
**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 June 30, 2018

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

Sesen Bio, Inc.

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction of
incorporation or organization)

26-2025616
(I.R.S. Employer
Identification No.)

245 First Street, Suite 1800
Cambridge, MA
(Address of principal executive offices)

02142
(Zip code)

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

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 every Interactive Data File required to be submitted pursuant to [Rule 405 of Regulation S-T \(§ 232.405](#) of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes No

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

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

Accelerated filer
Smaller reporting company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.):

Yes No

Number of outstanding shares of Common Stock as of August 10, 2018: 77,010,999

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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 need to raise substantial additional capital to fund our operations;
- the potential impairment of our goodwill and our indefinite-lived intangible assets;
- the effect of recent changes in our senior management team on our business;
- the success, cost and timing of our pre-clinical studies and clinical trials in the United States, Canada and 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, in the conduct of our pre-clinical studies and clinical trials;
- the difficulties and expenses associated with obtaining and maintaining regulatory approval of our product candidates and companion diagnostics, if any, in the United States, Canada and in other foreign jurisdictions, and the labeling under any approval we may obtain;
- our plans and ability to develop and commercialize our product candidates;
- our ability to achieve certain future regulatory, development and commercialization milestones under our license agreement, which we refer to as the License Agreement, with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., or collectively, Roche;
- market acceptance of our product candidates, the size and growth of the potential markets for our product candidates, and our ability to serve those markets;
- obtaining and maintaining intellectual property protection for our product candidates and our proprietary technology;
- the successful development of our commercialization capabilities, including sales and marketing capabilities; and
- the success of competing therapies and products that are or become available.

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

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

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

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

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

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 62,961	\$ 14,680
Prepaid expenses and other current assets	806	301
Total current assets	63,767	14,981
Property and equipment, net	421	522
Restricted cash	20	10
Intangible assets	46,400	46,400
Goodwill	13,064	13,064
Other assets	41	120
Total assets	<u>\$ 123,713</u>	<u>\$ 75,097</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,310	\$ 907
Accrued expenses	3,223	3,813
Total current liabilities	4,533	4,720
Other liabilities	288	215
Deferred tax liability	12,528	12,528
Contingent consideration	42,300	39,600
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value per share; 5,000,000 shares authorized at June 30, 2018 and December 31, 2017 and no shares issued and outstanding at June 30, 2018 and December 31, 2017	—	—
Common stock, \$0.001 par value per share; 200,000,000 shares authorized at June 30, 2018 and December 31, 2017 and 77,010,999 and 34,702,565 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	77	35
Additional paid-in capital	229,239	170,330
Accumulated deficit	(165,252)	(152,331)
Total stockholders' equity	64,064	18,034
Total liabilities and stockholders' equity	<u>\$ 123,713</u>	<u>\$ 75,097</u>

See accompanying notes.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenue:				
License revenue	—	—	—	425
Total revenue	—	—	—	425
Operating expenses:				
Research and development	2,779	2,909	6,034	5,783
General and administrative	2,351	2,241	4,303	4,454
Loss from change in fair value of contingent consideration	3,900	2,200	2,700	3,700
Total operating expenses	9,030	7,350	13,037	13,937
Loss from operations	(9,030)	(7,350)	(13,037)	(13,512)
Other income:				
Other income, net	72	34	116	135
Total other income, net	72	34	116	135
Net loss and comprehensive loss	\$ (8,958)	\$ (7,316)	\$ (12,921)	\$ (13,377)
Net loss per share — basic and diluted	\$ (0.16)	\$ (0.30)	\$ (0.28)	\$ (0.54)
Weighted-average number of common shares used in net loss per share — basic and diluted	56,421	24,685	46,105	24,648

See accompanying notes.

SESEN BIO, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	Six Months Ended	
	June 30,	
	2018	2017
Operating activities		
Net loss	\$ (12,921)	\$ (13,377)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	101	174
Stock-based compensation expense	686	566
Change in fair value of warrant liability	—	(5)
Loss from change in fair value of contingent consideration	2,700	3,700
Gain on sale of equipment	(5)	(79)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(426)	(200)
Accounts payable	403	(422)
Accrued expenses and other liabilities	(517)	359
Deferred revenue	—	(425)
Due to related party	—	4
Net cash used in operating activities	(9,979)	(9,705)
Investing activities		
Sales of equipment	5	69
Net cash provided by investing activities	5	69
Financing activities		
Proceeds from exercise of common stock options	29	40
Proceeds from issuance of common stock and the issuance and exercise of common stock warrants, net of issuance costs	58,226	—
Proceeds from sale of common stock pursuant to ESPP	10	5
Net cash provided by financing activities	58,265	45
Net increase (decrease) in cash, cash equivalents and restricted cash	48,291	(9,591)
Cash, cash equivalents and restricted cash at beginning of period	14,690	25,352
Cash, cash equivalents and restricted cash at end of period	\$ 62,981	\$ 15,761
Supplemental non-cash investing and financing activities		

See accompanying notes.

SESEN BIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. Organization and Basis of Presentation

Sesen Bio, Inc. (the "Company"), formerly Eleven Biotherapeutics, Inc., a Delaware corporation, is a late-stage clinical company developing next-generation antibody-drug conjugate (ADC) therapies for the treatment of cancer. The Company's platform is designed to deliver 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 while also having limited expression on normal cells. The Company has designed its next generation ADCs to overcome the fundamental efficacy and safety challenges inherent in existing ADCs, where a payload is chemically attached to a targeting antibody.

Basis of presentation

The condensed consolidated financial statements as of June 30, 2018 and December 31, 2017 and for the three and six months ended June 30, 2018 and 2017 and the related information contained within the notes to the condensed consolidated financial statements are unaudited. The unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting standards applicable to interim financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company's consolidated financial position as of June 30, 2018, its results of operations for the three and six months ended June 30, 2018 and 2017 and its cash flows for the six months ended June 30, 2018 and 2017. The financial data and the other financial information disclosed in these notes to the condensed consolidated financial statements related to the three and six-month periods are also unaudited. The results of operations for the three and six months ended June 30, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018 or for any other future annual or interim period. The condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017 that was filed with the Securities and Exchange Commission ("SEC") on April 2, 2018 (the "2017 Form 10-K").

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

The functional currency of Viventia Bio Inc., Viventia Bio USA Inc. and Viventia Biotech (EU) Limited is the U.S. dollar.

Liquidity

The Company has financed its operations to date primarily through debt and equity offerings and collaboration and licensing arrangements. As of June 30, 2018, the Company had cash and cash equivalents totaling \$63.0 million, net working capital of \$59.2 million and an accumulated deficit of \$165.3 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. In order to commercialize its product candidates, the Company needs to complete clinical development and comply with comprehensive regulatory requirements. The Company is subject to a number of risks similar to other early-stage life science companies, including, but not limited to, successful discovery and development of its product candidates, raising additional capital with favorable terms, development by its competitors of new technological innovations, protection of proprietary technology and market acceptance of the Company's products. The successful discovery and development of product candidates requires substantial working capital which may not be available to the Company on favorable terms or not at all.

On June 4, 2018, the Company raised approximately \$41.9 million of net proceeds from the sale of 25,555,556 shares of its common stock at a price of \$1.80 per share in an underwritten public offering (the "June 2018 Financing").

In addition, between April 1, 2018 and June 30, 2018, the Company received proceeds of \$6.9 million from the issuance of 8.3 million shares of its common stock due to the exercise of common stock purchase warrants issued in connection with (i) its underwritten public offering in November 2017 and (ii) its private placement of common stock warrants in March 2018.

To date, the Company has no revenue from product sales and management expects continuing operating losses in the future. As of June 30, 2018, the Company had available cash and cash equivalents of \$63.0 million, which it believes is sufficient to fund the Company's current operating plan for at least the next twelve months from the date of this Form 10-Q filing. There can be no assurance, however, that the current operating plan will be achieved in the timeframe anticipated by the Company, or that its

cash resources will fund the Company's operating plan for the period anticipated by the Company. Management expects to seek additional funds through equity or debt financings or through additional collaboration, licensing transactions or other sources. The Company may be unable to obtain equity or debt financings or enter into additional collaboration or licensing transactions and, if necessary, the Company will be required to implement cost reduction strategies.

2. Significant Accounting Policies and Recent Accounting Pronouncements

Recently adopted accounting standards

In May 2014, the FASB issued ASU No. 2014-09, codified as Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers* ("ASC 606"), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The new standard was effective on January 1, 2018 and the Company adopted this standard using the modified retrospective approach. As a result of this adoption, no amounts were recorded as a cumulative effect adjustment to accumulated deficit as of January 1, 2018.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"). This update clarifies the changes to terms or conditions of a share-based payment award that require an entity to apply modification accounting. ASU 2017-09 is effective as of January 1, 2018. The adoption of this guidance did not have an impact on the Company's financial position, results of operations or cash flows.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*. ASU 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents and amounts generally described as restricted cash or restricted cash equivalents. Amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 was effective for annual and interim periods beginning after December 15, 2017, with early adoption permitted. The Company adopted this standard effective January 1, 2018. Upon adoption of ASU 2016-18, the Company applied the retrospective transition method for each period presented and included \$10,000 and \$20,000 of restricted cash in the beginning-of-period and end-of-period cash, cash equivalents and restricted cash balance, respectively, in the condensed consolidated statement of cash flows for the six months ended June 30, 2017. A reconciliation of cash, cash equivalents and restricted cash for each period presented is provided in note 9 to the condensed consolidated financial statements.

On December 22, 2017, the Tax Cuts and Jobs Act (the "Act") was enacted in the United States. The Act reduces the U.S. federal corporate tax rate from 34% to 21%, requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred and creates new taxes on certain foreign sourced earnings. In December 2017, the SEC issued guidance under Staff Accounting Bulletin No. 118, *Income Tax Accounting Implications of the Tax Cuts and Jobs Act* directing taxpayers to consider the impact of the U.S. legislation as "provisional" when it does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete its accounting for the change in tax law. As of June 30, 2018, the Company had not yet completed its accounting for all of the tax effects of the enactment of the Act.

Recently issued accounting pronouncements

In February 2016, the FASB issued Accounting Standards 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 consolidated financial statements.

Critical accounting policies

There have been no material changes to the critical accounting policies recently disclosed in the 2017 Form 10-K other than the adoption of ASU 2014-09 and related updates which are codified as ASC 606.

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The Company enters into collaboration agreements with strategic partners for the development and commercialization of product candidates which are within the scope of ASC 606. Under these agreements, the Company license rights to certain of the Company's product candidates and may complete other performance obligations, such as the deliver of drug product or research and development services. The terms of these arrangements typically include payment of non-refundable upfront fees, milestone payments, and royalties on net sales of licensed products and may also contain additional payment provisions.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, the Company performs the following five steps: (i) identification of the promised goods or services in the contract, (ii) determination of whether the promised goods or services are performance obligations included whether they are distinct in the context of the contract, (iii) measurement of the transaction price, including the constraint on variable consideration, (iv) allocation of the transaction price to the performance obligations, and (v) recognition of revenue when the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect consideration it is entitled to in exchange for the goods or services it transfers to the customer.

The Company estimates the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include fixed consideration or variable consideration. At the inception of each arrangement that includes variable consideration, the Company evaluates the amount of potential payments and the likelihood that the payments will be received. The Company utilizes either the most likely amount method or expected amount method to estimate the amount expected to be received based on which method best predicts the amount expected to be received. The amount of variable consideration which is included in the transaction price may be constrained, and is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period.

The Company's contracts include development and regulatory milestone payments which are assessed under the most likely amount method and constrained if it is probable that a significant revenue reversal would occur. At the end of each reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue in the period of adjustment.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any consideration related to sales-based royalty revenue resulting from any of the Company's collaboration arrangements.

The Company allocates the transaction price based on the estimated stand-alone selling price of each of the performance obligations. The Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract.

The consideration allocated to each performance obligation is recognized as revenue when control is transferred for the related goods or services.

3. Fair Value of Financial Instruments

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

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

The following table summarizes the assets and liabilities measured at fair value on a recurring basis at June 30, 2018 (in thousands):

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Description	June 30, 2018	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	\$ 62,961	\$ 62,961	\$ —	\$ —
Restricted cash	20	20	—	—
Total assets	\$ 62,981	\$ 62,981	\$ —	\$ —
Liabilities:				
Contingent consideration	42,300	—	—	42,300
Total liabilities	\$ 42,300	\$ —	\$ —	\$ 42,300

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

Description	December 31, 2017	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	\$ 14,680	\$ 14,680	\$ —	\$ —
Restricted cash	10	10	—	—
Total assets	\$ 14,690	\$ 14,690	\$ —	\$ —
Liabilities:				
Contingent consideration	39,600	—	—	39,600
Total liabilities	\$ 39,600	\$ —	\$ —	\$ 39,600

Contingent consideration

In 2016, the Company acquired Viventia Bio, Inc. ("Viventia") through the issuance of common stock and contingent consideration (the "Acquisition"), pursuant to the terms of a share purchase agreement (the "Share Purchase Agreement"). The Company has valued the acquired assets and liabilities based on their estimated fair values as of September 20, 2016 and finalized its purchase accounting for the Acquisition during the third quarter of 2017. The contingent consideration relates to amounts potentially payable to Viventia's shareholders pursuant to the terms of the Share Purchase Agreement. Contingent consideration is measured at fair value and is based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The valuation of contingent consideration uses assumptions the Company believes would be made by a market participant. The Company assesses these estimates on an on-going basis as additional data impacting the assumptions is obtained. Future changes in the fair value of contingent consideration related to updated assumptions and estimates are recognized within the condensed consolidated statements of operations and comprehensive loss.

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

Beginning balance, December 31, 2017	\$ 39,600
Loss from change in fair value of contingent consideration	2,700
Ending balance, June 30, 2018	\$ 42,300

The fair value of the Company's contingent consideration was determined using probabilities of successful achievement of regulatory milestones and commercial sales, the period in which these milestones and sales are expected to be achieved ranging from 2020 to 2033, the level of commercial sales of Vicinium, and discount rates ranging from 8.3% to 10.5% as of December 31, 2017 and 7.9% to 10.0% as of June 30, 2018. Significant changes in any of these assumptions would result in a significantly higher or lower fair value measurement.

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There have been no changes to the valuation methods utilized during the three and six months ended June 30, 2018. 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 six months ended June 30, 2018.

4. License Agreement with Roche

On June 10, 2016, the Company entered into the License Agreement with F. Hoffmann-La Roche and Hoffmann La-Roche Inc. (collectively, "Roche"), which became effective on August 16, 2016 (the "License Agreement"). 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").

During 2016, the Company received an upfront license fee of \$7.5 million and a milestone payment of \$22.5 million. The Company is entitled to receive up to \$240.0 million in additional consideration upon the achievement of specified regulatory, development and commercial milestones. Specifically, an aggregate amount of up to \$175.0 million is payable to the Company for the achievement of specified milestones with respect to the first indication: \$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, 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 buy-out options.

The License Agreement is subject to the provisions of ASC 606, which was adopted effective January 1, 2018 utilizing a modified retrospective method. The Company concluded that all performance obligations had been achieved as of the adoption date and therefore the full transaction price was considered earned. The transaction price was determined to be the \$30.0 million received in 2016. Additional consideration to be paid to the Company upon the achievement of certain milestones will be included if it is expected that the amounts will be received and the amounts would not be subject to a constraint. As of the date of the adoption, no amounts were expected to be received from the achievement of any milestones due to the nature of the milestones and the development status of the product candidates at the time of the adoption. As a result, there were no amounts required to be recorded as a cumulative adoption adjustment as the consideration recognized under ASC 606 was consistent with the amounts recognized under the previous accounting literature.

As of June 30, 2018, the Company concluded that there would be no adjustments to the transaction price as the Company continued to not expect any amounts to be received from any milestones within the License Agreement. This is due to the nature of the milestones and the development status of the product candidates at the time of the adoption. As a result, no revenue was recognized during the six-month period ended June 30, 2018 as all performance obligations had been previously achieved and there was no change in the transaction price during the period. No revenue would have been recognized under the previous accounting literature during the six month period ended June 30, 2018 as no milestones were achieved in the period, which was the revenue recognition criteria under the previous accounting literature.

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	June 30, 2018	December 31, 2017
Development costs	\$ 2,274	\$ 2,581
Employee compensation (including reduction in workforce)	658	735
Professional fees	209	463
Other	82	34
	<u>\$ 3,223</u>	<u>\$ 3,813</u>

6. Share-Based Payments

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Pursuant to the terms of the Company's 2014 Stock Incentive Plan (the "2014 Plan"), the number of shares authorized for issuance automatically increases on the first day of each fiscal year. On January 1, 2018, the number of shares reserved for issuance under the 2014 Plan increased by 1,102,362 shares. As of June 30, 2018, the total number of shares of common stock available for issuance under the 2014 Plan was 873,812.

The Company also maintains the Company's 2009 Stock Incentive Plan, as amended and restated, and the Company's 2014 Employee Stock Purchase Plan ("2014 ESPP").

Stock-Based Compensation Expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Stock options	\$ 283	\$ 268	\$ 659	\$ 455
Restricted stock	—	51	\$ 22	102
Restricted stock units	—	—	\$ —	3
Employee stock purchase plan	2	3	5	6
	<u>\$ 285</u>	<u>\$ 322</u>	<u>\$ 686</u>	<u>\$ 566</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Research and development expense	\$ 123	\$ 83	\$ 288	\$ 123
General and administrative expense	162	239	\$ 398	\$ 443
	<u>\$ 285</u>	<u>\$ 322</u>	<u>\$ 686</u>	<u>\$ 566</u>

At June 30, 2018, there was \$2.7 million of total unrecognized compensation expense related to unvested stock options and shares issued pursuant to the 2014 ESPP. This unrecognized compensation expense is expected to be recognized over a weighted-average period of 2.63 years.

Stock Options

A summary of the stock option activity is presented below:

	Shares	Weighted-Average Exercise Price
Outstanding at December 31, 2017	2,695,796	\$ 3.16
Granted	1,643,400	1.82
Exercised	(55,259)	0.53
Cancelled or forfeited	(256,111)	2.95
Outstanding at June 30, 2018	<u>4,027,826</u>	\$ 2.66
Exercisable at June 30, 2018	<u>1,738,331</u>	\$ 3.53
Vested and expected to vest at June 30, 2018 ⁽¹⁾	<u>3,977,226</u>	\$ 2.67

(1) Represents the number of vested stock options, plus the number of unvested stock options expected to vest. The Company adopted ASU 2016-09 as of January 1, 2017 and records forfeitures as they occur.

During the fourth quarter of 2017, the Company issued stock option awards to certain employees which contained performance vesting conditions. Certain of the vesting milestones were achieved during the fourth quarter 2017 and the expense related to

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these awards was recognized in full during the period. Certain other performance conditions had previously not been considered probable of vesting and therefore no expense was recognized. During the first and second quarter of 2018, these conditions were deemed probable of occurring and the expense for these awards has been recognized over the estimated vesting period.

Restricted Stock

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

	Restricted Stock	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2017	4,430	\$ 11.43
Vested	(4,430)	11.43
Unvested at June 30, 2018	—	

Employee Stock Purchase Plan

On March 14, 2018, the Company issued and sold 9,565 shares of its common stock pursuant to the 2014 ESPP at a purchase price of \$0.98 per share. During the three months ended June 30, 2018, the Company did not issue or sell any shares of its common stock pursuant to the 2014 ESPP. The Company has estimated the number of shares to be issued at the end of the current offering period and recognizes expense over the requisite service period.

7. Net (Loss) Income Per Share

Basic net (loss) income per share is calculated by dividing net (loss) income by the weighted-average shares outstanding during the period, without consideration for common stock equivalents. Diluted net (loss) income per share is calculated by adjusting weighted-average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the diluted net (loss) income per share calculation, stock options, unvested restricted stock, and common stock warrants are considered to be common stock equivalents. Warrants to purchase the Company's common stock participate in any dividends declared by the Company and are therefore considered to be participating securities. Participating securities have the effect of diluting both basic and diluted earnings per share during periods of income. During periods of loss, no loss is allocated to the participating securities since they have no contractual obligation to share in the losses of the Company.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Stock options	4,027,826	1,965,206	4,027,826	1,965,206
Unvested restricted stock	—	13,290	—	13,290
Common stock warrants	9,307,632	926,840	9,307,632	926,840
	<u>13,335,458</u>	<u>2,905,336</u>	<u>13,335,458</u>	<u>2,905,336</u>

8. Reduction in Workforce

In 2017, the Company's board of directors (the "Board") approved a strategic restructuring of the Company to eliminate a portion of the Company's workforce and recorded restructuring costs, including severance and benefits in accordance with the Company's severance benefit plan, and recorded an accrued liability of \$0.1 million as of December 31, 2017. The Company paid \$0.1 million in severance costs during the six months ending June 30, 2018.

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

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Balance as of January 1, 2018	\$	111
Payments		(104)
Balance as of June 30, 2018	\$	7

9. Cash, cash equivalents and restricted cash

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same such amounts shown in the condensed consolidated statements of cash flows (in thousands):

	<u>June 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
Cash and cash equivalents	62,961	\$ 14,680
Restricted cash	20	10
Total cash, cash equivalents and restricted cash	<u>62,981</u>	<u>14,690</u>

Amounts included in restricted cash represent cash held to collateralize a credit limit with Silicon Valley Bank of \$20,000 and \$10,000 as of June 30, 2018 and December 31, 2017, respectively.

10. Related Party Transactions

The Company leases a manufacturing, laboratory, and office facility in Winnipeg, Manitoba, from an affiliate of Leslie L. Dan, a director of the Company, under a five-year renewable lease through September 2020 with a right to renew the lease for one subsequent five-year term. Rent expense was \$81,000 and \$141,000 for the three and six month periods ended June 30, 2018, respectively, and \$80,000 and \$154,000 for the three and six month periods ended June 30, 2017, respectively.

The Company leases an office facility in Toronto, Ontario from an affiliate of Mr. Dan. 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 \$4,700 and \$9,300 for the three and six month periods ended June 30, 2018, respectively, and \$4,500 and \$8,900 for the three and six month periods ended June 30, 2017, respectively.

The Company pays fees, under an intellectual property license agreement, to Protoden Technologies, Inc. ("Protoden"), a company owned by Clairmark Investments Ltd. ("Clairmark"), an affiliate of Mr. Dan, 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. During each of the three and six-month periods ended June 30, 2018 and June 30, 2017, \$25,000 and \$50,000 was paid, respectively, to Clairmark under the license agreement.

11. Subsequent Event

On August 7, 2018, the Company appointed Thomas Cannell, D.V.M. as its President and Chief Executive Officer and as a member of the Board. In connection with the appointment of Dr. Cannell, the Company entered into an employment agreement with Dr. Cannell that, among other things, provides for the grant of a non-statutory stock option outside of the 2014 Plan as an inducement material to Dr. Cannell's entering into employment with the Company in accordance with Nasdaq Stock Market Listing Rule 5635(c)(4). The stock option to purchase 1,350,000 shares of the company's common stock is being granted effective as of August 7, 2018. The stock option grant was approved by the independent compensation committee of the Board in accordance with Nasdaq Stock Market Listing Rule 5635(c)(4). The per share exercise price of the stock option is \$1.60, which is equal to the closing price per share of the Company's common stock on The Nasdaq Global Market on August 7, 2018. The stock option has a ten-year term and vests over a four-year period, with 25% percent of the shares underlying the stock option award vesting on the first anniversary of the date of grant and an additional 6.25% percent of the shares underlying the

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stock option vesting at the end of each successive three-month period following the one-year anniversary of the date of grant of the stock option, subject to Dr. Cannell's continued service with the Company through the applicable vesting dates.

On August 8, 2018, the Company received Fast Track designation from the FDA for Vicinium for the treatment of patients with high-grade NMIBC who have previously received two courses of bacillus Calmette-Guérin ("BCG") and whose disease is now BCG-unresponsive.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and the notes to those financial statements appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2017 included in our Annual Report on Form 10-K. This discussion and analysis contains forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in Part II, Item 1A, "Risk Factors" of this Quarterly Report on Form 10-Q and in Part I, Item 1A, "Risk Factors" of our Annual Report on Form 10-K which are incorporated herein by reference, our actual results could differ materially from the results described in or implied by the forward-looking statements.

Overview

We are a late-stage clinical company developing next-generation antibody-drug conjugate, or ADC, therapies for the treatment of cancer. Our platform is designed to deliver single protein therapeutics composed of targeting moieties genetically fused via a peptide linker domain 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 while having limited expression on normal cells. We have designed our next generation ADCs to overcome the fundamental efficacy and safety challenges inherent in existing ADCs, where a payload is chemically attached to a targeting antibody.

Our most advanced product candidate is VB4-845, also known as Vicinium™, for the treatment of high-grade non-muscle invasive bladder cancer, or NMIBC, which is a locally-administered next-generation ADC. Three-month data from an ongoing single-arm, multi-center, open-label Phase 3 clinical trial of Vicinium as a monotherapy in patients with high-grade, bacillus Calmette-Guérin, or BCG, unresponsive NMIBC, called the VISTA Trial, were presented on May 21, 2018 at the American Urological Association Annual Meeting. The primary endpoint of the trial is the complete response rate in patients with carcinoma in situ (CIS), or cancer found on the inner lining of the bladder that has not spread into muscle or other tissue, with or without papillary disease, or cancer that has grown from the bladder lining out into the bladder but has not spread into muscle or other tissue. The efficacy data reported were based on three-month follow-ups from 111 evaluable patients. As of the data cut-off date of April 20, 2018, patients treated with Vicinium demonstrated a three-month complete response rate of 39% in 72 evaluable patients with CIS with or without papillary disease whose cancer recurred within six months of their last course of BCG treatment and a three-month complete response rate of 80% in five patients with CIS with or without papillary disease whose cancer recurred after six months, but before 11 months, after their last course of BCG treatment. In an analysis assessing such 77 CIS patients, based on final U.S. Food and Drug Administration, or FDA, guidance on treatment of BCG-unresponsive CIS NMIBC patients (defined as patients with recurrent CIS within 12 months of adequate BCG therapy), patients treated with Vicinium demonstrated a complete response rate of 42% at three months. In addition, in 34 evaluable patients with papillary only tumors, patients treated with Vicinium demonstrated a 68% recurrence-free rate at three months.

To date, Vicinium has been well-tolerated in the VISTA Trial. In 129 treated patients across cohorts, 72% of all adverse events were Grade 1 or 2. The most commonly reported treatment-emergent adverse events (all grades) were urinary tract infection (29%), dysuria (19%), hematuria (16%), pollakiuria (12%), diarrhea (10%), fatigue (10%), micronutrition urgency (9%), nausea (8%) and increased lipase (8%, all asymptomatic). Of the treatment-related adverse events, 4% were Grade 3 or 4, with no Grade 5 treatment-related adverse events. Four treatment-related serious adverse events were reported, including three cases of acute kidney injury or renal failure and one case of cholestatic hepatitis.

The three-month Phase 3 data are consistent with findings on Vicinium from a completed Phase 2 clinical trial in NMIBC. In 45 evaluable patients, 40% achieved a complete response or no evidence of disease at three months while 16% remained disease-free for at least 18 months.

The Phase 3 VISTA Trial completed recruitment in March 2018 with a total of 133 enrolled patients with NMIBC. We expect to report 12-month data from the VISTA Trial by mid-2019.

On August 8, 2018, we received Fast Track designation from the FDA for Vicinium for the treatment of patients with high-grade NMIBC who have previously received two courses of BCG and whose disease is now BCG-unresponsive.

In June 2017, we entered into a Cooperative Research and Development Agreement, or CRADA, with the National Cancer Institute, or NCI, for the development of Vicinium in combination with AstraZeneca's immune checkpoint inhibitor, durvalumab, for the treatment of NMIBC. Under the terms of the CRADA, the NCI will conduct a Phase 1 clinical trial in patients with high-grade NMIBC to evaluate the safety, efficacy and biological correlates of Vicinium in combination with durvalumab. This Phase 1 trial is open and is actively recruiting patients.

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Vicinium has also been evaluated as a locally-administered, next-generation ADC for the treatment of squamous cell carcinoma of the head and neck, or SCCHN. Vicinium, or VB4-845, for the treatment of SCCHN had been previously designated as Proxinium™ to indicate its different fill volume and vial size for local administration via intratumoral injection. In our two Phase 1 clinical trials, 53% of evaluable patients treated with Vicinium demonstrated antitumor activity with epithelial cell adhesion molecule, or EpCAM-expressing tumors as assessed by the investigators' clinical measurements, the investigators' overall assessment including qualitative changes, and assessment of available radiologic data. In addition, three out of the four patients with complete responses of injected tumors had regression or complete resolution of adjacent non-injected lesions. In a Phase 2 clinical trial, we observed tumor shrinkage in 10 of the 14 evaluable patients (71.4%). We intend to initiate a Phase 1/2a clinical trial that will explore the potential of Vicinium in combination with a checkpoint inhibitor for the treatment of SCCHN and are actively seeking partners for a combination program.

Our pipeline also includes systemically-administered next-generation ADCs in development that are built around our proprietary de-immunized variant of the plant-derived cytotoxin bouganin, or deBouganin. Our lead systemically-administered product candidate, VB6-845d, is being developed for the treatment of multiple types of EpCAM-positive solid tumors. VB6-845d is administered by intravenous infusion. A Phase 1 clinical trial conducted with VB6-845, the prior version of VB6-845d, revealed significantly reduced immunogenicity of the deBouganin payload.

In April 2018, we presented preclinical data from our deBouganin program at the 2018 American Association for Cancer Research Annual meeting. The data presented suggest that VB6-845d mediates tumor cell killing by an immunogenic cell death pathway. The potential cross-priming effect initiated by deBouganin-mediated killing suggests that deBouganin-induced tumor cell death induces host anti-tumor immune responses that may enhance the effectiveness of immune checkpoint inhibitors. Additionally, in collaboration with Crescendo Biologics, Ltd., or Crescendo, we presented data demonstrating that a potent fusion protein comprised of our deBouganin payload and Crescendo's HumaBody® is expressible as a soluble protein in E. coli supernatant and capable of potent killing of cancer cell lines.

We have deferred further development of VB6-845d and of Vicinium for the treatment of SCCHN in order to focus our efforts and our resources on our ongoing development of Vicinium for the treatment of high-grade NMIBC. We are also exploring collaborations for Vicinium for the treatment of SCCHN and VB6-845d, and plan on submitting an Investigational New Drug application, or IND, with VB6-845d once funding or a partner is secured for this program.

We maintain global development, marketing and commercialization rights for all of our next-generation ADC-based product candidates. We intend to explore various commercialization strategies to market our approved products. If we obtain regulatory approval for Vicinium for the treatment of high-grade NMIBC, we may build a North American specialty urology sales force to market the product or seek commercialization partners. If we obtain regulatory approval for Vicinium for the treatment of SCCHN or for our other product candidates, including VB6-845d, we may seek partners with oncology expertise in order to maximize the commercial value of each asset or a portfolio of assets. We also own or exclusively license worldwide intellectual property rights for all of our next-generation ADC-based product candidates, covering our key patents with protection ranging from 2018 to 2036.

Our locally-administered next-generation ADCs contain a targeting moiety that is designed to bind to EpCAM, which is a protein over expressed in many cancers. This targeting moiety is genetically fused to a truncated form of ETA, which is an immunogenic cytotoxic protein payload that is produced by the bacterial species, Pseudomonas. These product candidates are designed to bind to EpCAM on the surface of cancer cells. The next-generation ADC-EpCAM complex is subsequently internalized into the cell and, once inside the cell, the next-generation ADC is cleaved by a cellular enzyme to release the cytotoxic protein payload, thus enabling cancer cell-killing. We believe that our next-generation ADCs designed for local administration may not only directly kill cancer cells through a targeted delivery of a cytotoxic protein payload, but also potentiate an anti-cancer therapeutic immune response in cancer cells near the site of administration. This immune response is believed to be triggered by both the immunogenic cell death of the cancer cells due to our payload's mechanism of action and the subsequent release of tumor antigens and the immunologically active setting created by the nature of the cytotoxic protein payloads.

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

On June 10, 2016, we entered into a License Agreement, or the License Agreement, with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., or collectively, Roche, pursuant to which we licensed our monoclonal antibody EBI-031 and all other IL-6 antagonist antibody technology owned by us. Under the License Agreement, Roche is required to continue developing EBI-031 at its cost. At the time of the License Agreement, EBI-031, which was derived using our previous AMP-Rx platform, was in pre-clinical development as an intravitreal injection for diabetic macular edema and uveitis. We have received \$30.0 million in payments from Roche pursuant to the License Agreement, including a \$7.5 million upfront payment and a \$22.5

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million milestone payment as a result of the investigational new drug application for EBI-031 becoming effective. We are also entitled to receive up to an additional \$240.0 million upon the achievement of other specified regulatory, development and commercial milestones, as well as royalties based on net sales of potential future products containing EBI-031 or any other potential future products containing other IL-6 compounds.

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

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

Liquidity

Since inception, we have incurred significant operating losses and expect to continue to incur operating losses for the foreseeable future. We had a net loss of \$12.9 million for the six months ended June 30, 2018. As of June 30, 2018, we had an accumulated deficit of \$165.3 million.

On June 4, 2018, we raised approximately \$41.9 million of net proceeds from the sale of 25,555,556 shares of our common stock in an underwritten public offering. We refer to this offering as the “June 2018 Financing.”

Additionally, from April 1, 2018 through June 30, 2018, we received approximately \$6.9 million in proceeds from the issuance of 8.3 million shares of common stock due to the exercise of common stock purchase warrants issued in connection with (i) our underwritten public offering completed in November 2017, or the November 2017 Financing and (ii) our private placement of common stock purchase warrants in March 2018, or the March 2018 Private Placement.

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

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

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

Accordingly, until such time that we can generate substantial revenue from product sales, if ever, we expect to finance our operations through public or private equity or debt financings, collaboration or licensing arrangements, 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 \$63.0 million as of June 30, 2018 will be sufficient to fund our current operating plan into 2020, however, we have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

Financial Operations Overview

Revenue

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

On June 10, 2016, the Company entered into the License Agreement with F. Hoffmann-La Roche and Hoffmann La-Roche Inc. (collectively, "Roche"), which became effective on August 16, 2016 (the "License Agreement"). 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").

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During 2016, the Company received an upfront license fee of \$7.5 million and a milestone payment of \$22.5 million. The Company is entitled to receive up to \$240.0 million in additional consideration upon the achievement of specified regulatory, development and commercial milestones. Specifically, an aggregate amount of up to \$175.0 million is payable to the Company for the achievement of specified milestones with respect to the first indication: \$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, 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 buy-out options.

The License Agreement is subject to the provisions of ASC 606, which was adopted effective January 1, 2018 utilizing a modified retrospective method. The Company concluded that all performance obligations had been achieved as of the adoption date and therefore the full transaction price was considered earned. The transaction price was determined to be the \$30.0 million received in 2016. Additional consideration to be paid to the Company upon the achievement of certain milestones will be included if it is expected that the amounts will be received and the amounts would not be subject to a constraint. As of the date of the adoption, no amounts were expected to be received from the achievement of any milestones due to the nature of the milestones and the development status of the product candidates at the time of the adoption. As a result, there were no amounts required to be recorded as a cumulative adoption adjustment as the consideration recognized under ASC 606 was consistent with the amounts recognized under the previous accounting literature.

As of June 30, 2018, the Company concluded that there would be no adjustments to the transaction price as the Company continued to not expect any amounts to be received from any milestones within the License Agreement. This is due to the nature of the milestones and the development status of the product candidates at the time of the adoption. As a result, no revenue was recognized during the six-month period ended June 30, 2018 as all performance obligations had been previously achieved and there was no change in the transaction price during the period. No revenue would have been recognized under the previous accounting literature during the six month period ended June 30, 2018 as no milestones were achieved in the period, which was the revenue recognition criteria under the previous accounting literature.

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;

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- 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, 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 may be 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 Vicinium for the treatment of high-grade NMIBC, Vicinium for the treatment of SCCHN, and VB6-845d product programs and other expenses by category. We have deferred further development of Vicinium for the treatment of SCCHN and VB6-845d in order to focus our efforts and our resources on our ongoing development of Vicinium for the treatment of NMIBC. Since our acquisition of Viventia Bio Inc., or Viventia, in September 2016, our research and development expenses have been related primarily to the development of Vicinium for the treatment of high-grade NMIBC. We expect our research and development expenses for Vicinium for the treatment of NMIBC will continue to increase during subsequent periods. We did not allocate research and development expenses to any other specific product program during the periods presented:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(in thousands)			
Programs:				
Vicinium, for the treatment of high-grade NMIBC (1)	\$ 1,649	\$ 1,600	3,571	3,119
Vicinium, for the treatment of SCCHN (2)	—	—	—	27
VB6-845d (2)	—	16	—	88
Total direct program expenses	1,649	1,616	3,571	3,234
Personnel and other expenses:				
Employee and contractor-related expenses	879	961	1,844	1,816
Platform-related lab expenses	37	164	100	291
Facility expenses	74	103	169	194
Other expenses	140	65	350	248
Total personnel and other expenses	1,130	1,293	2,463	2,549
Total research and development expenses	\$ 2,779	\$ 2,909	\$ 6,034	\$ 5,783

(1) We expect our development activities for Vicinium for the treatment of high-grade NMIBC will increase significantly during subsequent periods.

(2) We have deferred further development of Vicinium for the treatment of SCCHN and of VB6-845d in order to focus our efforts and our resources on our ongoing development of Vicinium for the treatment of high-grade NMIBC.

General and Administrative Expenses

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

Changes in Fair Value of Contingent Consideration

In connection with the acquisition of Viventia Bio, Inc., or Viventia, in September 2016, we recorded contingent consideration pertaining to the amounts potentially payable to Viventia's shareholders pursuant to the terms of the share purchase agreement between us, Viventia, and the other signatories thereto. The fair value of contingent consideration is assessed at each balance

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sheet date and changes, if any, to the fair value are recognized within the condensed consolidated statements of operations and comprehensive income (loss).

Other Income (Expense), Net

Other income (expense), net consists primarily of interest income earned on cash and cash equivalents.

Critical Accounting Policies and Significant Judgments and Estimates

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

Recently adopted accounting standards

In May 2014, the FASB issued ASU No. 2014-09, codified as ASC-606, *Revenue from Contracts with Customers*, or ASC-606, which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The new standard was effective on January 1, 2018 and we adopted this standard using the modified retrospective approach. All of the revenue generated in the six months ended June 30, 2017 is from our license arrangement with Roche. We did not record any revenue for the six months ended June 30, 2018. We evaluated variable consideration, and in particular, milestone payments from Roche to assess the timing of when to include them in the transaction price. This assessment did not result in earlier revenue recognition under ASC 606 compared to the current guidance and did not result in any revenue being recorded for the six months ended June 30, 2018. As such, the adoption of ASC 606 did not have material impact on its financial position and results of operations or cash flows.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*, or ASU 2017-09. This update clarifies the changes to terms or conditions of a share-based payment award that require an entity to apply modification accounting. ASU 2017-09 is effective as of January 1, 2018. The adoption of this guidance did not have a significant impact on our financial position, results of operations or cash flows.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*. ASU 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents and amounts generally described as restricted cash or restricted cash equivalents. Amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 was effective for annual and interim periods beginning after December 15, 2017, with early adoption permitted. We adopted this standard effective January 1, 2018. Upon adoption of ASU 2016-18, we applied the retrospective transition method for each period presented and included \$10,000 of restricted cash in the beginning-of-period and end-of-period cash, cash equivalents and restricted cash balance reflected in the condensed consolidated statement of cash flows for the six months ended June 30, 2017. A reconciliation of cash, cash equivalents and restricted cash for each period presented is provided in note 9 to the condensed consolidated financial statements.

On December 22, 2017, the Tax Cuts and Jobs Act (the "Act") was enacted in the United States. The Act reduces the U.S. federal corporate tax rate from 34% to 21%, requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred and creates new taxes on certain foreign sourced earnings. In December 2017, the SEC issued guidance under SAB No. 118, *Income Tax Accounting Implications of the Tax Cuts and Jobs Act* directing taxpayers to consider the impact of the U.S. legislation as "provisional" when it does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete its accounting for the change in tax law. As of June 30, 2018, we had not yet completed our accounting for all of the tax effects of the enactment of the Act.

Recently issued accounting pronouncements

In February 2016, the FASB issued Accounting Standards 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

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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 consolidated financial statements.

There have been no significant changes to our critical accounting policies discussed in our Annual Report on Form 10-K for the year ended December 31, 2017, which we refer to as our 2017 Form 10-K, other than the adoption of ASC 606.

Results of Operations

Comparison of the Three Months Ended June 30, 2018 and 2017

	Three Months Ended June 30,		Change
	2018	2017	
	(in thousands)		
Revenue:			
License revenue	\$ —	\$ —	\$ —
Total revenue	—	—	—
Operating expenses:			
Research and development	2,779	2,909	(130)
General and administrative	2,351	2,241	110
Loss from change in fair value of contingent consideration	3,900	2,200	1,700
Total operating expenses	9,030	7,350	1,680
Loss from operations	(9,030)	(7,350)	(1,680)
Other income, net	72	34	38
Net loss and comprehensive loss	\$ (8,958)	\$ (7,316)	\$ (1,642)

Revenue. We recorded no revenue for the three months ended June 30, 2018 and June 30, 2017, respectively.

Research and development expenses. Research and development expenses were \$2.8 million for the three months ended June 30, 2018 compared to \$2.9 million for the three months ended June 30, 2017. The decrease of \$(0.1) million was due primarily to increases in Vicinium for the treatment of high-grade NMIBC related development expenses of \$0.1 million, offset by decreases of \$0.1 million in pre-clinical and manufacturing expenses and \$0.1 million in professional fees.

General and administrative expenses. General and administrative expenses were \$2.4 million for the three months ended June 30, 2018 compared to \$2.2 million for the three months ended June 30, 2017. The increase of \$0.2 million was due primarily to an increase in professional fees.

Loss from change in fair value of contingent consideration. The change in fair value of contingent consideration was a \$3.9 million loss for the three months ended June 30, 2018 compared to a \$2.2 million loss for the three months ended June 30, 2017. The change of \$1.7 million was due primarily to changes in the discount rates.

Other income (expense), net. Other income, net was \$72,000 for the three months ended June 30, 2018 compared to other income, net of \$34,000 for the three months ended June 30, 2017. The change of \$38,000 was due primarily to the increase in interest income.

Comparison of the Six Months Ended June 30, 2018 and 2017

	Six Months Ended June 30,		Change
	2018	2017	
(in thousands)			
Revenue:			
License revenue	—	425	(425)
Total revenue	—	425	(425)
Operating expenses:			
Research and development	6,034	5,783	251
General and administrative	4,303	4,454	(151)
Loss from change in fair value of contingent consideration	2,700	3,700	(1,000)
Total operating expenses	13,037	13,937	(900)
Loss from operations	(13,037)	(13,512)	475
Other income, net	116	135	(19)
Net loss and comprehensive loss	\$ (12,921)	\$ (13,377)	\$ 456

Revenue. We recorded no revenue for the six months ended June 30, 2018 compared to \$0.4 million for the six months ended June 30, 2017. The decrease was due to a decrease in license revenue recognized pursuant to our License Agreement with Roche.

Research and development expenses. Research and development expenses were \$6.0 million for the six months ended June 30, 2018 compared to \$5.8 million for the six months ended June 30, 2017. The increase of \$0.2 million was due primarily to increases in Vicinium for the treatment of high-grade NMIBC related development expenses of \$0.4 million offset by decreases of \$0.2 million in pre-clinical and manufacturing expenses.

General and administrative expenses. General and administrative expenses were \$4.3 million for the six months ended June 30, 2018 compared to \$4.5 million for the six months ended June 30, 2017. The decrease of \$0.2 million was due to a decrease in professional fees of \$0.3 million, offset by an increase in employee compensation costs and rent of \$0.1 million.

Loss from change in fair value of contingent consideration. The change in fair value of contingent consideration was a \$2.7 million loss for the six months ended June 30, 2018 compared to a \$3.7 million loss for the three months ended June 30, 2017. The change of \$(1.0) million was due primarily to changes in the discount rates.

Other income (expense), net. Other income, net was \$116,000 for the six months ended June 30, 2018 compared to other income, net of \$135,000 for the six months ended June 30, 2017. The change of \$(19,000) was due to the decrease in proceeds from sales of equipment offset by an increase in interest income.

Liquidity and Capital Resources

Sources of Liquidity

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

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

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On June 4, 2018, we raised approximately \$41.9 million of net proceeds from the sale of 25,555,556 shares of our common stock in an underwritten public offering.

Between April 1, 2018 and June 30, 2018, we received approximately \$6.9 million in proceeds from the issuance of 8.3 million shares of common stock due to the exercise of common stock purchase warrants issued in connection with (i) the November 2017 Financing and (ii) the March 2018 Private Placement.

Cash Flows

As of June 30, 2018, we had cash and cash equivalents of \$63.0 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:

	Six Months Ended June 30,	
	2018	2017
	(in thousands)	
Net cash (used in) provided by :		
Operating activities	\$ (9,979)	\$ (9,705)
Investing activities	5	69
Financing activities	58,265	45
Net decrease in cash and cash equivalents	<u>\$ 48,291</u>	<u>\$ (9,591)</u>

Operating activities. Net cash used in operating activities was \$10.0 million for the six months ended June 30, 2018 and consisted primarily of net loss of \$12.9 million, adjusted for non-cash items, including stock-based compensation expense of \$0.7 million, a change in fair value of contingent consideration of \$2.7 million, and a net change in operating assets and liabilities of \$(0.5) million.

Net cash provided by operating activities was \$9.7 million for the six months ended June 30, 2017, and consisted primarily of net loss of \$13.4 million resulting from the License Agreement with Roche, adjusted for non-cash items, including stock-based compensation expense of \$0.6 million, depreciation expense of \$0.2 million, change in fair value of contingent consideration of \$3.7 million, gain on sale of property and equipment of \$(0.1) million and a net change in operating assets and liabilities of \$(0.7) million.

Investing activities. Net cash provided by investing activities consisted of sales of property and equipment. We had cash proceeds from the sale of property and equipment of approximately \$5,000 and \$76,000 for the three months ended June 30, 2018 and 2017, respectively.

Financing activities. Net cash provided by financing activities for the six months ended June 30, 2018 consisted of (i) net proceeds of \$8.7 million from the sale, on March 23, 2018, of 7,968,128 shares of our common stock in a registered direct offering, (ii) net proceeds of 0.3 million from the sale of common stock purchase warrants to purchase 7,968,128 shares of our common stock in the March 2018 Private Placement, (iii) net proceeds of \$41.9 million from the sale of 25,555,556 shares of our common stock in an underwritten public offering in connection with our June 2018 Financing, and (iv) proceeds of \$7.3 million from the cash exercise of common stock purchase warrants issued in connection with our November 2017 Financing and our March 2018 Private Placement.

Funding Requirements

We will incur substantial expenses if and as we:

- continue our Phase 3 clinical trial for Vicinium for the treatment of high-grade NMIBC;
- incur 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;

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- 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, regulatory, 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 \$63.0 million as of June 30, 2018 will be sufficient to fund our current operating plan into 2020; however, we have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

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

- the scope, initiation, progress, timing, costs and results of pre-clinical development and laboratory testing of our pre-clinical product candidates;
- the cost and timing of any new clinical trials or studies of our product candidates;
- our ability to establish collaborations on favorable terms, if at all, particularly manufacturing, marketing and distribution arrangements for our product candidates;
- the costs and timing of the implementation of commercial-scale manufacturing activities;
- the costs and timing of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- our obligation to make milestone, royalty and other payments to third party licensors under our licensing agreements;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- the outcome, timing and cost of regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities, including Health Canada, to require that we perform more studies 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 debt securities, such as the financings we completed in November 2017, March 2018 and June 2018, our stockholders' ownership interest will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights as holders of our common stock. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third-party funding, collaborations, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

The disclosure of our contractual obligations and commitments is set forth under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Contractual Obligations and Commitments” in our 2017 Form 10-K.

During the three and six months ended June 30, 2018, there were no material changes from the contractual commitments and obligations previously disclosed in our 2017 Form 10-K.

License Agreements

The disclosure of our obligations under our license agreements is set forth under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations — License Agreements” in our 2017 Form 10-K.

During the three and six months ended June 30, 2018, there were no material changes to our obligations under our license agreements previously disclosed in our 2017 Form 10-K.

Off-balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

We are exposed to market risk related to changes in interest rates. As of June 30, 2018, we had cash and cash equivalents of \$63.0 million, primarily money market mutual funds consisting of U.S. government-backed securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point (1.0%) change in interest rates would not have a material effect on the fair market value of our portfolio.

Foreign Currency Risk

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

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2018. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time period specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2018, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Notwithstanding our assessment that, as noted below, our internal control over financial reporting was not effective as of December 31, 2017 related to accounting for business combinations, our management concluded that our disclosure controls and procedures were effective at the reasonable assurance level. The material weakness in our internal control over financial reporting was attributable primarily to our lack of expertise in our finance and accounting group related to the accounting for business combinations.

As more fully discussed in our 2017 Form 10-K, to remediate the material weakness referenced above, we have implemented or have plans to implement the remediation initiatives described in Part II, Item 9A of our 2017 Form 10-K and will continue to evaluate the remediation and plan to implement additional measures in the future.

Previously Identified Material Weakness

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control system was designed to provide reasonable assurance to our management and our board of directors regarding the preparation and fair presentation of published financial statements. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2017. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway

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Commission in *Internal Control-Integrated Framework* (2013). Based on this evaluation, our management concluded that our internal control over financial reporting was not effective as of December 31, 2017.

As of December 31, 2017 there was a material weakness in our controls over the financial reporting process related to business combinations. As a result of a lack of expertise in our finance and accounting group related to the accounting for business combinations, we lacked sufficient review of assumptions used and conclusions reached from the perspective of a typical market participant used in the acquisition valuation model. As a result, our management concluded that our internal control over financial reporting was not effective as of December 31, 2017.

Remediation Status

As more fully discussed in our 2017 Form 10-K, to remediate the material weaknesses referenced above, we have implemented or have plans to implement the remediation initiatives described in Part II, Item 9A of our 2017 Form 10-K and will continue to evaluate the remediation and plan to implement additional measures in the future. Effective as of October 20, 2017, John McCabe resigned as our Chief Financial Officer and Richard Fitzgerald was appointed as our Interim Chief Financial Officer and on January 23, 2018, Mr. Fitzgerald was appointed as our Chief Financial Officer. In order to stabilize our remediation efforts in light of this transition, we also retained consultants to assist with the review of assumptions used and conclusions reached from the perspective of a typical market participant used in the acquisition valuation model for the final purchase price allocation. In connection with our remediation plan, in early 2018 we added an employee to our financial and accounting group and may add additional employees during 2018 to broaden capacity. We also continue to engage independent consultants to aid in the review of our financial reporting process and continue to evaluate steps to address the material weakness.

Changes in Internal Control Over Financial Reporting

During the three and six months ended June 30, 2018, management continued to implement certain remediation initiatives discussed in Part II, Item 9A of our 2017 Form 10-K. However, there were no material changes to our internal control over financial reporting during the period covered by this Quarterly Report on Form 10-Q that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors

There have been no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017.

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

Other than as previously disclosed on our Current Reports on Form 8-K filed with the SEC, we did not issue any unregistered equity securities during the three months ended June 30, 2018.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits

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

EXHIBIT INDEX

Exhibit No.	Description
3.1	Certificate of Amendment of Certificate of Incorporation. Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed with the SEC on May 17, 2018 (File No. 001-36296).
3.2	Amendment to Amended and Restated By-laws. Incorporated by reference to Exhibit 3.2 to our Current Report on Form 8-K filed with the SEC on May 17, 2018 (File No. 001-36296).
31.1*	Rule 13a-14(a) Certification of Principal Executive Officer
31.2*	Rule 13a-14(a) Certification of Principal Financial Officer
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. §1350
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

SIGNATURES

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

SESEN BIO, INC.

By: _____ /s/ Thomas R. Cannell, D.V.M.

Thomas R. Cannell, D.V.M.

President and Chief Executive Officer

(Principal Executive Officer and Duly Authorized Officer)

August 14, 2018

Rule 13a-14(a) CERTIFICATION

I, Thomas R. Cannell, D.V.M., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Sesen Bio, 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/ Thomas R. Cannell, D.V.M.

Thomas R. Cannell, D.V.M.
President and Chief Executive Officer
(Principal Executive Officer)

Dated: August 14, 2018

Rule 13a-14(a) CERTIFICATION

I, Richard F. Fitzgerald, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Sesen Bio, 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/ Richard F. Fitzgerald

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

Dated: August 14, 2018

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

In connection with the Quarterly Report on Form 10-Q of Sesen Bio, Inc. (the "Company") for the fiscal quarter ended June 30, 2018 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/ Thomas R. Cannell, D.V.M.

Thomas R. Cannell, D.V.M.
President and Chief Executive Officer
(Principal Executive Officer)

Dated: August 14, 2018

/s/ Richard F. Fitzgerald

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

Dated: August 14, 2018

