accelerated approval for multiple reasons, including if we fail to conduct any required postmarket study with due diligence, a postmarket study does not confirm the predicted clinical benefit, other evidence shows that the product is notsafe or effective under the conditions of use, or we disseminate promotional materials that are found by the FDA to be false and misleading.

Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics for our product candidates could impede development and commercialization.

We have developed a companion diagnostic for use with Proxinium. The FDA and comparable foreign regulatory authorities, including Health Canada, may require the development and regulatory approval of a companion diagnostic as a condition to approving Proxinium. Companion diagnostics developed in conjunction with clinical programs for the associated products are subject to regulation by the FDA and comparable foreign regulatory authorities, including Health Canada, as medical devices, and require separate approval prior to their commercialization. Each regulatory body that approves a product will independently need to approve the companion diagnostic before or concurrently with its approval of the product candidate, and before a product can be commercialized. During a Type C meeting with the FDA in 2007, the FDA noted that approval of a companion diagnostic for epithelial cell adhesion molecule, or EpCAM expression would need to coincide with Proxinium approval. We intend to clarify whether the FDA still believes that a companion diagnostic is necessary to receive approval. The FDA may still require that a companion diagnostic for EpCAM expression be approved before or at the time of Proxinium approval. We and any potential future third-party collaborators may encounter difficulties in developing and obtaining approval for any companion diagnostic. Any delay or failure by us or our future third-party collaborators to develop or obtain regulatory approval for a companion diagnostic could delay or prevent approval of Proxinium. We could also incur additional expense if the FDA or comparable regulatory authorities, including Health Canada, determine that further studies are required before our companion diagnostic may be approved. Even if approved, we may experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners for production, all of which may prevent us from commercializing our product candidates on a timely or profitable basis, if at all. Additionally, we or our collaborators may encounter production difficulties that could constrain the supply of the companion diagnostics, affect the ease of use, affect the price or have difficulties gaining acceptance of the use of the companion diagnostics in the clinical community. If the companion diagnostic for use with Proxinium fails to gain market acceptance, our ability to derive revenues from sales of Proxinium, if approved, could be harmed.

If we encounter difficulties in identifying and/or negotiating a commercial manufacturing agreement with a third party manufacturer of our product candidates, or if we experience problems with the third-party manufacturer, the manufacturing of our product candidates and our product development and commercialization efforts may be delayed, we may not be able to obtain regulatory approval of our product candidates, and our costs may be higher than expected, all of which could have a material adverse effect on our business.

We intend to rely upon a third-party manufacturer for the commercial supply of our product candidates. Our reliance on a third-party manufacturer will expose us to certain risks that we would not be subject to if we manufactured those products ourselves, including:

- The development of commercial-scale manufacturing capabilities may require our third-party manufacturer to invest substantial additional funds and hire and retain technical personnel who have the necessary manufacturing experience. Our third-party manufacturer may fail to devote sufficient time and resources to develop the capabilities to manufacture our product candidates.
- Because of the complex nature of our product candidates, our third party manufacturer, or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy commercial demand, may not be able to achieve such volume at an acceptable cost, may experience technical issues that impact comparability, quality, or compliance with applicable regulations governing the manufacture of biological products, and may experience shortages of qualified personnel to adequately staff production operations.
- Our third-party manufacturer could default on its agreement with us to meet our requirements for commercialization of our product candidates, or it may terminate or decide not to renew its agreement with us, based on its own business priorities, at a time that is costly or damaging to us. If our third-party manufacturer were to terminate our arrangement or fail to meet our commercial manufacturing demands, we may be delayed in our ability to obtain and maintain regulatory approval of our product candidates or, if approved, commercialize our product candidates.
- It may be difficult or impossible for us to find a replacement manufacturer on acceptable terms quickly, or at all. Identifying alternate manufacturers may be difficult because the number of potential manufacturers that have the

necessary expertise to produce biologics is limited. Additionally, the FDA must approve any alternative manufacturer before we may use the alternative manufacturer to produce commercial supply of a product candidate, if approved.

Our reliance on a third party manufacturer reduces our control over our product candidate development and commercialization activities but does not relieve us of our responsibility to ensure compliance with applicable legal and regulatory standards. The FDA and other foreign regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturer to comply with cGMP or to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention of product, refusal to permit the import or export of products, injunction, imposing civil penalties, or pursuing criminal prosecution.

Because we plan to produce commercial supply of our product candidate Vicinium through a third-party manufacturer, the FDA or foreign regulatory authorities may require us to demonstrate that the product manufactured by our third-party manufacturer is comparable in quality, safety, and efficacy to the product that was used in our clinical trials. If we experience challenges in demonstrating comparability, or if the FDA or foreign regulatory authorities require additional nonclinical or clinical studies to demonstrate comparability, the approval and/or commercialization of Vicinium could be delayed, adversely affected or terminated, or may result in significantly higher costs.

Our product candidate, Vicinium, has been produced in our own manufacturing facility for all clinical trials for Vicinium to date, and we also intend to utilize our own manufacturing facility to supply product for our ongoing Phase III clinical trial of Vicinium. We intend to utilize a third-party manufacturer to produce the commercial supply of Vicinium and plan to enter into discussions with the FDA and foreign regulatory authorities regarding the criteria for demonstrating comparability of Vicinium produced by our third-party manufacturer to Vicinium produced in our own manufacturing facility. Because this manufacturing change is being introduced at an advanced stage of development of Vicinium, the FDA and foreign regulatory authorities may require a comprehensive comparability assessment, potentially including additional nonclinical or clinical studies utilizing Vicinium produced by our third-party manufacturer, and/or a modification of our ongoing Phase III clinical trial to include Vicinium produced by our third-party manufacturer. Such requirements could result in lengthy delays and significantly higher costs for the clinical development, filing of a BLA, and potential commercialization of Vicinium. If we are unable to demonstrate comparability of Vicinium produced in our own manufacturing to Vicinium produced by our third-party manufacturer, we may not be able to obtain approval of a BLA for Vicinium. If we are unable to effectively transfer our manufacturing process to our third-party manufacturer, we may be unable to continue the clinical development of or seek approval of Vicinium.

Even if our product candidates receive regulatory approval, we may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for our product candidates, we would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities, including Health Canada, governing, among other things, the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The respective safety and efficacy profiles of our product candidates will continue to be closely monitored by the FDA and comparable foreign regulatory authorities, including Health Canada, if they are approved. If new safety information becomes available after approval of our product candidates, the FDA may require labeling changes or establishment of a Risk Evaluation and Mitigation Strategy, or REMS, and the FDA or comparable foreign regulatory authorities, including Health Canada, may require a similar strategy, impose significant restrictions on our product candidates' indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, and other regulations. If we or a regulatory agency discover problems with our manufacturing facility, a regulatory agency may impose restrictions on that product or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we fail to comply with applicable regulatory requirements, the FDA or comparable foreign regulatory agencies, including Health Canada, may:

- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;

- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials for new indications or product candidates;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit or preclude our ability to commercialize our product candidates and generate revenue.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by, among others, the FDA, the Department of Justice, or the DOJ, the Office of Inspector General of the Department of Health and Human Services, or HHS, and state attorneys general. Violations, including promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or other government agencies. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States may be similarly scrutinized by comparable foreign regulatory authorities, including Health Canada.

In the United States, engaging in impermissible promotion of approved products for off-label uses can also subject a company to false claims litigation under federal and state statutes, and other litigation and/or investigation, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which we promote or distribute our drug products. These false claims statutes include the federal False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. These False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements based on certain sales practices promoting off-label drug uses. This increasing focus and scrutiny has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from the Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and/or investigation and, if we are not successful in defending against such actions, those actions could compromise our ability to become profitable.

Failure to obtain regulatory approval in international jurisdictions would prevent our product candidates from being marketed abroad.

In order to market and sell our products in Canada, the European Union and many other jurisdictions, we 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 approved for sale in that country and/or to be financially successful or viable. We 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. If we are unable to obtain approval of our product candidates by regulatory authorities in Canada, the European Union or another jurisdiction, the commercial prospects of our product candidates may be significantly diminished and our business prospects could decline.

Risks Related to the Commercialization of Our Product Candidates

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, third-party payors and the medical community.

Even if we obtain regulatory approval for our product candidates, our product candidates may not gain market acceptance among physicians, patients, third-party payors or the medical community. The product candidates that we are developing are based on our TPT platform, which is a new technology and therapeutic approach. Market participants with significant influence over acceptance of new treatments, such as physicians and third-party payors, may not adopt a product or treatment based on our TPT platform and technologies, and we may not be able to convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any product candidates developed by us or any future collaborators. Market acceptance of our product candidates, if we receive approval, depends on a number of factors, including:

- the perceived efficacy and safety of our product candidates;
- clinical indications for which our product candidates are approved;
- availability of alternative effective treatments for the disease indications of our product candidates are intended to treat and the relative risks, benefits and costs of those treatments;
- acceptance by physicians, major operators of cancer clinics and patients of our product candidates as safe and effective treatments;
- the success of our physician education programs;
- potential and perceived advantages of our product candidates over alternative treatments;
- safety of our product candidates seen in a broader patient group, including their use outside the approved indications should physicians choose to prescribe them for such uses;
- prevalence and severity of any side effects;
- product labeling or patient information requirements imposed by the FDA or other foreign regulatory authorities, including Health Canada;
- timing of market introduction of our product candidates as well as competitive products;
- the pricing of our treatments, particularly in relation to alternative treatments;
- availability of coverage and adequate reimbursement and pricing by third-party payors and government authorities;
- relative convenience and ease of administration; and
- effectiveness of our sales and marketing efforts.

If our product candidates are approved but fail to achieve market acceptance among physicians, patients, third-party payors or the medical community, we may not be able to generate significant revenues, which would compromise our ability to become profitable.

The market opportunities for our product candidates may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small.

Cancer therapies are sometimes characterized as first-line, second-line or third-line. When cancer is detected early enough, first-line therapy, usually chemotherapy, hormone therapy, surgery, radiotherapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second-line and third-line therapies are administered to patients when prior therapy is not effective. We expect to seek approval of Vicinium for the treatment of high-grade NMIBC and approval for Proxinium for the treatment of late-stage SCCHN. Subsequently, for those product candidates that prove to be sufficiently beneficial, if any, we would expect to seek approval potentially earlier in the treatment paradigm, but there is no guarantee that our product candidates, even if approved, would be approved for first-line therapy, and, prior to any such approvals, we will have to conduct additional clinical trials.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers who have previously failed prior treatments, and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers and the number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if we receive regulatory approval for our product candidates and obtain significant market share, because the potential target populations are small, we may never achieve profitability

without obtaining regulatory approval for additional indications, including the use of the products as first-line or second-line therapy.

Our commercial success could depend upon the continued marketing of a regulatory approved product, or the approval of a product candidate, that is administered with our product candidates.

Some of our future clinical trials may involve marketed products or product candidates being developed by other pharmaceutical companies and some of the indications for which we are developing our product candidates may involve their use in combination with these other marketed products and product candidates. These marketed products or product candidates may be administered in a clinical trial in combination with one or more of our product candidates. In the event that any of these pharmaceutical companies have unforeseen issues that negatively impact their clinical development or marketing approval for their products or product candidates or otherwise negatively affect their ability to continue to clinically develop or market their products or product candidates, our ability to complete our applicable clinical trials and/or evaluate clinical results and, ultimately, our ability to receive regulatory approval for our product candidates for the indications we are pursuing may also be negatively impacted. As a result, this could adversely affect our ability to file for, gain or maintain regulatory approvals on a timely basis, if at all.

If we are unable to establish sales, marketing and distribution capabilities, we may not be successful in commercializing any 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.

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 any 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 any 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 may 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 any 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 any 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 our 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 any 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 our product candidates and will face competition with respect to any other product candidates that we may seek to develop or commercialize in the future, from both large and small pharmaceutical, biopharmaceutical and biotechnology companies,

academic institutions and other research organizations; specifically with companies, institutions and organizations that are actively researching and developing products that attach proprietary cell-killing payloads to antibodies for targeted delivery to cancer cells. There are a number of large pharmaceutical, biopharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the respective disease indications for which we are developing our product candidates. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we are currently developing, and may try to develop, product candidates. There is intense and rapidly evolving competition in the biotechnology, biopharmaceutical and antibody fragment and immuno-oncology therapeutics fields. Some of these competitive products and therapies are based on scientific approaches that are similar to our approach, and others are based on entirely different approaches. We are aware of several companies that are developing cancer immunotherapies and antibody drug conjugates, or ADCs, and we are also aware of several companies developing product candidates that target the same cancer pathways that we are targeting or that are testing product candidates in the same cancer indications that we are testing. For example, there are several companies who have programs that attach proprietary cell-killing payloads to antibodies for targeted delivery to cancer cells.

In addition to competition from alternative treatments, we may also face competition from products that are biosimilar to, and possibly interchangeable with, our product candidates. Biosimilar products are expected to become available over the coming years. Even if our product candidates achieve marketing approval, they may be priced at a significant premium over competitive biosimilar products, and insurers or other third party payors may encourage or even require the use of lower priced biosimilar products. In addition, we may face significant competition upon expiration of our intellectual property protection.

We also face substantial competition with respect to our EBI-031 program. The current standard of care for DME includes anti-VEGF therapies and corticosteroids. Some patients with DME are effectively treated by the current standard of care therapies. Approved anti-VEGF therapies for treating DME include Lucentis (ranibizumab) and Eylea® (aflibercept). Off-label use of Avastin (bevacizumab) is also seen in DME. Approved corticosteroid therapies include Ozurdex (dexamethasone implant) and Iluvien (fluocinolone implant). Laser photocoagulation was historically the standard of care for treating DME, in particular for a subcategory of DME called clinically significant macular edema, and is still used to treat some DME patients. However, anti-VEGF therapy has been proven in clinical trials to have superior efficacy over laser photocoagulation.

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 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. If any product candidate that we may develop achieves marketing approval, we expect that it will be priced at a significant premium over competitive generic products.

More established companies may have a competitive advantage over us due to their greater size, cash flow and institutional experience. Compared to us, many of our competitors may have significantly greater financial, technical and human resources. As a result of these factors, our competitors may obtain regulatory approval of their product candidates before we are able to, which may limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are safer, more effective, more widely used and cheaper than ours, and may also be more successful than us in manufacturing and marketing their products. These appreciable advantages could render our product candidates obsolete or non-competitive before we can recover the expenses of development and commercialization.

If the proposed framework published by the American Society of Clinical Oncology, or ASCO, to assess the value of cancer treatment options is adopted and utilized by payors and physicians and we were to receive low ratings, it could adversely affect the price and reimbursement of our products, if approved, reduce prescriptions and harm our business.

On June 22, 2015, ASCO published a proposed framework to assess the value of cancer treatment options. The framework was developed in response to concern that new, expensive cancer treatments may not be supported by adequate medical evidence. The purpose of the framework is to provide a standardized quantification of cancer treatments and assist oncologists and patients in deciding between new cancer treatments and the standard of care. The framework takes into account a medication’s (i) efficacy, (ii) safety and (iii) cost, to derive an overall treatment value.

This framework is described by ASCO as an initial approach that is not yet suitable for use by doctors and patients. While we believe that the safety and efficacy profiles of our product candidates are potentially better than that of the standard of care and, if approved, we intend to price our products competitively, we do not know how the data will be assessed by ASCO. It is also unknown whether the framework will change and whether any changes could adversely affect the assessment of any of our product candidates. If this framework were adopted and utilized by payors and physicians, and if our product candidates were to receive low ratings, this could adversely affect the price and reimbursement of our products, if approved, reduce prescriptions and harm our business.

Even if we are able to commercialize any 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 any 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 any 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 any 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, including Health Canada. 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.

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 any 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 $10.0 million CAD in product liability insurance coverage in the aggregate, with a per incident limit of $10.0 million CAD, which may not be adequate to cover all liabilities that we may incur. We would need to increase our insurance coverage if we expand our clinical development activities beyond historical levels. We would need to further increase our insurance coverage if we commence commercialization of any 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.

We conduct certain elements of our business internationally, and the decisions of sovereign governments could have a material adverse effect on our business, financial condition and results of operations.

Viventia was founded as a Canadian company and conducted its business internationally. In addition to our clinical trials in the United States, Viventia has historically conducted clinical trials in Russia, Brazil and Canada. We intend to, and may, conduct clinical trials in other jurisdictions. Sovereign governments, including Canada, may establish laws or regulations that will be deleterious to our interests or that will affect our ability, to obtain access to regulatory agencies in Russia, Brazil, Canada, and/or other jurisdictions. Governments have also, from time to time, established foreign exchange controls which could have a material adverse effect on our business, financial condition and results of operations. To date, neither our operations nor our financial condition have been materially impacted due to laws or regulations of sovereign governments.

Risks Related to the License Agreement with Roche

We depend on our license agreement with Roche for the development and commercialization of EBI-031.

On June 10, 2016, we entered into a license agreement, which we refer to herein as the License Agreement with Roche. The License Agreement became effective on August 16, 2016, following stockholder approval. Under the License Agreement, we granted Roche an exclusive, worldwide license, including the right to sublicense, to our patent rights and know-how related to our monoclonal antibody EBI-031 or any other IL-6 antagonist anti-IL-6 monoclonal antibody, to make, have made, use, have used, register, have registered, sell, have sold, offer for sale, import and export any product containing such an antibody or any companion diagnostic used to predict or monitor response to treatment with such a product, or collectively, Licensed Intellectual Property.

Pursuant to the terms of the License Agreement, Roche is required to continue developing EBI-031 and any other product made from the Licensed Intellectual Property that contains an IL-6 antagonist anti-IL-6 monoclonal antibody, or Licensed Product, at its cost.

Roche paid an up-front license fee of $7.5 million upon effectiveness of the license under the License Agreement, and agreed to pay up to an additional $262.5 million upon the achievement of specified regulatory, development and commercial milestones

with respect to up to two unrelated indications. Specifically, an aggregate amount of up to $197.5 million is payable to us for the achievement of specified milestones with respect to the first indication: consisting of $72.5 million in development milestones, $50.0 million in regulatory milestones and $75.0 million in commercialization milestones.

The first development milestone payment equaled $22.5 million as a result of the IND application for EBI-031 becoming effective on or before September 15, 2016, and which was paid to us in September 2016. Additional amounts of up to $65.0 million are payable upon the achievement of specified development and regulatory milestones in a second indication.

In addition, we are entitled to receive royalty payments in accordance with a tiered royalty rate scale, with rates ranging from 7.5% to 15% for net sales of potential future products containing EBI-031 and up to 50% of these rates for net sales of potential future products containing other IL-6 compounds, with each of the royalties subject to reduction under certain circumstances and to the buy-out options of Roche further described below.

The License Agreement provides for two "option periods" during which Roche may elect to make a one-time payment to us and, in turn, terminate its diligence, milestone and royalty payment obligations under the License Agreement. Specifically, (i) Roche may exercise a buy-out option following the first dosing, or Initiation, in the first Phase II study for a Licensed Product until the day before Initiation of the first Phase III study for a Licensed Product, in which case Roche is required to pay us $135 million within 30 days after Roche's exercise of such buy-out option and receipt of an invoice from us, or (ii) Roche may exercise a buy-out option following the day after Initiation of the first Phase III study for a Licensed Product until the day before the acceptance for review by the FDA or other regulatory authority of a BLA or similar application for marketing approval for a Licensed Product in either the United States or in the European Union, in which case Roche is required to pay us, within 30 days after Roche's exercise of such buy-out option and receipt of an invoice from us, $265 million, which amount would be reduced to $220 million if none of our patent rights containing a composition of matter claim covering any compound or Licensed Product has issued in the European Union.

The right to potential future payments under the License Agreement represents a significant portion of the value of the License Agreement to the Company. We cannot be certain that we will receive any future payments under the License Agreement, which would adversely affect the trading price of our common stock and our business prospects.

Additionally, if Roche were to breach or terminate the License Agreement, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for EBI-031 and will not be able to, or may be delayed in our efforts to, successfully commercialize EBI-031. We may not be able to seek and obtain a viable, alternative collaborator to partner for the development and commercialization of the licensed products on similar terms or at all.

Risks Related to Our Dependence on Third Parties

We may enter into collaborations or license agreements with third parties for the development or commercialization of our product candidates. If our collaborations or licenses are not successful, we may not be able to capitalize on the market potential of these product candidates.

We may seek third-party collaborators or licensees for development and commercialization of our product candidates. Our likely collaborators or licensees 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, other than the License Agreement with Roche. Our ability to generate revenues from these arrangements will depend on our collaborators' or licensee's abilities and efforts to successfully perform the functions assigned to them in these arrangements.

Collaborations and licenses involving our product candidates, including the License Agreement with Roche, pose a number of risks, including the following:

- collaborators or licensees have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations or licenses;
- collaborators or licensees may not perform their obligations as expected;
- collaborators or licensees 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' or licensees' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;

- collaborators or licensees 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 or licensees could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators or licensees 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 under the collaboration or license with us may be viewed by our collaborators or licensees as competitive with their own product candidates or products, which may cause collaborators or licensees to cease to devote resources to the commercialization of our product candidates;
- a collaborator or licensee 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 or licensees, 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 or licensees 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 or licensees may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations or licenses may be terminated for the convenience of the collaborator or licensee and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements and licenses may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If any collaborations or licenses that we enter into, do not result in the successful development and commercialization of products or if one of our collaborators or licensees terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration or license. For example, we were collaborating with ThromboGenics, N.V., or ThromboGenics, under a collaboration and license agreement, to identify protein or peptide therapeutics that directly modulate any of a specified set of targets in a novel pathway in retinal disease. On August 1, 2016, we received notice from ThromboGenics of its termination, which became effective on October 31, 2016, of the collaboration and license agreement. No collaboration products were identified under the agreement. We do not expect to receive payment for any future potential milestones or royalties under the ThromboGenics collaboration and license agreement. 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 and licensees.

Additionally, subject to its contractual obligations to us, if a collaborator or licensee 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 or licensees terminates its agreement with us, we may find it more difficult to attract new collaborators or licensees 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 or biotechnology companies for the development and potential commercialization of such product candidates. 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, including Health Canada, 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 on third parties to conduct our pre-clinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We rely on domestic and international third-party CROs to monitor and manage data for our ongoing pre-clinical and clinical programs. We rely on these parties for execution of our pre-clinical studies and clinical trials, and we control only some aspects of their activities. Nevertheless, we are responsible for ensuring that each of our pre-clinical studies and clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We also rely on third parties to assist in conducting our pre-clinical studies in accordance with Good Laboratory Practices, or GLP, and the Animal Welfare Act requirements. We and our CROs are required to comply with U.S. federal regulations and current Good Clinical Practices, or GCP, which are international standards meant to protect the rights and health of subjects that are enforced by the FDA, Health Canada, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities, including Health Canada, may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. Failure to comply with these regulations may require us to repeat pre-clinical studies and clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, non-clinical and pre-clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our pre-clinical studies and clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Because we have relied and will continue to rely on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

If we lose our relationships with CROs, our product development efforts could be delayed.

We rely on domestic and international third-party vendors and CROs for pre-clinical studies and clinical trials related to our product development efforts. Switching or adding additional CROs would involve additional cost and requires management time and focus. Our CROs generally have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements and/or research projects with us pursuant to such agreements if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination in accordance with the reasonable opinion of the relevant CRO, if we are liquidated. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. If any of our relationships with our third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms.

Our experience manufacturing our product candidates is limited to our pre-clinical studies and clinical trials. We have no experience manufacturing our product candidates on a commercial scale. We are dependent on third parties for our supply chain, and if we experience problems with any such third parties, the manufacturing of our product candidates could be delayed.

We maintain an approximately 31,400 square foot manufacturing, laboratory, warehouse and office facility in Winnipeg, Manitoba, Canada. We have three 15 liter fermentors, one 150 liter fermentor, one 500 liter fermentor and one 1,500 liter fermentor. Our classified fermentation suite and post-production processing capabilities are currently dedicated to producing our pre-clinical study and clinical trial batches.

Our manufacturing facility has been audited by a third party for compliance with cGMP. The most recent audit was in January 2014 and it did not identify any major impediments to the cGMP manufacturing of product candidates up to and including Phase 3 production. Manufacturing of drugs and product candidates, including Vicinium, Proxinium, VB6-845d and EBI-031, must comply with FDA cGMP standards and other regulations. Methods of manufacture as well as validation of manufacturing procedures and quality control systems are reviewed by regulatory authorities, such as the FDA and Heath Canada, to determine their effect on the quality, purity and potency of product candidates. All such manufacturing procedures, validation programs and quality assessment activities must be properly documented in accordance with regulatory requirements. Both the FDA and Health Canada conduct inspections to determine compliance with cGMP to ensure that product candidates used in human testing are adequately characterized in terms of identity, potency and purity. cGMP standards become more stringent as the stage of human testing increases, and material used in pivotal Phase 3 clinical trials is generally required to comport with standards expected of marketed drugs.

Our manufacturing facility is intended to produce multiple product candidates per year, and we believe it will produce sufficient quantities of our product candidates to meet our currently anticipated pre-clinical study and clinical trial needs. In the event we obtain approval from the FDA to market any of our product candidates, we will likely need to outsource our commercial scale manufacturing to contract manufacturing organizations, or CMOs. We do not have experience in manufacturing products at commercial scale. Additionally, the facilities used by any CMO to manufacture any of our product candidates must be the subject of a satisfactory inspection before the FDA and other applicable regulatory authorities to approve a BLA or marketing authorization for each of our product candidates manufactured at that facility. We will depend on these third-party manufacturing partners for compliance with the FDA's and comparable foreign regulatory authorities', including Health Canada's, requirements for the manufacture of our finished products.

Any significant disruption in our supplier relationships could harm our business. Any significant delay in the supply of a product candidate or its key materials for an ongoing pre-clinical study or clinical trial could considerably delay completion of such pre-clinical study or clinical trial, product testing and potential regulatory approval of a product candidate. If our CMOs or we are unable to purchase these key materials after regulatory approval has been obtained for a product candidate, the commercial launch of such product candidate would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of such product candidate.

In the event that manufacturing process changes are necessary for the further development of a product candidate, we may not be able to reach agreement with regulatory agencies on the criteria for demonstrating comparability to the original product, which would require us to repeat clinical trials performed with the original product. This could result in lengthy delays in implementing the new process or site and substantial lost sales as a result of our inability to meet commercial demand. If we reach agreement with regulatory agencies on the criteria for establishing comparability, we may not be able to meet these criteria or may suffer lengthy delays in meeting these criteria. This may result in significant lost sales due to inability to meet commercial demand with the original product. Furthermore, studies to demonstrate comparability, or any other studies on the

new process or site such as validation studies, may uncover findings that result in regulatory agencies delaying or refusing to approve the new process or site.

Any contamination in our manufacturing process, shortages of raw materials or failure of any of our key suppliers to deliver necessary components of our TPT platform could result in delays in our clinical development or marketing schedules.

Given the nature of biologics manufacturing, there is a risk of contamination. Any contamination could materially adversely affect our ability to produce our product candidates on schedule and could therefore could halt or delay our clinical development programs.

Some of the raw materials required in our manufacturing process are derived from biological sources. Such raw materials are difficult to procure and may also be subject to contamination or recall. A material shortage, contamination, recall, or restriction on the use of biologically derived substances in the manufacture of our product candidates could halt or delay our clinical development programs or disrupt the commercial manufacturing of our product candidates, which could materially and adversely affect our business.

The successful commercialization and continued development of EBI-031 depends substantially on the License Agreement with Roche. If Roche is unable or unwilling to commercialize or further develop EBI-031, or experiences significant delays in doing so, our business will be materially harmed.

On June 10, 2016, we entered into the License Agreement with Roche for the development and commercialization of EBI-031. Prior to this agreement, we did not have a history of working with Roche. The License Agreement provides for milestone payments to us based on the achievement of specified development, regulatory and commercial milestones, and provides us with royalty-based revenue if EBI-031 is successfully commercialized. We cannot predict the success of the License Agreement.

We are substantially dependent on Roche to develop and commercialize EBI-031. Under the License Agreement, Roche has significant control over the conduct and timing of development and commercialization efforts with respect to EBI-031. We have little control over the amount, timing and quality of resources that Roche devotes to the development or commercialization of EBI-031. If Roche fails to devote sufficient financial and other resources to the future development or commercialization of EBI-031, the development and commercialization of EBI-031 would be delayed or could fail. This would result in a delay in our receiving milestone payments or royalties at all.

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 pre-clinical 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 USPTO, 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.

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 not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our product candidates and technologies throughout the world would be prohibitively expensive, and our or our licensors' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws and practices of some foreign countries do not protect
intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we and our licensors may not be able to prevent third parties from practicing our and our licensors' inventions in all countries outside the United States, or from selling or importing products made using our and our licensors' inventions in and into the United States
or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and may export infringing products to territories where we or our licensors have patent protection, but where enforcement is not as strong as in the United States. These products may compete with our products in jurisdictions

where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our or our licensor's patents or marketing of competing products in violation of our proprietary rights generally in those countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our and our licensors' patents at risk of being invalidated or being interpreted narrowly and put our and our licensors' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors. We or our licensors may not prevail in any lawsuits that we or our licensors initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

The laws of certain foreign countries may not protect our rights to the same extent as the laws of the United States, and these foreign laws may also be subject to change. For example, methods of treatment and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries, particularly developing countries. Furthermore, generic and/or biosimilar product manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings.

Generic or biosimilar product manufacturers may develop, seek approval for, and launch biosimilar versions or generic versions, respectively, of our products. The FDA published draft guidance documents on biosimilar product development. If a biosimilar product is also found to be interchangeable with a reference product, it may be substituted for the reference product.
Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation, which are still being worked out by the FDA. If any of our product candidates are approved by the FDA, the approval of a biologic product biosimilar to or interchangeable with one of our products could have a material impact on our business. In particular, a biosimilar could be significantly less costly to bring to market and priced significantly lower than our products, if approved by the FDA.

Many countries, including European Union countries, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which
could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

We have not yet registered our trademarks in all of our potential markets, and failure to secure those registrations could adversely affect our business.

Our future trademark applications may not be allowed for registration, and our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections from the USPTO or other applicable foreign intellectual property offices. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections, or have to expend additional resources to secure registrations, such as commencing cancellation proceedings against third-party trademark registrations to remove them as obstacles to our trademark applications. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

We depend on our license agreements with the University of Zurich and Merck KGaA and if we cannot meet the requirements under the agreements we could lose important rights to Vicinium, Proxinium or VB6-845d , which could have material adverse effect on our business.

We have an exclusive license agreement with the University of Zurich, or Zurich. Pursuant to the agreement, we were granted an exclusive license, with the right to sublicense, under certain patents primarily relating, in part, to our targeting agents, EpCAM chimera and immunoconjugates (including aspects of Vicinium and Proxinium) and methods of use, to make, use, sell and import products that would otherwise infringe such patents in the field of the treatment, stasis and palliation of disease in humans. If we fail to meet our obligations under the license agreement, Zurich may have the right to terminate our license, and

upon the effective date of such termination, our right to use the licensed Zurich patent rights would end. To the extent such licensed technology or patent rights relate to our product candidates, we would expect to exercise all rights and remedies available to us, including attempting to cure any breach by us, and otherwise seek to preserve our rights under the patent rights licensed to us, but we may not be able to do so in a timely manner, at an acceptable cost to us or at all. Any uncured, material breach under the license agreement could result in our loss of rights to practice the patent rights licensed to us under the license agreement, and to the extent such patent rights and other technology relate to our product candidates or other of our compounds, it could have a material adverse effect on our commercialization efforts for our product candidates, including Vicinium and Proxinium.

We also have a license agreement with Merck KGaA, or Merck, which grants us an exclusive license, with the right to sublicense, under certain patents and technology relating to the de-immunization of our cytotoxin Bouganin for therapeutic and in vivo diagnostic purposes in humans. If we fail to meet our obligations under this license agreement, Merck may have the right to terminate our license, and upon the effective date of such termination, our right to use the licensed Merck patent rights and technology would end. To the extent such licensed technology or patent rights relate to our product candidates, we would expect to exercise all rights and remedies available to us, including attempting to cure any breach by us, and otherwise seek to preserve our rights under the patent rights and technology licensed to us, but we may not be able to do so in a timely manner, at an acceptable cost to us or at all. Any uncured, material breach under the license agreement could result in our loss of rights to practice the patent and technology rights licensed to us under the license agreement, and to the extent such patent rights and other technology relate to our product candidates, it could have a material adverse effect on our commercialization efforts for product candidates.

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 USPTO. 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 any 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, consultants, independent contractors or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees and our licensors' employees, including our senior management, were previously employed at universities, medical institutions or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, including members of our senior management, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. 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.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make product candidates that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have licensed;
- biosimilar product manufacturers may develop, seek approval for, and launch biosimilar versions of our products, which could be significantly less costly to bring to market and priced significantly lower than our products;
- we or our licensors might not have been the first inventor to file patent applications covering certain of our inventions;
- others may design around our intellectual property rights or independently develop similar or alternative technologies or duplicate any of our technologies without infringing or misappropriating our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents with claims that cover our products or even issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies or product candidates that are patentable; and
- the intellectual property rights of others may have an adverse effect on our business.

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, or there are delays in obtaining approvals, we will not be able to commercialize any 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 licensees or collaborators, will obtain marketing approval to commercialize any product candidate.

To date, we have not obtained approval from the FDA or any foreign regulatory authority, including Health Canada, to market or sell any of our product candidates. 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 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, Health Canada 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 pre-clinical 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, Health Canada, EMA or other regulatory authorities may determine that any 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. The FDA and comparable regulatory authorities in other countries, including Health Canada, 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 pre-clinical, clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent marketing approval of a product candidate.

The different requirements of the EMA and Health Canada compared with the FDA 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.

Some of our product candidates may quality for orphan drug designation, and if we obtain approval for these product candidates, orphan drug exclusivity may afford limited protection. If another party obtains orphan drug exclusivity before we do for the same drug for the same indication we are targeting, we may be precluded from commercializing our product candidate in that indication until the other party's period of exclusivity has ended.

Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs and biologics intended to treat relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a biologic intended to treat a rare disease or condition, which generally means a disease or condition that affects fewer than 200,000 individuals in the United States. The first BLA applicant with an orphan drug designation that receives FDA approval is entitled to a seven-year period of orphan drug exclusivity in the United States, during which the FDA generally may not approve another application for a product with the same principal molecular structural features for the same indication.

We have obtained orphan drug designation from the FDA and the European Medicines Agency for Proxinium to treat Ep-CAM-positive SCCHN, and where appropriate we intend to seek orphan drug designation for our other product candidates. We cannot assure that any or all of our product candidates that receive orphan drug designation will, upon approval, have seven years of orphan drug exclusivity. The FDA may revoke orphan drug designation under certain circumstances, including if the agency determines that the request for orphan drug designation omitted material information or subsequently finds that the biologic had not been eligible for orphan drug designation at the time the request for designation was submitted. Revocation of orphan drug designation suspends the associated orphan drug exclusivity. Also, the FDA may approve another sponsor's application for the same drug for the same use, prior to the expiration of our product's orphan drug exclusivity, under certain circumstances, including if we are unable to assure sufficient quantity of our product, or if the other sponsor can demonstrate that its product candidate is clinically superior to ours by showing superior safety or efficacy or a major contribution to patient care. In addition, if a competitor obtains approval and orphan drug exclusivity for a product that is the same as a product candidate we are pursuing for the same indication, approval of our product candidate would be blocked during the period of the competitor's orphan drug exclusivity, unless we could demonstrate that our product candidate is clinically superior to the approved product. Also, if a competitor obtains approval for a drug that is the same as a product candidate we are pursuing for a different orphan indication, the competitor's approval may negatively impact the market opportunity for our product candidate, even if our product is granted orphan drug exclusivity.

Our 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 biosimilars 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 any product candidate that we may develop in the European Union, Canada and many other jurisdictions, we or our third-party licensees or 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, including Health Canada, 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 our third-party licensees or collaborators, obtain marketing approvals for our 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 any 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 federal and state 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 Federal Food, Drug and Cosmetic Act, or 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 letters 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 detention; 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 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 or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties, currently set at $5,500 to $11,000 per false claim;

- 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;

- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered products to report payments and other transfers of value to physicians and teaching hospitals;

- 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 and transparency statutes, 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.

Current and future legislation may increase the difficulty and cost for us and any collaborators to obtain marketing approval of our product candidates and affect the prices we, or they, may obtain.

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, among other things, prevent or delay marketing approval of our other product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any collaborators, to profitably sell any products for which we, or they, obtain marketing approval. We expect that 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, or any collaborators, may receive for any approved products.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, established the Medicare Part D program and authorized limiting the number of covered drugs in any therapeutic class. The Medicare Modernization Act, including its cost reduction initiatives, could decrease the coverage and reimbursement rate that we may receive for any of our product candidates, if approved. The Centers for Medicare and Medicaid Services, the agency that runs the Medicare program, also may revise reimbursement and implement coverage restrictions. Cost reduction initiatives and changes in coverage could decrease utilization of and reimbursement for any approved products, which would then affect the price we can receive. Private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement from federal legislation or regulation may lead to similar reductions in private payor reimbursement.

In addition, 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 the PPACA. Among the provisions of the PPACA of potential importance to our business and our product candidates are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription products and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand products to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient products to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report product samples that manufacturers and distributors provide to physicians;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a new Independent Payment Advisory Board, or IPAB, which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription products; and
- established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models.

Other legislative changes have been proposed and adopted since the PPACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in 2013 and, due to subsequent legislation, will continue until 2025. In addition, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several 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 and otherwise affect the prices we may obtain for any of our product candidates for which regulatory approval is obtained, which could have a material adverse effect on our financial operations. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and
promotional activities for pharmaceutical products. Additional legislative changes, FDA regulations, guidance or interpretations could be adopted, which may impact the marketing approvals and reimbursement of our product candidates. For example, in November 2015, the U.S. House of Representatives formed an Affordable Drug Pricing Task Force to advance legislation

intended to control pharmaceutical drug costs and investigate pharmaceutical drug pricing, and the U.S. Senate has requested information from certain pharmaceutical companies in connection with an investigation into pharmaceutical drug pricing practices. If healthcare policies or reforms intended to curb healthcare costs are adopted or if we experience negative
publicity with respect to pricing of our products or the pricing of pharmaceutical drugs generally, the prices that we charge for any approved products may be limited, our commercial opportunity may be limited and/or our revenues from sales of our products may be negatively impacted.

We expect that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Moreover, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the United States Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us and any collaborators to more stringent product labeling and post-marketing testing and other requirements.

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, including Health Canada, provide accurate information to the FDA or comparable non-U.S. regulatory authorities, including Health Canada, 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 a failure 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 attract, retain and motivate qualified personnel.

Our future growth and success depend on our ability to recruit, retain, manage and motivate our employees. The loss of any member of our senior management team or the inability to hire or retain experienced management personnel could compromise our ability to execute our business plan and harm our operating results. 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 will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of October 31, 2016, we had 36 full-time employees and two part-time employees, seven of whom are temporary employees, seven hold Ph.D. degrees and two are medical doctors. As our development and commercialization plans and

strategies develop, or as a result of any future acquisitions, we will need additional managerial, operational, sales, marketing, financial and other resources. Our management, personnel and systems that are currently in place may not be adequate to support this future growth. Future growth would impose significant added responsibilities on members of management, including:

- managing our clinical trials effectively;identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational and finance systems; and
- expanding our facilities.

As our operations expand, we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates, if approved, and to compete effectively will depend, in part, on our ability to effectively manage any future growth. To that end, we must be able to effectively manage our development efforts and clinical trials and hire, train and integrate additional management, administrative and sales and marketing personnel. Our failure to accomplish any of these tasks could prevent us from successfully growing our company.

If we expand our development and regulatory capabilities or implement sales, marketing and distribution capabilities, we may encounter difficulties in managing our growth, which could disrupt our operations.

To manage 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 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 October 31, 2016 , our current 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 64.3% 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 has been volatile and may fluctuate in the future, which could result in substantial losses for our stockholders.

The trading price of our common stock has and may continue to fluctuate significantly. During the period from January 4, 2016 to October 31, 2016 , the closing sales price of our common stock ranged from a high of $5.97 per share to a low of $0.25 per share. Our stock price experienced significant volatility in May 2015 after we announced that we failed to meet either of the two co-primary endpoints in our Phase 3 clinical trial of isunakinra in patients with moderate to severe dry eye disease and in January 2016 after we announced that we failed to meet the primary endpoint in our Phase 3 clinical trial of isunakinra in patients with allergic conjunctivitis. Furthermore, 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 Vicinium, Proxinium 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 Vicinium or Proxinium. 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, 2015, we had federal net operating loss, or NOL, carryforwards of $120.0 million, state NOL carryforwards of $118.2 million and federal and state research and development tax credit carryforwards of $1.7 million and $1.2 million, respectively. These federal and state NOL carryforwards and federal and state tax credit carryforwards expire at various dates beginning in 2029 through 2035, 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 determined that it is more likely than not that our net operating and tax credit amounts disclosed are subject to a material limitation under Section 382 resulting in available federal net operating loss, or NOL, carryforwards of $119.2 million, state NOL carryforwards of $117.4 million and federal and state research and development credit carryforwards of $1.6 million and $1.2 million, respectively, available to reduce future taxable income. 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 October 31, 2016 , we had outstanding 24,238,369 shares of common stock. Of these shares, 6,002,242 shares are restricted securities under Rule 144 under the Securities Act, 4,031,431 of which are subject to lock-up restrictions in connection with our acquisition of Viventia. Any of our remaining shares that are not restricted securities under Rule 144 under the Securities Act may be resold in the public market without restriction unless purchased by our affiliates.

Moreover, holders of an aggregate of 11,251,235 shares of our common stock, including 3,582,328 shares of common stock issued in connection with the acquisition of Viventia Bio Inc., have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have filed registration statements on April 9, 2014, March 12, 2015 and March 31, 2016 registering all shares of common stock that we may issue under our equity compensation plans. As of October 31, 2016 , we had outstanding options to purchase an aggregate of approximately 2,678,558 shares of our common stock, of which options to purchase approximately 1,618,299 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 have taken advantage of reduced reporting burdens in our Annual Report on Form 10-K for the annual period ended December 31, 2015, or the 2015 10-K. In particular, the 2015 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.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

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. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for shares of our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on us. If no securities or industry analysts commence coverage of us, the trading price for shares of our common stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade shares of our common stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for shares of our common stock could decrease, which might cause our stock price and trading volume to decline.

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

On September 20, 2016, the Company entered into a Share Purchase Agreement, or the Share Purchase Agreement, with Viventia Bio Inc., or Viventia, a corporation incorporated under the laws of the Province of Ontario, Canada, the shareholders of Viventia named therein (the "Selling Shareholders") and, solely in its capacity as seller representative, Clairmark Investments Ltd., or Clairmark, a corporation incorporated under the laws of the Province of Ontario, Canada, pursuant to which the Company agreed to and simultaneously completed the acquisition of all of the outstanding capital stock of Viventia from the Selling Shareholders, or the Acquisition. In connection with the closing of the Acquisition, the Company issued 4,013,431 shares of its common stock to the Selling Shareholders, which represented approximately 19.9% of the voting power of the Company as of immediately prior to the issuance of such shares of the Company's common stock.

The shares of the Company's common stock issued to the Selling Shareholders were issued in reliance upon the exemptions from registration afforded by Section 4(a)(2) of the Securities Act of 1933, as amended, or the Securities Act, and Regulation S and/or Rule 506 of Regulation D promulgated thereunder. Each Selling Shareholder represented that it was either an accredited investor or not a U.S. person and was acquiring the shares for its own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the shares for an indefinite period of time.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits

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

SIGNATURES

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

ELEVEN BIOTHERAPEUTICS, INC.

By: /s/ John J. McCabe

John J. McCabe

Chief Financial Officer (Principal Financial and Accounting Officer)

November 14, 2016

EXHIBIT INDEX

Exhibit No.	Description
2.1	Share Purchase Agreement, effective as of September 20, 2016, by and between Eleven Biotherapeutics, Inc., Viventia Bio Inc. and Clairmark Investments Ltd., as representative of the selling shareholders (the Company hereby agrees to furnish supplementally a copy of any omitted schedules to the SEC upon request). Incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on September 21, 2016 (File No. 001-36296).
4.1	Registration Rights Agreement, dated as of September 20, 2016 by and among Eleven Biotherapeutics, Inc. and the shareholders named therein. Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on September 21, 2016 (File No. 001-36296).
10.1†	License Agreement, effective January 13, 2003, as amended and restated on October 14, 2015, by and between The University of Zurich and Viventia Bio Inc. Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 21, 2016 (File No. 001-36296).
10.2†	Amended & Restated Exclusive License Agreement, dated October 14, 2015, by and between Merck KGaA and Viventia Bio Inc. Incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on September 21, 2016 (File No. 001-36296).
10.3	Amended and Restated License Agreement, dated October 17, 2014, by and between Clairmark Investments Ltd. (successor in interest of Protoden Technologies Inc.) and Viventia Bio Inc. Incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on September 21, 2016 (File No. 001-36296).
10.4	Indenture, dated March 31, 2000, between 131-149 Hamelin Street Leaseholds Limited (successor in interest of Almad Investments Limited) and Viventia Bio Inc. (successor in interest of Viventia Biotech Inc.), as amended by Lease Amending Agreement, dated June 26, 2003, as further amended by Lease Amending Agreement, dated January 26, 2004, and as further amended by Letter Agreement, dated June 25, 2008, and as further amended by Lease Amending Agreement, September 16, 2015. Incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on September 21, 2016 (File No. 001-36296).
10.5	Separation Agreement dated September 20, 2016 between the Eleven Biotherapeutics, Inc. and Abbie C. Celniker. Incorporated herein by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed on September 21, 2016 (File No. 001-36296).
10.6	Separation Agreement dated September 20, 2016 between the Eleven Biotherapeutics, Inc. and Karen L. Tubridy. Incorporated herein by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed on September 21, 2016 (File No. 001-36296).
10.7	Retention Letter Agreement dated September 20, 2016 between the Eleven Biotherapeutics, Inc. and John J. McCabe. Incorporated herein by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed on September 21, 2016 (File No. 001-36296).
10.8	Employment Agreement dated September 20, 2016 between the Eleven Biotherapeutics, Inc. and Stephen A. Hurly. Incorporated herein by reference to Exhibit 10.8 to the Company's Current Report on Form 8-K filed on September 21, 2016 (File No. 001-36296).
10.9	Employment Agreement dated September 20, 2016 between the Eleven Biotherapeutics, Inc. and Arthur P. DeCillis. Incorporated herein by reference to Exhibit 10.9 to the Company's Current Report on Form 8-K filed on September 21, 2016 (File No. 001-36296).
10.10*	Agreement for Termination of Lease and Voluntary Surrender of Premises, dated October 14, 2016, between the Eleven Biotherapeutics, Inc. and ARE-MA Region No. 38, LLC.
31.1	Rule 13a-14(a) Certification of Principal Executive Officer
31.2	Rule 13a-14(a) Certification of Principal Financial Officer
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. §1350
101.INS*	XBRL Instance Document

101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

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* Filed herewith.

† Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

AGREEMENT FOR TERMINATION OF LEASE
AND VOLUNTARY SURRENDER OF PREMISES

This Agreement for Termination of Lease and Voluntary Surrender of Premises (this " **Agreement** ") is made and entered into as of October 14 , 2016, by and between **ARE-MA REGION NO. 38, LLC** , a Delaware limited liability company (" **Landlord** "), and **ELEVEN BIOTHERAPEUTICS, INC.** , a Delaware corporation (" **Tenant** "), with reference to the following:

RECITALS

A. Landlord and Tenant are now parties to that certain Lease Agreement dated as of January 14, 2010, as amended by that certain First Amendment to Lease dated as of November 30, 2013, as further amended by that certain letter agreement dated as of February 28, 2015, and as further amended by that certain Second Amendment to Lease dated as of August 18, 2015 (as amended, the " **Lease** "), Tenant leases certain premises at the improved real property located at 215 First Street, Cambridge, Massachusetts, and which premises are more particularly described in the Lease (the " **Premises** ").

B. The term of the Lease is scheduled to expire on April 30, 2018.

C. Tenant desires to accelerate the expiration date of the Lease, and Landlord is willing to accept such acceleration of the expiration date of the Lease pursuant to the terms of this Agreement.

D. Capitalized terms used herein without definition shall have the meanings defined for such terms in the Lease.

NOW, THEREFORE, in consideration of the foregoing and of the mutual promises made herein, and for other good and valuable consideration the receipt of which is hereby acknowledged, Landlord and Tenant agree as follows:

1. **Termination Date** . Landlord and Tenant agree, subject to Tenant's satisfaction or Landlord's waiver of all of the terms and conditions set forth herein, to accelerate the expiration date of the Lease to October 10, 2016 (the " **Termination Date** ").

2. **Base Rent, Operating Expenses and Parking Charges** . Tenant shall continue to pay all Base Rent, Operating Expenses, parking charges and any other obligations due under the Lease through the Termination Date. Tenant shall not be required to pay Base Rent, Operating Expenses or parking charges for any period following the Termination Date so long as Tenant surrenders the Premises as provided for in this Agreement and Tenant is not in breach hereof.

3. **Termination and Surrender** . Tenant shall voluntarily surrender the Premises as provided in this Agreement. Tenant agrees to cooperate reasonably with Landlord in all matters relating to surrendering the Premises, on or before the Termination Date, in accordance with the surrender requirements and in the condition required pursuant to the Lease. After the Termination Date, Tenant shall have no further rights of any kind with respect to the Premises. Notwithstanding the foregoing, as provided in Section 4 hereof, those provisions of the Lease which, by their terms, survive the termination of the Lease shall survive the surrender of the Premises and the termination of the Lease provided for herein.

4. **No Further Obligations** . Landlord and Tenant each agree that the other is excused as of the Termination Date from any further obligations under the Lease with respect to the Premises, excepting only such obligations under the Lease which are, by their terms, intended to survive termination of the Lease, and as otherwise provided herein. In addition, nothing herein shall be deemed to limit or terminate any common law or statutory rights Landlord may have with respect to Tenant in connection with any Hazardous Materials or for violations of any governmental requirements or requirements of applicable law. Nothing

herein shall excuse Tenant or Landlord from their respective obligations under the Lease, as modified by this Agreement, prior to the Termination Date.

5. **Release of Liability** . As of the Termination Date, Tenant releases and exculpates Landlord from any liability arising from the Lease with respect to the Premises. Tenant acknowledges that this release and waiver are an essential and material term of this Agreement, without which Landlord would not become a party to this Agreement.

6. **Condition Precedent** . Notwithstanding anything to the contrary contained in this Agreement, Tenant and Landlord acknowledge and agree that the effectiveness of this Agreement shall be subject to the following condition precedent (" **Condition Precedent** ") having been satisfied: Landlord shall have entered into a lease agreement with Goldfinch Biopharma, Inc. (" **Goldfinch** ") on or before October 7, 2016, pursuant to which Goldfinch agrees to lease the Premises, which lease agreement shall be on terms and conditions acceptable to Landlord, in Landlord's sole and absolute discretion. In the event that the Condition Precedent is not satisfied, Landlord shall have the right to terminate this Agreement upon delivery of written notice to Tenant delivered on or before October 7, 2016. Landlord shall have no liability whatsoever to Tenant relating to or arising from Landlord's inability or failure to cause the Condition Precedent to be satisfied.

7. **Removal of Personal Property** . Any personal property of Tenant remaining in the Premises after the Termination Date, if any, is hereby agreed to be abandoned by Tenant and may be disposed of by Landlord, in Landlord's sole discretion, without obligation or liability of any kind to Tenant.

8. **Acknowledgment** . Tenant acknowledges that it has read the provisions of this Agreement, understands them, and is bound by them. Time is of the essence in this Agreement.

9. **No Assignment** . Tenant represents and warrants that Tenant has not assigned, mortgaged, subleased, pledged, encumbered or otherwise transferred any interest in the Lease and that Tenant holds the interest in the Premises as set forth in the Lease as of the date of this Agreement.

10. **No Modification** . This Agreement may not be modified or terminated except in writing signed by all parties. This Agreement may be signed in counterparts which taken together shall constitute one agreement binding upon the parties.

11. **Successors and Assigns** . The covenants and agreements herein contained shall inure to the benefit and be binding upon the parties and their respective successors and assigns.

12. **Attorneys' Fees** . In the event of a dispute between the parties, the prevailing party shall be entitled to have its reasonable attorneys' fees and costs paid by the other party. Each party shall be responsible for its own costs and legal fees in connection with the negotiation, execution and delivery of this Agreement and the consummation of the transactions contemplated hereby.

13. **Governing Law** . This Agreement shall be governed by the laws of the state in which the Premises are located.

[Signatures are on the next page]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

TENANT:

ELEVEN BIOTHERAPEUTICS, INC.,
a Delaware corporation

By: JOHN J. MCCABE
Its: CFO

LANDLORD:

ARE-MA REGION NO. 38, LLC,
a Delaware limited liability company

By: Alexandria Real Estate Equities, L.P.,
a Delaware limited partnership,
managing member

By: ARE-QRS Corp., a Maryland corporation,
general partner

By: _____
Its: Eric S. Johnson
Senior Vice President
RE Legal Affairs

Exhibit 31.1

Rule 13a-14(a) CERTIFICATION

I, Stephen A. Hurly, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Eleven Biotherapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Stephen A. Hurly

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

Dated: November 14, 2016

Exhibit 31.2

Rule 13a-14(a) CERTIFICATION

I, John J. McCabe, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Eleven Biotherapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ John J. McCabe

John J. McCabe

Chief Financial Officer

(Principal Financial Officer)

Dated: November 14, 2016

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Eleven Biotherapeutics, Inc. (the "Company") for the fiscal quarter ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. Section 1350, that, to the best of their knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Stephen A. Hurly

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

Dated: November 14, 2016

/s/ John J. McCabe

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

Dated: November 14, 2016