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

FORM 10-K

(Mark One)

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended **December 31, 2019**

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 Number: **001-36296**

Sesen Bio, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	SESN	The Nasdaq Global Market

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [ ] No [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes [ ] No [X]

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 [X] 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes [X] No [ ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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	[ ]	Smaller reporting company	[X]
Accelerated filer	[X]	Emerging growth company	[ ]
Non-accelerated filer	[ ]		

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 [X]

The aggregate market value of common stock held by non-affiliates of the registrant, computed by reference to the closing price of the common stock on the Nasdaq Global Market on June 28, 2019, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $137.2 million.

There were 109,988,768 shares of the registrant's common stock outstanding as February 29, 2020.

Documents Incorporated by Reference

Portions of the registrant's Definitive Proxy Statement relating to the 2020 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended December 31, 2019, are incorporated by reference into Part III of this Annual Report on Form 10-K.

SESEN BIO, INC.

Annual Report on Form 10-K for the Fiscal Year ended December 31, 2019

Table of Contents

Unless the context otherwise requires, all references in this Annual Report on Form 10-K to "Sesen," the "Company," "we,""us," and "our" include Sesen Bio, Inc. and its subsidiaries.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Annual Report on Form 10-K, 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 Annual Report on Form 10-K include, among other things, statements about:

- our plans and ability to commercialize Vicinium® for the treatment of high-risk, non-muscle invasive bladder cancer ("NMIBC"), if approved;
- our expected future loss and accumulated deficit levels;
- the difficulties and expenses associated with obtaining and maintaining regulatory approval of Vicinium for the treatment of high-risk NMIBC in the United States, Canada and other jurisdictions, and the labeling under any approval we may obtain;
- our projected financial position and estimated cash burn rate;
- our estimates regarding expenses, future revenues, capital requirements and needs for, and ability to obtain, additional financing;
- our ability to continue as a going concern;
- our need to raise substantial additional capital to fund our operations;
- the potential impairment of our goodwill and indefinite lived intangible assets;
- the success, cost and timing of our pre-clinical studies and clinical trials in the United States, Canada and in other foreign jurisdictions;
- the potential that results of pre-clinical studies and clinical trials indicate our product candidates are unsafe or ineffective;
- our dependence on third parties, including contract research organizations ("CROs") in the conduct of our pre-clinical studies and clinical trials;
- our ability to achieve certain future regulatory, development and commercialization milestones under our License Agreement with F. Hoffmann-La Roche Ltd and Hoffmann La-Roche Inc. (collectively, "Roche") (the "License Agreement with Roche");
- the timing and costs associated with our manufacturing process and technology transfer of Vicinium to FUJIFILM Diosynth Biotechnologies U.S.A., Inc. ("Fujifilm") and our reliance on Fujifilm to perform under our agreement with Fujifilm for our Vicinium manufacturing process and technology transfer;
- 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 Vicinium, our other product candidates and our proprietary technology;
- the successful development of our commercialization capabilities, including sales and marketing capabilities; and
- the success of competing therapies and products that are or become available.

Our product candidates are investigational biologics undergoing clinical development and have not been approved by the United States Food and Drug Administration ("FDA"), Health Canada or the European Medicines Agency ("EMA"). Although we have not formally submitted the Biologics License Application ("BLA") for Vicinium for the treatment of high-risk NMIBC to the FDA, on December 6, 2019, we initiated our BLA submission for Vicinium under Rolling Review. The submission consisted of Modules 1, 2, 4 and 5, with information amendments to be submitted to these modules throughout 2020. We anticipate completing Module 3 (chemistry, manufacturing and controls ("CMC")) to finalize the BLA submission in the second half of 2020. 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 Annual Report on Form 10-K, 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 Annual Report on Form 10-K and the documents that we have filed as exhibits to this Annual Report on Form 10-K 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 Annual Report on Form 10-K are made as of the date of this Annual Report on Form 10-K, 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

Item 1. Business.

Overview

We are a late-stage clinical company advancing targeted fusion protein therapeutics ("TFPTs") for the treatment of patients with cancer. We genetically fuse the targeting antibody fragment and the cytotoxic protein payload into a single molecule which is produced through our proprietary one-step, microbial manufacturing process. We target tumor cell surface antigens with limited expression on normal cells. Binding of the target antigen by the TFPT allows for rapid internalization into the targeted cancer cell. We have designed our targeted proteins to overcome the fundamental efficacy and safety challenges inherent in existing antibody-drug conjugates ("ADCs") where a payload is chemically attached to a targeting antibody.

Our most advanced product candidate, Vicinium, also known as VB4-845, is a locally-administered targeted fusion protein composed of an anti-epithelial cell adhesion molecule ("EpCAM") antibody fragment tethered to a truncated form of *Pseudomonas exotoxin A* for the treatment of high-risk NMIBC.

On December 6, 2019, we initiated our BLA submission for Vicinium to the FDA under Rolling Review. "Rolling Review" of the BLA enables individual modules to be submitted and reviewed on an ongoing basis, rather than waiting for all sections to be completed before submission. The submission consisted of Modules 1, 2, 4 and 5, with information amendments to be submitted to these modules throughout 2020. We anticipate completing Module 3 (CMC) to finalize the BLA submission in the second half of 2020.

In August 2019, we reported updated preliminary efficacy data from our ongoing single-arm, multi-center, open-label Phase 3 clinical trial of Vicinium as a monotherapy in patients with high-risk, bacillus Calmette-Guérin ("BCG")-unresponsive NMIBC (the "VISTA Trial"). As of the May 29, 2019 data cutoff date, the data reported the preliminary complete response rates ("CRRs") in evaluable carcinoma *in situ* ("CIS") patients following three, six, nine and 12 months of treatment in the clinical trial. The results were consistent with the results observed in the previously completed Phase 1 and Phase 2 clinical trials of Vicinium for the treatment of high-risk NMIBC. The VISTA Trial completed enrollment in April 2018 with a total of 133 patients across three cohorts based on histology and time to disease recurrence after adequate BCG treatment (under 2018 FDA guidance on treatment of NMIBC, adequate BCG is defined as at least two courses of BCG with at least five doses in an initial induction course of treatment, plus at least two doses in a second course of treatment):

- Cohort 1 (n=86): Patients with CIS with or without papillary disease that recurred within six months of their last course of adequate BCG;
- Cohort 2 (n=7): Patients with CIS with or without papillary disease that was determined to be refractory or recurred after six months, but less than 11 months, after their last course of adequate BCG; and
- Cohort 3 (n=40): Patients with high-risk (Ta or T1) papillary disease without CIS that was determined to be refractory or recurred within six months of their last course of adequate BCG.

The primary endpoints of the VISTA Trial are CRR at 3 months in patients with CIS (with or without papillary disease) whose disease is BCG-unresponsive and duration of response ("DoR") for BCG-unresponsive CIS patients who experience a complete response ("CR").

As of the May 29, 2019 data cutoff date, preliminary primary and secondary endpoint data for each of the trial cohorts were as follows:

Cohort 1 (n=86) Evaluable Population (n=82) Complete Response Rate, for CIS:

Time Point	Evaluable Patients*	Complete Response Rate (95% Confidence Interval)
3-months	n=82	39% (28%-50%)
6-months	n=82	26% (17%-36%)
9-months	n=82	20% (12%-30%)
12-months	n=82	17% (10%-27%)

**Response-evaluable population includes any modified intention-to-treat ("mITT") subject who completed the induction phase.*

Cohort 2 (n=7) Evaluable Population (n=7) Complete Response Rate, for CIS:

Time Point	Evaluable Patients*	Complete Response Rate (95% Confidence Interval)
3-months	n=7	57% (18%-90%)
6-months	n=7	57% (18%-90%)
9-months	n=7	43% (10%-82%)
12-months	n=7	14% (0%-58%)

**Response-evaluable population includes any mITT subject who completed the induction phase.*

Pooled Cohorts 1 and 2 Evaluable Population (n=89) Complete Response Rate, for CIS:

Time Point	Evaluable Patients*	Complete Response Rate (95% Confidence Interval)
3-months	n=89	40% (30%-51%)
6-months	n=89	28% (19%-39%)
9-months	n=89	21% (13%-31%)
12-months	n=89	17% (10%-26%)

**Response-evaluable population includes any mITT subject who completed the induction phase.*

Phase 3 Pooled Complete Response Rate vs. Phase 2 Pooled Complete Response Rate:

Time Point	Preliminary Phase 3 Pooled CRR (95% Confidence Interval)	Phase 2 Pooled CRR (95% Confidence Interval)
3-months	40% (30%-51%)	40% (26%-56%)
6-months	28% (19%-39%)	27% (15%-42%)
9-months	21% (13%-31%)	18% (8%-32%)
12-months	17% (10%-26%)	16% (7%-30%)

Cohort 3 (n=40) Evaluable Population (n=38) Recurrence-Free Rate†:

Time Point	Evaluable Patients*	Recurrence-Free Rate (95% Confidence Interval)
3-months	n=38	71% (54%-85%)
6-months	n=38	58% (41%-74%)
9-months	n=38	45% (29%-62%)
12-months	n=38	42% (26%-59%)

†Recurrence-free rate is defined as the percentage of patients that are recurrence-free at the given assessment time point.
**Response-evaluable population includes any mITT subject who completed the induction phase.*

Duration of Response: The median DoR for patients in Cohort 1 and Cohort 2 combined (n=93) is 287 days (lower 95% confidence interval ("CI") = 154 days, upper 95% confidence interval is not estimable ("NE") due to the limited number of events occurring beyond the median), using the Kaplan-Meier method. The Kaplan-Meier method is a non-parametric statistical analysis used to estimate survival times and times to event when incomplete observations in data exist. Additional *ad hoc* analysis of pooled data for all patients with CIS (Cohorts 1 and 2, n=93) shows that among patients who achieved a complete response at 3 months, 52% remained disease-free for a total of 12 months or longer after starting treatment, using the Kaplan-Meier method. DoR is defined as the time from first occurrence of complete response to documentation of treatment failure or death.

We have conducted additional analyses for secondary endpoints based on the May 29, 2019 data cutoff date. These additional preliminary data include the following:

- ***Time to Cystectomy:*** Across all 133 patients treated with Vicinium in the VISTA Trial, greater than 75% of all patients are estimated to remain cystectomy-free at 2.5 years, using the Kaplan-Meier method. Additional *ad hoc* analysis shows that approximately 88% of responders are estimated to remain cystectomy-free at 3 years. Time to cystectomy is defined as the time from the date of first dose of study treatment to surgical bladder removal. The first 2018 FDA guidance on treatment of BCG-unresponsive NMIBC patients states that the goal of therapy in such patients is to avoid cystectomy. Therefore, time to cystectomy is a key secondary endpoint in the VISTA Trial.
- ***Time to Disease Recurrence:*** High-grade papillary (Ta or T1) NMIBC is associated with higher rates of progression and recurrence. The median time to disease recurrence for patients in Cohort 3 (n=40) is 402 days (95% CI, 170-NE), using the Kaplan-Meier method. Time to disease recurrence is defined as the time from the date of the first dose of study treatment to the first occurrence of treatment failure or death on or prior to treatment discontinuation.
- ***Progression-Free Survival ("PFS"):*** 90% of all 133 patients treated with Vicinium in the VISTA Trial are estimated to remain progression-free for 2 years or greater, using the Kaplan-Meier method. PFS is defined as the time from the date of first dose of study treatment to the first occurrence of disease progression (e.g. T2 or more advanced disease) or death on or prior to treatment discontinuation.
- ***Event-Free Survival:*** 29% of all 133 patients treated with Vicinium in the VISTA Trial are estimated to remain event-free at 12 months, using the Kaplan-Meier method. Event-free survival is defined as the time from the date of first dose of study treatment to the first occurrence of disease recurrence, progression or death on or prior to treatment discontinuation.
- ***Overall Survival ("OS"):*** 96% of all 133 patients treated with Vicinium in the VISTA Trial are estimated to have an overall survival of 2 years or greater, using the Kaplan-Meier method. OS is defined as the time from the date of first dose of study treatment to death from any cause.

Preliminary Safety Results

As of the May 29, 2019 data cutoff date, in patients across all cohorts (n=133) of our Phase 3 VISTA Trial of Vicinium for the treatment of high-risk NMIBC, 88% experienced at least one adverse event, with 95% of adverse events being Grade 1 or 2. The most commonly reported treatment-related adverse events were dysuria (14%), hematuria (13%) and urinary tract infection (12%) - all of which are consistent with the profile of bladder cancer patients and the use of catheterization for treatment delivery. These adverse events were determined by the clinical investigators to be manageable and reversible, and only four patients (3%) discontinued treatment due to an adverse event. Serious adverse events, regardless of treatment attribution, were reported in 14% of patients. There were four treatment-related serious adverse events reported in three patients including acute kidney injury (Grade 3), pyrexia (Grade 2), cholestatic hepatitis (Grade 4) and renal failure (Grade 5). There were no age-related increases in adverse events observed in the VISTA Trial.

Other Vicinium Activity

In August 2018, we received Fast Track designation from the FDA for Vicinium for the treatment of high-risk NMIBC.

In May 2019, we met with the FDA for a Type C meeting for CMC and reached agreement with the FDA on the analytical comparability plan to be used to assess comparability between the drug supply used in clinical trials and the potential commercial drug supply to be produced by Fujifilm. We also confirmed with the FDA that, subject to final comparability data to be provided in the BLA submission, no additional clinical trials were deemed necessary to establish comparability.

In June 2019, we met with the FDA for a Type B Pre-BLA meeting regarding the approval pathway for Vicinium for the treatment of patients with high-risk, BCG-unresponsive NMIBC. At the meeting, we reached alignment with the FDA on an accelerated approval pathway for Vicinium along with Rolling Review. The FDA also indicated that the clinical data, nonclinical data, clinical pharmacology data, and the safety database were sufficient to support a BLA submission, and that no additional clinical trials were necessary for a BLA submission. Per the official FDA minutes received post-meeting, the FDA stated that the pre-licensing inspection may be completed at the time of process performance qualification manufacturing, which we believe will benefit the overall review timeline for the BLA. In addition, the FDA communicated that they expect that a meeting with the FDA's Oncologic Drugs Advisory Committee ("ODAC") will be required as part of the accelerated approval pathway. If Vicinium receives marketing approval for treatment of NMIBC, a post-marketing confirmatory trial will also be required.

In November 2019, we met with the FDA for a Type C meeting to discuss the details of a post-marketing confirmatory trial for Vicinium for the treatment of high-risk NMIBC. At that meeting, we reached agreement with the FDA that the post-marketing confirmatory trial for Vicinium will enroll BCG-refractory patients who have received less-than-adequate BCG, which is especially important in light of the ongoing BCG shortage. This represents a broader patient population than the BCG-intolerant population originally proposed. We anticipate that, if Vicinium is approved by the FDA, the initial indication will be for BCG-

unresponsive patients who have received adequate BCG. If the post-marketing confirmatory trial is successful, it could result in an expanded label to include this additional population of patients who have received less-than-adequate BCG.

On December 4, 2019, we met with the FDA for a Type B pre-BLA meeting for CMC. At that meeting, we reached agreement with the FDA on the final content for Module 3 (CMC) of the BLA.

On December 6, 2019, we initiated our BLA submission for Vicinium to the FDA under Rolling Review. The submission consisted of Modules 1, 2, 4 and 5, with information amendments to be submitted to these modules throughout 2020. We anticipate completing Module 3 (CMC) to finalize the BLA submission in the second half of 2020.

Manufacturing

In October 2018, we entered into a Master Bioprocessing Services Agreement with Fujifilm (the "Fujifilm MSA") for the manufacturing process and technology transfer of Vicinium drug substance production. In April 2019, the first full, commercial-scale cGMP run was completed at Fujifilm. Full quality release testing has been completed and all Phase 3 release specifications were met, supporting Fujifilm's ability to produce the bulk drug substance form of Vicinium for commercial purposes if we receive regulatory approval to market Vicinium for the treatment of high-risk NMIBC.

Joint Development

In June 2017, we entered into a Cooperative Research and Development Agreement ("CRADA") with the National Cancer Institute ("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-risk NMIBC to evaluate the safety, efficacy and biological correlates of Vicinium in combination with durvalumab. This Phase 1 clinical trial is open and is actively recruiting patients.

Vicinium has also been evaluated for the treatment of squamous cell carcinoma of the head and neck ("SCCHN"). Vicinium for the treatment of SCCHN had previously been designated as Proxinium™ to indicate its different fill volume and vial size as well as its different route for local administration via intratumoral injection. In addition to our locally-administered TFPTs, our pipeline also includes systemically-administered TFPTs that are built around our proprietary de-immunized variant of the plant-derived cytotoxin bouganin ("deBouganin"). One of these product candidates, VB6-845d, is a TFPT consisting of an EpCAM-targeting fragment antigen binding domain ("Fab") genetically linked to deBouganin, a novel plant derived cytotoxic payload that we have optimized for minimal immunogenic potential and is administered by intravenous infusion. 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-risk NMIBC. We are also exploring collaborations for Vicinium for the treatment of SCCHN and for VB6-845d.

We maintain global development, marketing and commercialization rights for all of our TFPT-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-risk NMIBC, we intend to build a North American specialty urology sales force to market the product in the United States and Canada. Outside the United States and Canada, we will seek commercialization partners with urology expertise. We also own or exclusively license worldwide intellectual property rights for all of our TFPT-based product candidates, covering our key patents with protection into 2036. See ‘‘Our Intellectual Property’’ below for additional details.

Our License Agreement with Roche

In June 2016, we entered into the License Agreement with Roche, pursuant to which we granted Roche an exclusive, worldwide license, including the right to sublicense, to our patent rights and know-how related to our monoclonal antibody EBI-031 and all other IL-6 anti-IL antagonist monoclonal antibody technology owned by us (collectively, the "Licensed Intellectual Property"). Under the License Agreement, Roche is required to continue developing, at its cost, EBI-031 and any other product made from the Licensed Intellectual Property that contains an IL-6 antagonist anti-IL monoclonal antibody ("Licensed Product") and pursue ongoing patent prosecution, 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.

Through December 31, 2019, we have received a total of $30.0 million in payments from Roche pursuant to the License Agreement, including a $7.5 million upfront payment in August 2016 and a $22.5 million milestone payment in September 2016 as a result of the investigational new drug ("IND") application for EBI-031 becoming effective. We are also entitled to receive up to an additional $240.0 million upon the achievement of other specified regulatory, development and commercial milestones, as well as royalty payments in accordance with a tiered royalty rate scale, with rates ranging from 7.5% to 15% of net sales of potential future products containing EBI-031 and up to 50% of these rates for net sales of potential future products containing other IL-6 compounds, with each of the royalties subject to reduction under certain circumstances and to the buy-out options of Roche. See "Our Pipeline - EBI-031 - License Agreement with Roche" below for additional information.

Our TFTP Platform

Our current product candidates are based on our proprietary TFPT platform and are focused on addressing areas of unmet medical need in cancer. Our novel TFPTs have been designed to overcome the efficacy and safety challenges of existing ADCs and are being developed for both local and systemic administration. Our TFPTs are single protein therapeutics composed of targeting domains genetically fused via peptide linkers to cytotoxic protein payloads that are produced through our proprietary recombinant one-step, microbial manufacturing process. Our TFPT platform uses protein binding antibody fragments, which include Fabs, single chain variable domains ("ScFvs"), and non-covalent scFv dimers ("diabodies"), derived from the domains of antibodies that confer antigen recognition. We select antibody fragments for our product candidates depending upon the target therapeutic indication. We target tumor cell surface antigens that allow for rapid internalization into the targeted cancer cell and that also have limited expression in normal cells. For local administrations, we utilize an immunogenic cytotoxic protein payload designed to both target cancer cells and promote a heightened local immune response against the tumor. For systemic administrations, we use a deBouganin, a plant-derived, protein payload of reduced immunogenic potential that we believe can be repeatedly administered via infusion without the generation of an efficacy-limiting immune response against the payload.

Locally-administered TFPTs

We utilize our TFPTs with immunogenic cytotoxic protein payloads for tumors that can be targeted locally rather than systemically. Local administration allows for the TFPT to reach the tumor without being cleared by the immune system, which enables us to maximize the concentration of TFPTs directly to tumors. Our locally-administered TFPT Vicinium, which is our lead product candidate in development for the treatment of high-risk NMIBC, contains a targeting antibody binding domain that is designed to bind to EpCAM, a protein over-expressed in many cancers. This binding domain is genetically fused to a truncated form of *exotoxin A* ("ETA"), which is an immunogenic cytotoxic protein payload that is produced by the bacterial species *Pseudomonas*. This product candidate is designed to bind to EpCAM on the surface of cancer cells. The TFPT-EpCAM complex is subsequently internalized into the cell and, once inside the cell, the TFPT is cleaved by a cellular enzyme to release the cytotoxic protein payload, thus enabling cancer-cell killing.

We also believe that our TFPTs 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. 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. We believe that this immune response may also enhance the action of checkpoint inhibitors, which require a pre-existing immune response for maximum efficacy.

Our most advanced locally-administered TFTP product candidate is Vicinium, in development for the treatment of high-risk NMIBC and recurrent, locally advanced or metastatic EpCAM-expressing SCCHN. This TFTP is not, however, suitable for systemic administration over multiple doses because the body’s immune system would recognize and eliminate foreign proteins, such as ETA, prior to their reaching targeted cancer cells.

Systemically-administered TFPTs

We also utilize our TFPTs with a de-immunized payload where systemic administration is required. Our systemically-administered TFPTs are built around deBouganin. Since the body’s immune system naturally recognizes and attempts to eliminate foreign proteins, we designed our systemically administered TFPTs with a deBouganin payload to avoid inducing an immunogenic response. DeBouganin is constructed by mutating the immunogenic T-cell epitopes from bouganin so that they are not recognized as foreign by the immune system. However, we also believe that deBouganin may enhance the action of checkpoint inhibitors as a result of the promotion of a local tumor immune response following the death of cancer cells. Our systemically-administered product candidate is VB6-845d for the treatment of multiple types of EpCAM-positive solid tumors.

Our Differentiated Approach to Targeted Therapies

We believe that our TFPT platform will address many challenges experienced with existing ADCs. The basic construct for our TFPTs and existing ADCs is similar as each is comprised of a targeting domain that specifically binds to cancer cells and delivers a cytotoxic payload. However, existing ADCs have been associated with limitations that we believe are addressed by our TFPTs.

Limitations of Existing ADC Approaches to Treating Tumors

We believe existing ADCs have the following fundamental efficacy and safety challenges:

- ***Deliver insufficient drug to tumors.*** Existing ADCs utilize full-length antibodies, which, due to their large size, have a reduced ability to penetrate tumors, thereby potentially reducing their efficacy.

- ***Inability to kill a broad array of cancer cells within a tumor.*** Subsets of cancer cells within tumors may have mechanisms to resist and not be responsive to the cytotoxic payloads, or small molecule chemotherapies, used in existing ADCs.
- ***Off-target toxicities due to unstable chemical linkage between targeting antibody and cytotoxic payload.*** Existing ADCs utilize chemical linkage strategies to join antibodies to small molecule cytotoxic payloads. While in the circulatory system, these chemical linkages can break and release free cytotoxic payloads in the circulation. These free small molecule cytotoxic payloads are not targeted and cannot discriminate between dividing cancer cells and non-cancerous cells, thus resulting in increased off-target toxicities.
- ***Limited combination therapy potential.*** Adverse events may limit the potential utility of existing ADCs in combination therapies with immune checkpoint inhibitors which have their own adverse events, including immune-related adverse events.
- ***Complex and challenging manufacturing process.*** The multi-step manufacturing process of existing ADCs creates a non-homogeneous product that limits efficacy and drives greater costs than our manufacturing process.

Advantages of our TFPT Platform

We believe our TFPTs offer the following key advantages:

- ***Deliver a greater amount of drug to tumors.*** Our TFPTs are designed using smaller targeting proteins that have an increased ability to exit the circulatory system and have binding properties designed to enable deeper penetration into targeted tumors, and we believe this will increase efficacy.
- ***Ability to kill a broader array of cancer cells within a tumor.*** Our novel cytotoxic payloads consist of proteins rather than small molecule cytotoxic payloads. We believe the larger size of our cytotoxic protein payloads helps circumvent multi-drug resistance mechanisms that can make certain cancer cells resistant to small molecule cytotoxic payloads. By contrast to existing ADCs, which employ cytotoxic payloads that inhibit cellular replication and are effective at killing rapidly proliferating cancer cells, our cytotoxic protein payloads inhibit protein synthesis and are designed to kill not only rapidly proliferating, but also slowly growing cancer cells including tumor progenitor cells/cancer stem-like cells.
- ***Increase safety due to a more stable linkage between targeting protein and cytotoxic payload.*** Our single protein molecules are designed to remain intact until they reach the inside of the cancer cell and to not release free cytotoxins into the circulatory system, thereby minimizing off-target toxicity.
- ***Promote a therapeutic immune response.*** We believe that the potent TFPT toxin-mediated killing of cancer cells in this immunologically active setting leads to the efficient presentation of cancer antigens to the immune system, thereby promoting an anti-tumor cellular immune response. Our locally-administered TFPTs utilize an immunogenic cytotoxic payload that we believe promotes a heightened immune response in the local tumor environment.
- ***Potential combination with checkpoint inhibitors.*** We believe that the potential effect of checkpoint inhibitors, which are antibodies that promote the action of anti-tumor T-cells by blocking inhibitory ligand/receptor interactions that include PD-1 and PD-L1, may be enhanced when used in combination with other agents. We believe that, by mediating specific killing of tumor cells and promoting anti-tumor immune responses, our TFPTs, while potentially effective on their own, may complement checkpoint inhibitors. In particular, we believe that our use of our cytotoxin payload ETA, which induces immunogenic cell death, may facilitate the presentation of tumor cell surface antigens following the death of cancer cells, thereby providing a tumor immune response to enhance the action of checkpoint inhibitor therapies.
- ***Utilize a simpler and more efficient manufacturing process.*** Our proprietary recombinant one-step manufacturing process creates a homogeneous product that we believe will improve efficacy and result in lower manufacturing costs.

Our Strategy

We are committed to designing, engineering, developing and commercializing TFPTs to identify and address oncology indications that suffer from a high unmet medical need. The key elements of our strategy are as follows:

- ***Obtain regulatory approval of Vicinium for the treatment of high-risk NMIBC.*** On December 6, 2019, we initiated our BLA submission for Vicinium to the FDA under Rolling Review. The submission consisted of Modules 1, 2, 4 and 5, with information amendments to be submitted to these modules throughout 2020. We anticipate completing Module 3 (CMC) to finalize the BLA submission in the second half of 2020. We also intend to initiate discussions with the EMA in 2020 regarding a regulatory pathway for European Union ("E.U.") approval.
- ***Explore opportunities in combination therapies.*** We plan to continue discussions with potential partners that utilize technologies whose mechanism of action could be complementary to our TFPT platform. These technologies include, but are not limited to, checkpoint inhibitors, immune modulators and other immuno-oncology agents. In June 2017, we entered into a CRADA with the 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-risk NMIBC to evaluate the safety, efficacy and biological correlates of Vicinium in combination with durvalumab. This Phase 1 clinical trial is open and is actively recruiting patients.
- ***Expand on the value of Vicinium through strategic partnerships.*** We may decide to selectively partner with pharmaceutical and biopharmaceutical companies when we believe that a partner could bring additional resources and expertise to maximize the value of Vicinium for the treatment of high-risk NMIBC. If we obtain regulatory approval for Vicinium for the treatment of high-risk NMIBC, we intend to build a North American specialty urology sales force to market the product in the United States and Canada. Outside the United States and Canada, we will seek commercialization partners with urology expertise.

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-risk NMIBC. We are also exploring collaborations for Vicinium for the treatment of SCCHN and for VB6-845d.

Our Product Pipeline

At this time, we are focused exclusively on the clinical development of Vicinium for the treatment of high-risk NMIBC and have deferred further development of our other product candidates. The following table sets forth our current development stage programs:

PRODUCT CANDIDATE	PAYLOAD	INDICATION	PRECLINICAL	Ph I	Ph II	Ph III	BLA
Locally-administered TFPTs							
Vicinium	**ETA**	BCG-unresponsive high-risk NMIBC	Submission Initiated				
Vicinium	**ETA**	SCCHN	Complete				
Locally-administered TFPT + Systemic Checkpoint Inhibitor							
Vicinium + Durvalumab	**ETA & IO**	BCG-unresponsive high-risk NMIBC	Ongoing				
Vicinium (Combination with checkpoint inhibitor)	**ETA & IO**	SCCHN	Anticipated				

Vicinium for the Treatment of High-Risk NMIBC

Overview

Vicinium is being developed for the treatment of high-risk NMIBC in patients who have previously received adequate BCG and whose disease is now BCG-unresponsive. Vicinium is administered by intravesical administration directly into the bladder. Vicinium utilizes an immunogenic cytotoxic protein payload that is a truncated form of ETA produced by the bacterial species *Pseudomonas*. Vicinium also includes an anti-EpCAM ScFv targeting domain that is required to deliver the ETA into EpCAM-expressing cancer cells. The toxicity to non-cancerous bladder cells is minimized due to their not having EpCAM over-expressed on their surface.

Based upon our September 2014 end of Phase 2 meeting with the FDA, we, through our subsidiary Viventia, commenced the Phase 3 VISTA Trial in patients with high-risk NMIBC who have received adequate BCG and whose disease is now BCG-unresponsive, and for whom the current standard of care is the surgical removal of their bladder, or a radical cystectomy, in the third quarter of 2015 in the United States and Canada. Based on safety and efficacy data observed with the longer 12-week induction in our Phase 2 clinical trial, the FDA agreed to our plan to employ more frequent dosing in our Phase 3 clinical trial, in which the primary end points are CR and DoR in patients with CIS whose disease is BCG-unresponsive. In November 2016, the FDA issued draft guidance regarding appropriate clinical trial design for new drugs and biologics for BCG-unresponsive NMIBC, including the use of single-arm studies. The FDA finalized this guidance in February 2018 and retained many of the recommendations from the 2016 draft guidance regarding clinical trial design, including the use of single-arm studies. We believe that our VISTA Trial design is consistent with these aspects of the FDA's guidance. We completed enrollment in the VISTA Trial in April 2018 and reported updated preliminary efficacy data in August 2019. In August 2018, we received Fast Track designation from the FDA for Vicinium for the treatment of high-risk NMIBC. On December 6, 2019, we initiated our BLA submission for Vicinium to the FDA under Rolling Review. The submission consisted of Modules 1, 2, 4 and 5, with information amendments to be submitted to these modules throughout 2020. We anticipate completing Module 3 (CMC) to finalize the BLA submission in the second half of 2020. We also intend to initiate discussions with the EMA in 2020 regarding a regulatory pathway for E.U. approval.

Overall, we believe that our efficacy and safety data support the continued clinical development of Vicinium to fulfill a significant unmet medical need in patients with high-risk NMIBC. Because Vicinium contains ETA, an immunogenic cytotoxic payload that elicits an anti-ETA immune response, we believe the local administration of Vicinium may amplify the local host immune response within the tumor environment killing bladder cancer cells through an Immunogenic Cell Death ("ICD") mechanism. In addition, we believe that this ICD response, which potentiates host immune responses against neoantigens present on the cancer cells, can lead to a heightened host immune response against their own tumor and potentially complement checkpoint inhibitor therapies.

We own or exclusively license worldwide rights to our Vicinium intellectual property portfolio that provides unextended patent term until June 2025, and, when our pending patent applications for Vicinium are granted, patent protection until at least 2036. See ‘‘Our Intellectual Property’’ below for additional details.

Disease Overview

Most cancers that form in the bladder are transitional cell carcinomas that derive from the transitional cell lining of the bladder. Transitional cell carcinoma of the bladder can be characterized as either high-grade or low-grade. Low-grade bladder cancer often recurs in the lining of the bladder after treatment, but rarely invades the muscular wall of the bladder or spreads to other parts of the body and is unlikely to be fatal. High-grade bladder cancer commonly recurs in the bladder, has a strong tendency to invade the muscular wall of the bladder, and spread to other parts of the body and is much more likely to result in death. Bladder cancer is also divided into muscle-invasive and NMIBC, based on invasion of the *muscularis propria*, which is the thick muscle deep in the bladder wall. Muscle-invasive disease is more likely to spread to other parts of the body.

There are three forms of high-grade NMIBC: Ta, a papillary tumor in the innermost layer of the bladder lining; T1, a papillary tumor that has started to grow into the connective tissue beneath the bladder lining; and CIS, flat lesions of the transitional cell lining of the bladder. Papillary tumors are generally low-grade with low risk of progression, although about two to nine percent are high-grade, with a moderately high risk of progression to muscle-invasive bladder cancer. CIS tumors are always high-grade, with a worse prognosis than papillary tumors, as such CIS tumors are more aggressive, with a higher probability of progression to muscle-invasive disease. Furthermore, the incidence of CIS in conjunction with Ta or T1 tumors results in a higher risk of recurrence and progression. About 75% to 85% of bladder cancers are non-muscle invasive. Of these, Ta tumors account for about 70%, T1 tumors account for about 20% and CIS lesions account for about 10%.

Bladder cancer is the twelfth most common cancer diagnosed worldwide and the second most common malignancy of the genitourinary system. In 2018, there were an estimated 539,000 new cases of bladder cancer diagnosed and 200,000 deaths worldwide. The global prevalence of bladder cancer is estimated at 2.7 million individuals. The NCI's Surveillance, Epidemiology and End-Result Program ("SEER") estimated that approximately 81,000 new cases of bladder cancer would be diagnosed in 2019 and there would be approximately 18,000 deaths due to bladder cancer in the United States during 2019. Based on a 2014 publication

in Current Opinion in Urology, among cancers in the United States, bladder cancer has the highest per-patient treatment costs, with an estimated overall cost of approximately $4.0 billion annually. In the United States, bladder cancer has the highest overall cost among the elderly. Based on our assessment of the market, the treatment paradigm has remained the same since those figures were generated, and we believe the cost of care has increased.

NMIBC makes up 75% to 85% of all bladder cancers. The high recurrence rate and ongoing invasive monitoring requirement of bladder cancers are the key contributors to the economic and human toll of this disease. Bladder cancer occurs predominantly in older patients (about nine of the 10 people with bladder cancer are over the age of 55 years). The median age at diagnosis is approximately 72 years. Overall, the five-year survival rate for bladder cancer in the United States is 77%. While the five-year survival rates are 98% for stage zero and 88% for stage one NMIBC, once the cancer becomes invasive, the rates drop dramatically with five-year survival rates of 63%, 46% and 15% for stage two, three and four muscle invasive bladder cancers, respectively. We are targeting patients with BCG-unresponsive high-risk NMIBC. Our initial target market includes the approximately 25,000 patients diagnosed annually, including those patients who have previously failed BCG and have refused cystectomy. We would expect that, if Vicinium for the treatment of high-risk NMIBC is approved by the FDA, patients would receive treatment until the earlier of 2 years and disease recurrence.

Current Approaches to Treatment

Within high-risk NMIBC, the initial treatment of Ta or T1 is transurethral resection of the bladder tumor ("TURBT") followed by BCG treatment. For CIS, whether or not TURBT is an option, BCG is the standard of care. BCG is a live attenuated strain of *Mycobacterium bovis*, with a diminished virulence in humans. Since BCG works by utilizing an immune/inflammatory mechanism, BCG is generally initiated only two to four weeks after TURBT, allowing the urothelium to heal and lowering the risk of systemic infection. When high-grade bladder tumors have been completely resected, BCG is used as adjuvant therapy to prevent recurrence. In patients with residual disease after resection, BCG helps to eradicate residual disease and delay progression. The BCG regimen consists of an induction phase followed by a maintenance phase. The induction phase involves six consecutive once-weekly instillations of the drug into the bladder. The maintenance phase involves three consecutive once-weekly instillations repeated every three to six months for at least one year. The response rate to a single induction phase of BCG is 60% to 70% with an additional 30% to 50% of the non-responders becoming responders following a second induction phase. However, BCG’s failure rate for all responders is estimated to be as high as 50% within the first 12 months of treatment and 90% within five years.

For patients who received BCG and whose disease is now BCG-unresponsive, radical cystectomy has been recommended due to the risk of progression to muscle invasive disease, which greatly reduces a patient’s prognosis. Radical cystectomy is a complex surgery associated with a significant morbidity rate of 28% to 45% and a mortality rate of 8% within six months of surgery. The surgery also entails a number of short-term risks including bleeding and/or clots, infections, bowel obstruction, bowel perforation, peritonitis and injury to the urethra. More than 25% of radical cystectomy patients require readmission for surgery-related complications within 90 days following surgery, and 34% require emergency room visits. The impact of radical cystectomy is life-altering, with major lifestyle changes, including incontinence and sexual dysfunction, and daily issues related to management of the external bag for urine collection.

In January 2020, the FDA approved Merck & Co., Inc.'s Keytruda (pembrolizumab) as a systemic monotherapy to treat patients with BCG-unresponsive, high-risk NMIBC with CIS with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy. In 2009, Endo Pharmaceuticals Inc.'s Valstar (valrubicin) was re-launched in the United States for the treatment of BCG-refractory CIS bladder cancer in patients for whom radical cystectomy is not an option. Valstar is administered intravesically directly into the bladder once a week for six weeks. Due to drug resistance and toxicities, Valstar has had limited utility. Other than Keytruda and Valstar, there are no other approved therapies for BCG-unresponsive CIS bladder cancer. However, there are various other intravesical product candidates in development for the treatment of NMIBC, including product candidates developed by FerGene Inc. (Adstiladrin/nadofaragene firadenovec (rAd-IFN/Syn3)), AADi, LLC (ABI-009), ImmunityBio (N-803 in combination with BCG) and Cold Genesys, Inc. (CG0070). In addition, systemically-administered checkpoint inhibitors are being evaluated for the treatment of NMIBC.

Phase 1 and 2 Clinical Trials

Phase 1 Clinical Trial. We initiated an open-label, dose-escalating Phase 1 clinical trial of Vicinium for the treatment of high-risk NMIBC in September 2004 at 22 sites in Canada. We enrolled 64 patients with high-grade Ta or T1 tumors with or without CIS (17 of which had CIS) and who had previously received at least one treatment of BCG. The Phase 1 clinical trial was designed to assess safety and determine the maximum tolerated dose, and the recommended Phase 2 dose. The secondary objective was to explore the anti-tumor activity of Vicinium.

Eight dose levels were initially evaluated, ranging from 0.1 to 10.56 mg dose given once weekly for six consecutive weeks. Each dose was administered by instillation and held for two hours prior to voiding. Safety data from each dose cohort was evaluated after three weeks of treatment before proceeding to the next dose cohort. A maximum tolerated dose was not reached; therefore, additional escalations through 13.73 mg, 17.85 mg, 23.20 mg and 30.16 mg were undertaken. No dose-limiting toxicities

("DLTs") were reported and no maximum tolerated dose was reached in these additional dose-escalations. Vicinium was generally well-tolerated at each of these escalated doses.

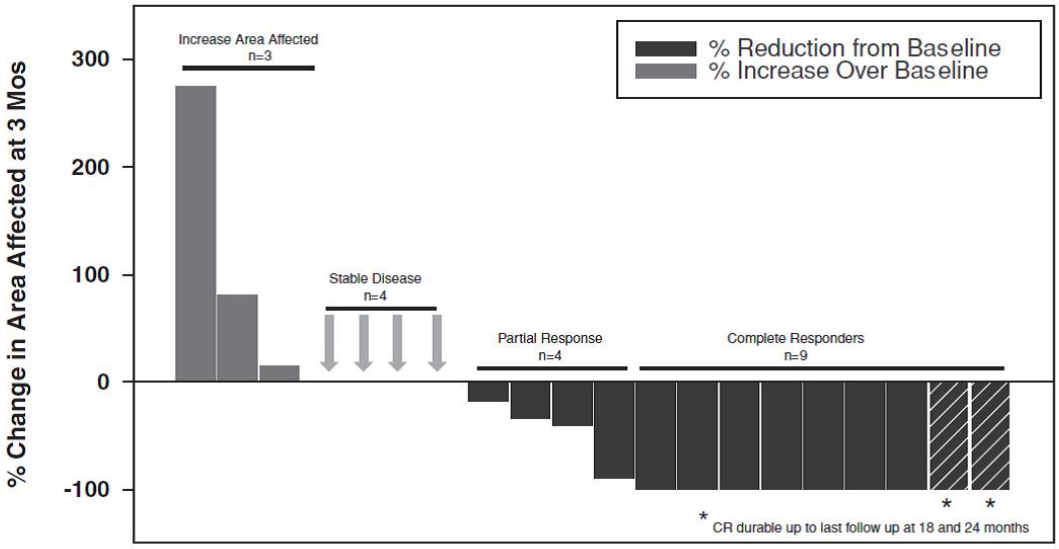
A CR was defined in this Phase 1 clinical trial as non-positive urinary cytology and either normal cystoscopy or abnormal cystoscopy with negative biopsy. Of the 64 patients enrolled, only 61 were considered to be evaluable for efficacy as two patients were excluded from the analysis due to an absence of BCG treatment prior to this Phase 1 clinical trial, and there was one unrelated death for whom no final tumor assessment was obtained. Evidence of clinical efficacy, as defined by a CR, was achieved by 24 of the 61 randomized patients (39%). Only three of the 17 patients (18%) treated in the 0.1-<1mg/dose range were CRs. In contrast, seven of the 14 patients (50%) treated in 1.0-<10mg/dose range and 14 of the 30 patients (46.7%) treated in the ≥10mg/dose range experienced CRs at the three-month assessment. Of the patients with CIS, five of the 17 patients (29%) achieved a CR, while non-recurrence was observed in seven of the 16 patients with T1 (43.8%) and 12 of the 28 patients with Ta (42.8%). This Phase 1 clinical trial was completed in April 2006.

Phase 2 Clinical Trial. Based on our Phase 1 clinical trial conducted in Canada, we submitted the IND for Vicinium for the treatment of high-risk NMIBC to the FDA in August 2005, and we initiated an open-label Phase 2 clinical trial of Vicinium in March 2007 at 20 sites in Canada and the United States. We enrolled 46 patients with CIS (with or without Ta or T1) who had previously received at least one treatment of BCG. Of the 46 patients enrolled, 27 patients (58.7%) had received at least two treatments of BCG. The Phase 2 clinical trial was designed to determine the tolerability and explore the potential for clinical benefit from Vicinium. Clinical benefit was defined in this Phase 2 clinical trial as a CR or no evidence of disease at the three-month evaluation. A CR was defined in this Phase 2 clinical trial as no histological evidence of disease and negative urine cytology. Any cases with no histological evidence of disease on initial biopsy but atypical or suspicious urine cytology were also considered CRs only if they remained negative after being evaluated with repeat biopsy, directed and random. A patient was considered to have a durable CR if that patient obtained a CR and remained disease-free for a period of at least 12 months from initiation of treatment.

The dosing regimen for our Phase 2 clinical trial included an induction phase followed by a maintenance phase, consisting of three weekly treatments and then nine weeks of no treatment repeated every three months for at least one year and ending with nine weeks of no treatment. There were two treatment groups in this Phase 2 clinical trial. Treatment Arm A consisted of 23 patients, of which 22 were ultimately evaluable as one patient violated eligibility requirements early in this Phase 2 clinical trial. Twenty-two patients in the induction phase received six consecutive once-weekly instillations of 30 mg of Vicinium. At the three-month assessment, patients with residual disease but no disease progression-where disease progression is defined as being muscle invasive-were eligible for either a second induction phase or a maintenance phase, which consisted of three consecutive once-weekly instillations repeated every three months for at least one year. Of the 13 patients unable to achieve a CR at the three-month assessment, nine patients elected additional treatment. From these nine, two became CRs after receiving maintenance dosing. Treatment Arm B was added to evaluate a longer induction cycle. In Treatment Arm B, 23 patients in the induction phase received 12 consecutive once-weekly instillations of 30 mg Vicinium. At the three-month assessment, the CR rates for both treatment arms were 40%. At the 12-month assessment, the CR rate in Treatment Arm A was 13%, but 17% in Treatment Arm B. Of those patients who did not achieve a CR at the three-month assessment, 73% had either a reduction in tumor size or did not experience further tumor growth.

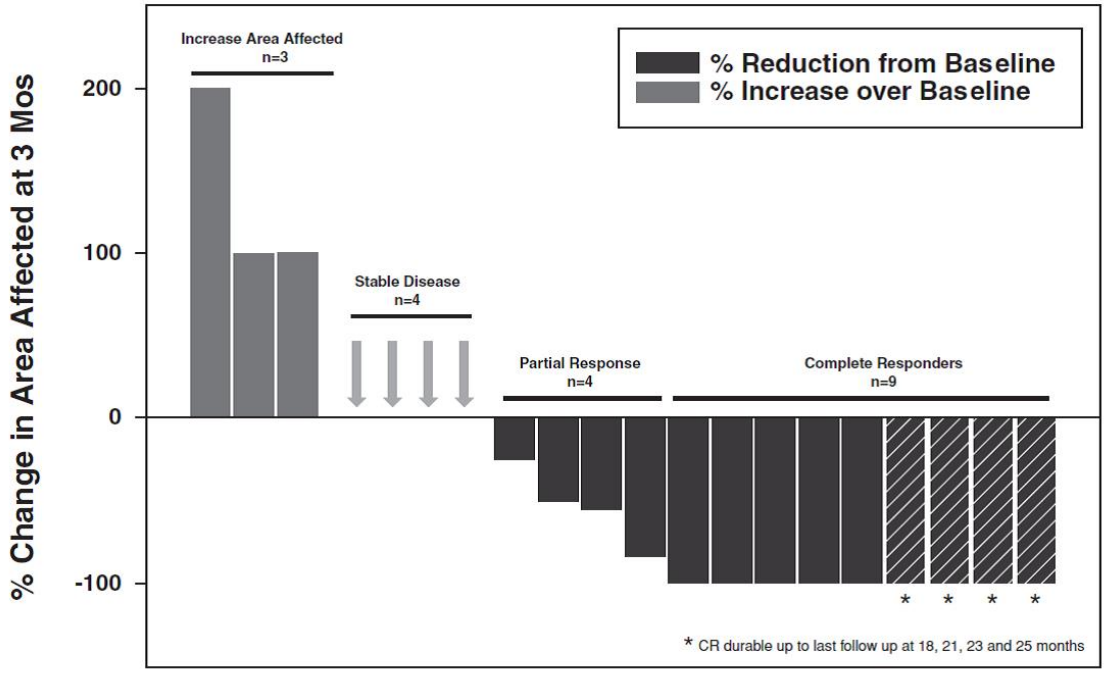
The data below shows the percentage change in surface area of cancer within the bladder, based on bladder mapping data utilizing cystoscopy in 40 patients. The following charts demonstrate the responses in this Phase 2 clinical trial in Treatment Arm A and Treatment Arm B:

Treatment Arm A



Treatment Arm A Patients (N=20)

Treatment Arm B



Treatment Arm B Patients (N=20)

This Phase 2 clinical trial was completed in September 2009.

Near the completion of this Phase 2 clinical trial in 2009, Valstar was re-launched in the United States for the treatment of BCG-refractory CIS bladder cancer in patients for whom immediate cystectomy would be associated with unacceptable morbidity or mortality. However, because physicians were not widely prescribing Valstar to their patients and it was not an approved therapy in Europe, this disrupted our originally designed clinical path of a head-to-head pivotal Phase 3 clinical trial of Vicinium against Valstar. Due to the uncertainty of the standard of care in this space, our efforts were put on hold until a clear clinical path was established. In May 2013, the FDA co-sponsored a public workshop where it evaluated potential trial designs for the development of therapies for NMIBC and specifically provided regulatory guidance supporting the idea that a single-arm clinical trial could provide sufficient evidence of benefit if the results were robust. The panel suggested it is acceptable to include high-risk papillary patients without CIS in a clinical trial with CIS patients because the clinical management and outcome if left untreated is considered to be the same. In September 2014, we conducted an end of Phase 2 meeting with the FDA and, consistent with our interactions with the FDA during this meeting, refocused our resources to commence an open-label, non-randomized Phase 3 clinical trial of Vicinium in patients with high-risk NMIBC.

Safety data. We believe that our safety data from 110 patients in our Phase 1 and Phase 2 clinical trials support further development of Vicinium for the treatment of high-risk NMIBC. There were no Grade 4 or Grade 5 serious adverse events that were considered by the clinical investigators to be related to Vicinium during the Phase 1 and Phase 2 clinical trials of Vicinium for the treatment of high-risk NMIBC. There was one Grade 5 serious adverse event, or death, which was determined by the clinical investigator to be unrelated to Vicinium. The most common reported treatment-related adverse events were an abnormally frequent passage of small amounts of urine, blood in the urine and painful urination, the majority of which were considered to be mild or moderate in severity. No patients discontinued treatment due to a Vicinium-related adverse event during the Phase 1 and Phase 2 clinical trials.

Phase 3 Clinical Trial

Based upon our September 2014 end of Phase 2 meeting with the FDA, we, through our subsidiary Viventia, commenced the Phase 3 VISTA Trial in patients with high-risk NMIBC who have received adequate BCG and whose disease is now BCG-unresponsive, and for whom the current standard of care is the surgical removal of their bladder, or a radical cystectomy, in the third quarter of 2015 in the United States and Canada. Based on safety and efficacy data observed with the longer 12-week induction in our Phase 2 clinical trial, the FDA agreed to our plan to employ more frequent dosing in our Phase 3 clinical trial, in which the primary end points are CR and DoR in patients with CIS whose disease is BCG-unresponsive. In November 2016, the FDA issued draft guidance regarding appropriate clinical trial design for new drugs and biologics for BCG-unresponsive NMIBC, including the use of single-arm studies. The FDA finalized this guidance in February 2018 and retained many of the recommendations from the 2016 draft guidance regarding clinical trial design, including the use of single-arm studies. We believe that our VISTA Trial design is consistent with these aspects of the FDA's guidance.

As part of this trial, in July 2015, we submitted a Clinical Trial Application ("CTA") to Health Canada to include Canadian sites. In September 2015, we received a No Objection Letter from Health Canada, permitting us to proceed with our Phase 3 VISTA Trial in Canada.

The primary and secondary endpoints for the VISTA Trial are as follows:

Dose	30 mg of Vicinium (in 50 mL of saline)
Estimated total enrollment	133 patients, including 93 CIS patients whose disease is BCG-unresponsive
Primary endpoints	• CRR at 3 months in patients with CIS (with or without papillary disease) whose disease is BCG-unresponsive; and • Kaplan-Meier estimate of DoR for BCG-unresponsive CIS patients who experience a CR.

Patients with CIS will be considered to have a CR if at the time of any disease status evaluation (per protocol every 13 weeks or any unscheduled evaluation) there is no evidence of high-grade disease (CIS, high-grade Ta or any grade T1 disease) or disease progression (e.g., to muscle invasive disease). Low-grade disease is not considered a treatment failure in these patients, and they may remain on study treatment following TURBT.

Secondary endpoints	• Event-free survival in all patients; • CRR at 6, 9, 12, 15, 18, 21 and 24 months in patients with CIS whose disease is BCG-unresponsive; • Time to cystectomy in all patients; • Time to disease recurrence in papillary patients; • PFS in all patients; • OS in all patients; and • Safety and tolerability of Vicinium therapy in all patients.
Exploratory endpoint	To evaluate biomarkers that may be associated with response or disease progression or treatment failure, which may include, for example, EpCAM status, tumor subtype morphology, furin levels in tumor cell endosomes, presence of a glycosaminoglycan coat and presence of receptors that could impede a host anti-tumor immune response, such as PD-L1.

The VISTA Trial completed enrollment in April 2018 with a total of 133 patients across three cohorts based on histology and time to disease recurrence after adequate BCG treatment (under 2018 FDA guidance on treatment of NMIBC, adequate BCG is defined as at least two courses of BCG with at least five doses in an initial induction course of treatment, plus at least two doses in a second course of treatment):

- Cohort 1 (n=86): Patients with CIS with or without papillary disease that recurred within six months of their last course of adequate BCG;
- Cohort 2 (n=7): Patients with CIS with or without papillary disease that was determined to be refractory or recurred after six months, but less than 11 months, after their last course of adequate BCG; and
- Cohort 3 (n=40): Patients with high-risk (Ta or T1) papillary disease without CIS that was determined to be refractory or recurred within six months of their last course of adequate BCG.

As of the May 29, 2019 data cutoff date, preliminary primary and secondary endpoint data for each of the trial cohorts were as follows:

Cohort 1 (n=86) Evaluable Population (n=82) Complete Response Rate, for CIS:

Time Point	Evaluable Patients*	Complete Response Rate (95% Confidence Interval)
3-months	n=82	39% (28%-50%)
6-months	n=82	26% (17%-36%)
9-months	n=82	20% (12%-30%)
12-months	n=82	17% (10%-27%)

**Response-evaluable population includes any mITT subject who completed the induction phase.*

Cohort 2 (n=7) Evaluable Population (n=7) Complete Response Rate, for CIS:

Time Point	Evaluable Patients*	Complete Response Rate (95% Confidence Interval)
3-months	n=7	57% (18%-90%)
6-months	n=7	57% (18%-90%)
9-months	n=7	43% (10%-82%)
12-months	n=7	14% (0%-58%)

**Response-evaluable population includes any mITT subject who completed the induction phase.*

Pooled Cohorts 1 and 2 Evaluable Population (n=89) Complete Response Rate, for CIS:

Time Point	Evaluable Patients*	Complete Response Rate (95% Confidence Interval)
3-months	n=89	40% (30%-51%)
6-months	n=89	28% (19%-39%)
9-months	n=89	21% (13%-31%)
12-months	n=89	17% (10%-26%)

**Response-evaluable population includes any mITT subject who completed the induction phase.*

Phase 3 Pooled Complete Response Rate vs. Phase 2 Pooled Complete Response Rate:

Time Point	Preliminary Phase 3 Pooled CRR (95% Confidence Interval)	Phase 2 Pooled CRR (95% Confidence Interval)
3-months	40% (30%-51%)	40% (26%-56%)
6-months	28% (19%-39%)	27% (15%-42%)
9-months	21% (13%-31%)	18% (8%-32%)
12-months	17% (10%-26%)	16% (7%-30%)

Cohort 3 (n=40) Evaluable Population (n=38) Recurrence-Free Rate†:

Time Point	Evaluable Patients*	Recurrence-Free Rate (95% Confidence Interval)
3-months	n=38	71% (54%-85%)
6-months	n=38	58% (41%-74%)
9-months	n=38	45% (29%-62%)
12-months	n=38	42% (26%-59%)

†Recurrence-free rate is defined as the percentage of patients that are recurrence-free at the given assessment time point.
**Response-evaluable population includes any mITT subject who completed the induction phase.*

Duration of Response: The median DoR for patients in Cohort 1 and Cohort 2 combined (n=93) is 287 days (95% CI, 154-NE), using the Kaplan-Meier method. Additional *ad hoc* analysis of pooled data for all patients with CIS (Cohorts 1 and 2, n=93) shows that among patients who achieved a complete response at 3 months, 52% remained disease-free for a total of 12 months or longer after starting treatment, using the Kaplan-Meier method. DoR is defined as the time from first occurrence of complete response to documentation of treatment failure or death.

We have conducted additional analyses for secondary endpoints based on the May 29, 2019 data cutoff date. These additional preliminary data include the following:

- ***Time to Cystectomy:*** Across all 133 patients treated with Vicinium in the VISTA Trial, greater than 75% of all patients are estimated to remain cystectomy-free at 2.5 years, using the Kaplan-Meier method. Additional *ad hoc* analysis shows that approximately 88% of responders are estimated to remain cystectomy-free at 3 years. Time to cystectomy is defined as the time from the date of first dose of study treatment to surgical bladder removal. The first 2018 FDA guidance on treatment of BCG-unresponsive NMIBC patients states that the goal of therapy in such patients is to avoid cystectomy. Therefore, time to cystectomy is a key secondary endpoint in the VISTA Trial.
- ***Time to Disease Recurrence:*** High-grade papillary (Ta or T1) NMIBC is associated with higher rates of progression and recurrence. The median time to disease recurrence for patients in Cohort 3 (n=40) is 402 days (95% CI, 170-NE), using the Kaplan-Meier method. Time to disease recurrence is defined as the time from the date of the first dose of study treatment to the first occurrence of treatment failure or death on or prior to treatment discontinuation.
- ***Progression-Free Survival ("PFS"):*** 90% of all 133 patients treated with Vicinium in the VISTA Trial are estimated to remain progression-free for 2 years or greater, using the Kaplan-Meier method. PFS is defined as the time from the date of first dose of study treatment to the first occurrence of disease progression (e.g. T2 or more advanced disease) or death on or prior to treatment discontinuation.
- ***Event-Free Survival:*** 29% of all 133 patients treated with Vicinium in the VISTA Trial are estimated to remain event-free at 12 months, using the Kaplan-Meier method. Event-free survival is defined as the time from the date of first dose of study treatment to the first occurrence of disease recurrence, progression or death on or prior to treatment discontinuation.
- ***Overall Survival ("OS"):*** 96% of all 133 patients treated with Vicinium in the VISTA Trial are estimated to have an overall survival of 2 years or greater, using the Kaplan-Meier method. OS is defined as the time from the date of first dose of study treatment to death from any cause.

Preliminary Safety Results

As of the May 29, 2019 data cutoff date, in patients across all cohorts (n=133) of our Phase 3 VISTA Trial of Vicinium for the treatment of high-risk NMIBC, 88% experienced at least one adverse event, with 95% of adverse events being Grade 1 or 2. The most commonly reported treatment-related adverse events were dysuria (14%), hematuria (13%) and urinary tract infection (12%) - all of which are consistent with the profile of bladder cancer patients and the use of catheterization for treatment delivery. These adverse events were determined by the clinical investigators to be manageable and reversible, and only four patients (3%) discontinued treatment due to an adverse event. Serious adverse events, regardless of treatment attribution, were reported in 14% of patients. There were four treatment-related serious adverse events reported in three patients including acute kidney injury (Grade 3), pyrexia (Grade 2), cholestatic hepatitis (Grade 4) and renal failure (Grade 5). There were no age-related increases in adverse events observed in the VISTA Trial.

Vicinium for the Treatment of SCCHN

Vicinium (formerly referred to as Proxinium in publications focused on this clinical setting), is also being developed as a treatment for patients with recurrent or metastatic EpCAM-expressing SCCHN who have received at least one prior platinum-based chemotherapy regimen with recurrent, locally advanced or metastatic EpCAM-expressing SCCHN. To treat SCCHN, Vicinium is administered via injection directly into the targeted tumor, or intratumoral injection. Vicinium for the treatment of SCCHN has received Orphan Drug Designation from the FDA and the EMA and Fast Track designation from the FDA.

In our two Phase 1 clinical trials, patients treated with Vicinium had demonstrated antitumor activity in 53% of evaluable patients with 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 CRs 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%). Combined results from two Phase 1 clinical trials encompassing 44 patients have shown complete resolution or reduction in size of injected tumors in 16 of the 30 evaluable EpCAM-positive patients (53.3%). An additional 27% of evaluable patients had stable disease and, therefore, the results indicate an overall tumor control rate of approximately 80%. Vicinium was generally well-tolerated during the clinical trials. Dose-limiting toxicity in the Phase 1 clinical trials was transaminase elevation in liver enzymes.

In our clinical trials involving Vicinium for the treatment of SCCHN, we also observed some stabilization, partial reduction and complete resolution of non-injected tumors. We believe that TFPT mediated killing of cancer cells occurs via a mechanism known as ICD, which is known to enhance the presentation of neoantigens to the immune system. We believe that this, combined with the immunogenic nature of our cytotoxic protein payload creates a heightened immune response, wherein naive cytotoxic T-cells are stimulated by antigen presenting cells, such as dendritic cells, presenting tumor cell surface antigens following the death of cancer cells. We believe that this anti-tumor response may complement checkpoint inhibitor therapies.

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. We anticipate that the Phase 1/2a clinical trial will explore the potential for Vicinium, due to its potential immunogenic effect, to enhance checkpoint inhibitors in combination therapy for the treatment of SCCHN. We will be measuring both the objective response rates and immune response biomarkers in a Phase 1/2a clinical trial. Should a trial yield encouraging results and we are able to secure additional funding, we will move into later stage trials.

During a Type C meeting with FDA in 2007, the FDA noted that approval of a companion diagnostic for EpCAM expression would need to coincide with Vicinium approval for the treatment of SCCHN. During the clinical evaluation of Vicinium for the treatment of SCCHN, we developed an immunohistochemical test to determine whether clinical trial patients are EpCAM-positive. Internal examination from head and neck cancer patients showed that our EpCAM antibody bound to 84% of all patient tumor samples we assessed. We intend to seek the FDA’s input as to whether this immunohistochemical test satisfies the FDA’s request for a companion diagnostic for EpCAM expression in this indication and whether we will need to submit this test for pre-market approval as a companion diagnostic in conjunction with Vicinium.

Overall, we believe that our efficacy and safety data support the continued clinical development of Vicinium for the treatment of SCCHN to fulfill a significant unmet medical need in patients with recurrent, locally advanced or metastatic EpCAM-expressing SCCHN.

We believe the local administration of Vicinium mediates ICD of cancer cells leading to the release of tumor-specific neoantigens and attracting/activating cells of the host immune system. Further, Vicinium contains ETA, an immunogenic cytotoxic payload. The local activation of an anti-ETA response may further heighten the local immune response. We also believe that the effect of checkpoint inhibitors may be enhanced if they are used in combination with Vicinium due to its potential immunogenic effect.

We have deferred further development 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-risk NMIBC. We are also exploring collaborations for the development of Vicinium for the treatment of SCCHN.

We own or exclusively license worldwide rights to our Vicinium for the treatment of SCCHN intellectual property portfolio that provide an unextended patent term until June 2025 and, when our pending method of treatment patent applications for Vicinium are granted, until at least 2036. See ‘‘Our Intellectual Property’’ below for additional details.

VB6-845d

Our lead systemically-administered product candidate, VB6-845d, is being developed as a treatment for multiple types of EpCAM-positive solid tumors. VB6-845d is a TFPT consisting of an EpCAM targeting Fab genetically linked to deBouganin, which is administered by intravenous infusion. EpCAM is over-expressed on the cell surface of many solid tumors, including breast, colorectal, gastric, lung, ovarian and prostate. EpCAM overexpression has been shown to be involved in promoting malignant progression. In addition, EpCAM overexpression is associated with increased tumor grade, disease progression, increased proliferative phenotypes and diminished survival. EpCAM is also a cancer stem cell marker. A Phase 1 clinical trial conducted with VB6-845, the prior version of VB6-845d, revealed no clinically relevant immune response to the deBouganin payload. Five of seven patients (71.4%) maintained stable disease (meaning no change in tumor size from baseline) after one completed cycle of treatment (four weeks). Two patients had decreases in target tumor size, and one subject who continued treatment through a third cycle (12 weeks) maintained stable disease. Interim safety data from our Phase 1 clinical trial was consistent with expectations for the study population of patients with advanced solid tumors and the anticipated effects of targeted biological therapies containing immunogenic sequences.

Based upon the hypersensitivity reactions seen in our Phase 1 clinical trial conducted in Russia and in the country of Georgia, we de-immunized the Fab portion of VB6-845 to create VB6-845d. In April 2016, we submitted an IND to the FDA in preparation of initiating a Phase 1/2 clinical trial of VB6-845d in patients with EpCAM-positive cancers in the United States. The IND was withdrawn in July 2016 after we received initial feedback from the FDA indicating that they had identified hold and non-hold deficiencies that needed to be addressed. In December 2016, we submitted a request for a pre-IND meeting to seek input on the manufacturing, nonclinical and clinical plans for VB6-845d prior to resubmitting an IND. In February 2017, the FDA provided guidance on our manufacturing and nonclinical plans for VB6-845d. Based on this guidance, we intend to perform additional studies and submit an updated IND once funding or a partner is secured for this program.

Overall, we believe that our pre-clinical data and the interim Phase 1 clinical data support further clinical investigation of VB6-845d to explore whether it may fulfill the significant unmet medical need in the treatment of patients with EpCAM-positive solid tumors. Specifically, we believe that VB6-845d has potential to be a first-in-class TFPT capable of providing clinical benefit in these difficult to treat patient populations.

We are currently developing VB6-845d, a recombinant fusion protein consisting of an anti-EpCAM fragment fused to a deBouganin payload for the systemic treatment of advanced solid tumors. DeBouganin acts by inhibiting protein synthesis and helps circumvent multi-drug resistance mechanisms. Solid tumors form an abnormal and discrete tumor mass in the body that usually does not contain cysts or liquid areas.

We believe that our TFPTs utilizing our de-immunized deBouganin payload may be enhanced if combined with checkpoint inhibitors. We believe that deBouganin's potential effect on cancer cells could promote an immunogenic response that may enhance the action of checkpoint inhibitors.

We have deferred further development of VB6-845d in order to focus our efforts and our resources on our ongoing development of Vicinium for the treatment of high-risk NMIBC. We are also exploring collaborations for VB6-845d.

We own or exclusively license worldwide rights to our VB6-845d intellectual property portfolio that provides for an unextended patent term until at least June 2025 and, when our pending method of treatment patent applications for VB6-845d are granted, until at least 2036. See ''Our Intellectual Property'' below for additional details.

EBI-031 - License Agreement with Roche

In June 2016, we entered into the License Agreement with Roche, pursuant to which we granted Roche an exclusive, worldwide license, including the right to sublicense, to the Licensed Intellectual Property. Under the License Agreement, Roche is required to continue developing, at its cost, EBI-031 and any other product made from the Licensed Intellectual Property that contains a Licensed Product and pursue ongoing patent prosecution, 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.

Financial Terms

We received from Roche an upfront license fee of $7.5 million in August 2016 upon the effectiveness of the License Agreement with Roche following approval by our stockholders, and Roche agreed to pay up to an additional $262.5 million upon the achievement of specified regulatory, development and commercial milestones with respect to up to two unrelated indications. Specifically, an aggregate amount of up to $197.5 million is payable to 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. In September 2016, Roche paid us the first development milestone of $22.5 million as a result of the IND application for EBI-031 becoming effective on or before September 15, 2016. Additional amounts of up to $65.0 million are payable upon the achievement of specified development and regulatory milestones in a second indication.

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

Buy-Out Options

The License Agreement with Roche provides for two “option periods” during which Roche may elect to make a one-time payment to us and, in turn, terminate its diligence, milestone and royalty payment obligations under the License Agreement. Specifically, (i) Roche may exercise a buy-out option following the first dosing ("Initiation") in the first Phase 2 study for a Licensed Product until the day before Initiation of the first Phase 3 study for a Licensed Product, in which case Roche is required to pay us $135.0 million within 30 days after Roche’s exercise of such buy-out option and receipt of an invoice from us, or (ii) Roche may exercise a buy-out option following the day after Initiation of the first Phase 3 study for a Licensed Product until the day before the acceptance for review by the FDA or other regulatory authority of a BLA or similar application for marketing approval for a Licensed Product in either the United States or in the E.U., in which case Roche is required to pay us, within 30 days after Roche’s exercise of such buy-out option and receipt of an invoice from us, $265.0 million, which amount would be reduced to $220.0 million if none of our patent rights containing a composition of matter claim covering any compound or Licensed Product has issued in the E.U.

Termination

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

Clinical Development

In July 2019, Roche reported that it started a multi-center, non-randomized, open-label, multiple ascending dose Phase 1 study to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of intravitreal EBI-031 monotherapy in patients with diabetic macular edema. Further, Roche reported that once determined, an extended cohort will be dosed with the optimal dose of EBI-031 while another arm of the trial will test EBI-031 in combination with Lucentis (ranibizumab) following intravitreal administration in patients with diabetic macular edema.

Our Intellectual Property

We currently own or exclusively license approximately 15 families of patents and applications, which generally relate to our TFPT-based product candidates and evolving our platform of targeting agents, cytotoxins (such as deBouganin) and linker technologies. As our product candidates evolve through clinical development, we continue to monitor advancements and bolster patent coverage with the goal of attaining durable patent protection for at least 15 years from product launch. In addition, we may prepare and file a number of additional applications around our platform technology, including our various targeting agents, cytotoxins, and linkers that, if issued, would expire in 2038 and beyond.

Product Candidate - Vicinium

We exclusively license two families (77 patents and 1 application) under a License Agreement with the University of Zurich ("Zurich") (the "License Agreement with Zurich") which, among other things, include composition of matter claims directed to EpCAM antibody chimeras, EpCAM antibody chimera-cytotoxin conjugates, and their potential use in treating bladder and head and neck cancer. These families claim all or portions of Vicinium, as well as certain of their respective indications under clinical development. The first family includes composition of matter claims directed to the EpCAM antibody chimeras that are used in Vicinium. The first family consists of 23 patents in the United States, Canada, Europe and Japan, which expire in 2020 to 2021, subject to any applicable patent term adjustment or extension that may be available on a jurisdictional basis. The second family includes claims directed to the use of Vicinium in the treatment of bladder and head and neck cancer, respectively, and consists of 54 issued patents in the United States, Europe, Canada, China, Israel and Japan and pending applications in the United States. The expiry dates of the patents in this family are April 2024 and June 2025, subject to any applicable patent term adjustment or extension that may be available on a jurisdictional basis.

In addition to the Zurich portfolio, we own one issued U.S. patent with composition of matter claims directed to modified nucleic acid sequences that encode Vicinium and are potentially useful for high expression yield of Vicinium. The expiry date of this patent is in February 2029, subject to any applicable patent term extension that may be available on a jurisdictional basis. In

addition, we have two allowed United States patent applications relating to the methods of treatment using Vicinium that will expire in 2036. See "Our Vicinium License Agreements" below for additional information.

Additionally, we have a License Agreement with Micromet AG ("Micromet") (the "License Agreement with Micromet"), now part of Amgen, Inc., which grants us non-exclusive rights, with certain sublicense rights, for know-how and patents allowing exploitation of certain single chain antibody products. These patents cover some key aspects of Vicinium. See "Our Vicinium License Agreements" below for additional information.

We also have a License Agreement with XOMA Ireland Limited ("XOMA") (the "License Agreement with XOMA") which grants us non-exclusive rights to certain XOMA patent rights and know-how related to certain expression technology, including plasmids, expression strains, plasmid maps and production systems. These patents and related know-how cover some key aspects of Vicinium. See "Our Vicinium License Agreements" below for additional information.

EBI-031 and our Legacy Product Candidates

We own the following families of patents and patent applications related to EBI-031 and our legacy product candidates. As of February 29, 2020, our patent portfolio includes the following patents and applications related to our legacy product candidates:

- a provisional application directed to compositions and methods for increasing the retention of therapeutic agents in the eye which, if converted and granted, is expected to expire in 2038.
- a provisional application directed to compositions and methods for increasing the retention of anti-VEGF therapeutic agents in the eye which, if converted and granted, is expected to expire in 2038; and
- a provisional application directed to compositions and methods for increasing the retention of RGD therapeutic agents in the eye which, if converted and granted, is expected to expire in 2038.

To the best of our knowledge based on correspondence received on March 2, 2020, the following families are owned by us, and licensed to Roche pursuant to the License Agreement dated June 10, 2016:

- patents covering the IL-6 antagonistic anti-IL6 monoclonal antibodies and active fragments thereof, including IL-6 antibody EBI-029, filed in the United States, Australia, China, Japan, New Zealand, Russia and South Africa, that expire in November 2033;
- patent applications covering the IL-6 antagonistic anti-IL6 monoclonal antibodies and active fragments thereof, including IL-6 antibody EBI-029, filed in the Brazil, Canada, Europe, India, Korea, Mexico and Singapore, and, if granted, are expected to expire in 2033;
- patents covering IL-6 antagonistic anti-IL6 monoclonal antibodies and active fragments thereof, including the IL-6 antibody EBI-031, in Austria, Belgium, Bulgaria, Columbia, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Indonesia, Ireland, Italy, Japan, Lithuania, Morocco, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovenia, Slovakia, South Africa, Spain, Sweden, Switzerland, Turkey and United Kingdom, that expire in November 2035;
- patent applications covering IL-6 antagonistic anti-IL6 monoclonal antibodies and active fragments thereof, including the IL-6 antibody EBI-031, having applications pending or to be filed in Algeria, Australia, Bahrain, Brazil, Canada, Chile, China, Costa Rica, Egypt, Hong Kong, India, Israel, Korea, Malaysia, Mexico, New Zealand, Oman, Peru, Philippines, Qatar, Saudi Arabia, Singapore, Thailand, Ukraine, United Arab Emirates, United States and Vietnam, and, if granted, are expected to expire in 2035; and
- a PCT Application and applications in Argentina, Australia, Brazil, Canada, China, Europe, Hong Kong, Korea, Israel, Mexico and Japan, each corresponding to a United States provisional application covering the IL-6 antibody EBI-031 formulation, which, if granted, are expected to expire in 2036.

Our Vicinium License Agreements

License Agreement with Zurich

Overview and Exclusivity

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

Under the terms of the License Agreement with Zurich, we may be obligated to pay $0.75 million in milestone payments for the first product candidate that achieves applicable clinical development milestones. Based on current clinical status, we anticipate that these milestones may be triggered by Vicinium’s clinical development pathway. As part of the consideration, we

will also be obligated to pay up to a 4% royalty on the net product sales for products covered by or manufactured using a method covered by a valid claim in the Zurich patent rights. Royalties owed to Zurich will be reduced if the total royalty rate owed by us to Zurich and any other third party is 10% or greater, provided that the royalty rate to Zurich may not be less than 2% of net sales. The obligation to pay royalties in a particular country expires upon the expiration or termination of the last of the Zurich patent rights that covers the manufacture, use or sale of a product. There is no obligation to pay royalties in a country if there is no valid claim that covers the product or a method of manufacturing the product. Through December 31, 2019, aggregate license fees of $0.3 million have been paid to Zurich since the inception of the license agreement. There were no payments made for the year ended December 31, 2019.

Patent Rights

We are responsible for the patent filing, prosecution and maintenance activities pertaining to the patent rights, at our sole expense, while Zurich is afforded reasonable opportunities to review and comment on such activities. If appropriate, we shall apply for an extension of the term of any licensed patent where available, for example, in at least the United States, Europe and Japan. In the event of any substantial infringement of the patent rights, we may request Zurich to take action to enforce the licensed patents against third parties. If the infringing activity is not abated within 90 days and Zurich has elected not to take legal action, we may bring suit in our own name (and in Zurich's name, if necessary). Such action will be at our own expense and Zurich will have the opportunity to join at its own expense. Recoveries from any action shall generally belong to the party bringing the suit, but (a) in the event that we bring the action and an acceptable settlement or monetary damages are awarded, then Zurich will be reimbursed for any amount that would have been due to Zurich if the products sold by the infringer actually had been sold by us, or (b) in the event a joint legal action is brought, then the parties shall share the expense and recoveries shall be shared in proportion to the share of expense paid by the respective party. Each party is required to cooperate with the other in litigation proceedings at the expense of the party bringing the action.

Term and Termination

The term of the License Agreement with Zurich expires as of the expiration date of the last patent to expire within the Zurich patent rights. We are currently projecting an expiration date for the United States licensed patents in June 2025, subject to any applicable patent term extension that may be available on a jurisdictional basis. Zurich has the right to terminate the License Agreement if we breach any obligation of the agreement and fail to cure such breach within the applicable cure periods. We have the right to terminate the License Agreement at any time and for any reason by giving 90 days written notice to Zurich.

License Agreement with Micromet

Overview

We have a License Agreement with Micromet, now part of Amgen, Inc., which grants us nonexclusive rights, with certain sublicense rights, for know-how and patents allowing exploitation of certain single chain antibody products. These patents cover some key aspects of Vicinium. Under the terms of the License Agreement with Micromet, an initial license fee of €0.45 million was paid to Micromet by Viventia prior to our acquisition of Viventia, and we may be obligated to pay up to €3.6 million in milestone payments for the first product candidate that achieves applicable clinical development milestones. Based on current clinical status, we anticipate that certain of these milestones may be triggered by Vicinium's clinical development pathway. We are also required to pay up to a 3.5% royalty on the net sales for products covered by the agreement, which includes Vicinium. The royalty rate owed to Micromet in a particular country will be reduced to 1.5% if there are no valid claims covering the product in that country. The obligation to pay royalties in a particular country expires upon the later of the expiration date of the last valid claim covering the product and the tenth anniversary of the first commercial sale of the product in such country. Finally, we are required to pay to Micromet an annual license maintenance fee of €50,000, which can be credited towards any royalty payment we owe to Micromet. Through December 31, 2019, aggregate license fees of €1.8 million have been paid to Micromet since the inception of the license agreement. We paid €50,000 in annual license maintenance fees during each of the years ended December 31, 2019, 2018 and 2017.

Patent Rights

Micromet, at its sole expense, is responsible for the patent filing, prosecution and maintenance activities pertaining to the patent rights. In any patent enforcement action initiated by Micromet, we may be required, upon the request of Micromet and at Micromet's expense, to provide reasonable assistance to Micromet with respect to such enforcement action.

Term and Termination

The term of the License Agreement with Micromet expires as of the expiration of any royalty obligations under the License Agreement. Either party has the right to terminate the License Agreement if the other party fails to comply with any of its material obligations under the License Agreement and fails to cure such non-compliance within the applicable cure periods.

License Agreement with XOMA

Overview

We have a License Agreement with XOMA which grants us non-exclusive rights to certain XOMA patent rights and know-how related to certain expression technology, including plasmids, expression strains, plasmid maps and production systems. These patents and related know-how cover some key aspects of Vicinium. Under the terms of the License Agreement with XOMA, an initial access fee of $0.25 million was paid to XOMA by Viventia prior to our acquisition of Viventia, and we are required to pay up to $0.25 million in milestone payments for a product candidate that incorporates know-how under the license and achieves applicable clinical development milestones. Based on current clinical status, we anticipate that these milestones may be triggered by Vicinium's clinical development pathway. We are also required to pay a 2.5% royalty on the net sales for products incorporating XOMA's technology, which includes Vicinium. We have the right to reduce the amount of royalties owed to XOMA on a country-by-country basis by the amount of royalties paid to other third parties, provided that the royalty rate to XOMA may not be less than 1.75% of net sales. In addition, the foregoing royalty rates are reduced by 50% with respect to products that are not covered by a valid patent claim in the country of sale. The obligation to pay royalties in a particular country expires upon the later of the expiration date of the last valid claim covering the product and the tenth anniversary of the first commercial sale of the product in such country. Through December 31, 2019, aggregate license fees of $0.4 million have been paid to XOMA since the inception of the license agreement. There were no payments made for the year ended December 31, 2019.

Patent Rights

XOMA, at its sole expense, is responsible for the patent filing, prosecution and maintenance activities pertaining to the patent rights. In any patent enforcement action initiated by XOMA, we may be required, upon the request of XOMA and at XOMA's expense, to provide reasonable assistance to XOMA with respect to such enforcement action.

Term and Termination

The term of the License Agreement with XOMA expires as of the expiration of any royalty obligations under the License Agreement. Either party has the right to terminate the License Agreement if the other party fails to comply with any of its material obligations under the License Agreement and fails to cure such non-compliance within the applicable cure periods.

Our Manufacturing

We lease a 31,100 square foot manufacturing, laboratory, warehouse and office facility in Winnipeg, Manitoba. We have three 15-liter fermenters, one 30-liter fermenter, one 150-liter fermenter, one 500-liter fermenter and one 1,500-liter fermenter. Our classified fermentation suite and post-production processing capabilities were dedicated to producing our pre-clinical study and clinical trial batches of Vicinium. In September 2017, we completed the manufacturing of all Vicinium necessary for our ongoing Phase 3 VISTA Trial and for our CRADA with the NCI. In conjunction with this achievement, we ended our manufacturing activities in Winnipeg and have redirected our resources toward completing the technology transfer process necessary to outsource commercial scale drug supply manufacturing in the event we obtain approval from the FDA to market Vicinium for the treatment of high-risk NMIBC.

In October 2018, we entered into the Fujifilm MSA for the manufacturing process and technology transfer of Vicinium drug substance production. In April 2019, the first full, commercial-scale cGMP run was completed at Fujifilm. Full quality release testing has been completed and all Phase 3 release specifications were met, supporting Fujifilm's ability to produce the bulk drug substance form of Vicinium for commercial purposes if we receive regulatory approval to market Vicinium for the treatment of high-risk NMIBC.

Our Commercial Operations

We do not currently have an organization structured for the sales, marketing and distribution of products. We may rely on licensing and co-promotion agreements with strategic collaborators for the commercialization of our products in the United States and other territories. We intend to build a North American specialty urology sales force to market Vicinium for the treatment of high-risk NMIBC in the United States and Canada, which we expect will be supported by sales management, internal sales support, an internal marketing group and distribution support. To develop the appropriate commercial infrastructure internally, we would have to invest financial and management resources, some of which would have to be deployed prior to the approval of any of our product candidates.

Our Competition

The pharmaceutical industry is highly competitive, subject to rapid and significant technological change and has a strong emphasis on developing proprietary products. While we believe that our next generation TFPT platform, knowledge, experience and scientific resources provide us with competitive advantages, we face competition from both large and small pharmaceutical and biotechnology companies, academic institutions and other research organizations; specifically with companies, institutions and organizations that are actively researching and developing products that attach proprietary cell-killing payloads to antibodies for targeted delivery to cancer cells. Our competitors include, but are not limited to:

- NMIBC: Merck & Co., Inc. (Keytruda/pembrolizumab and BCG) (approved drugs), Endo Pharmaceuticals Inc. (Valstar/valrubicin) (approved drug), FerGene Inc. (Adstiladrin/nadofaragene firadenovec (rAd-IFN/Syn3)), Medical Enterprises Ltd. (Synergo RITE plus mitomycin C), Aadi, LLC (ABI-009), ImmunityBio (N-803 in combination with BCG), Cold Genesys, Inc. (CG0070), Theralase Technologies Inc. (TLD-1433 photodynamic compound), Bristol-Myers Squibb (Opdivo/nivolumab with or without BCG or BMS-986205), AstraZeneca (Imfinzi/durvalumab with or without BCG or External Beam Radiotherapy), Eli Lilly and Company (Gemcitabine) and Telormedix SA (Vesimune);
- SCCHN: Bristol-Myers Squibb Company (Opdivo/nivolumab) (approved drug), Eli Lilly and Company, and Merck (Erbitux, pembrolizumab) (approved drugs);
- Multiple types of solid tumors: Amgen Inc. (Panitumumab) (approved drug), Bayer AG and Onyx Pharmaceuticals (Sorafenib) (approved drug), Bristol-Myers Squibb Company, Eli Lilly and Company, and Merck (Erbitux) (approved drug), F. Hoffmann-La Roche AG (Bevacizumab) (approved drug), Genentech, Inc. (Bevacizumab, Erlotinib and Trastuzumab) (approved drugs), Pfizer, Inc. (Sunitinib) and Trion Research GmbH (Removab); and
- In addition to competition from alternative treatments, we may also face competition from products that are biosimilar to, and possibly interchangeable with, our product candidates. Biosimilar products are expected to become available over the coming years. Even if our product candidates achieve marketing approval, they may be priced at a significant premium over competitive biosimilar products if any have been approved by then and insurers or other third-party payors may encourage or even require the use of lower priced biosimilar products. Even if our treatments receive market authorization, they may not be listed on the formularies of payors (public or private insurers) or reimbursed. This may impact the uptake of the drug as a treatment option for patients and/or the price at which the drug can be sold at. Further, if the drug is reimbursed it may be at a narrower indication than the full scope of market authorization.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical studies, conducting clinical trials, obtaining regulatory approval and marketing than we do. These competitors are also active in seeking patent protection and licensing arrangements in anticipation of collecting royalties for use of technology that they have developed. Moreover, specialized biologics, biopharmaceutical and biotechnology companies may prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity could be substantially limited in the event that our competitors develop and commercialize products that are more effective, safer, less toxic, more convenient or cheaper than our comparable products. In geographies that are critical to our commercial success, competitors may also obtain regulatory approvals before us, resulting in our competitors building a strong market position in advance of our product's entry. We believe the factors determining the success of our programs will be the drug design, effectiveness against multi-drug resistance mechanisms, efficacy, safety, price and convenience of our product candidates.

Government Regulation

As a clinical-stage biologics company, we are subject to extensive regulation by the FDA, Health Canada and other national, supranational, state, provincial and local regulatory agencies. We are also subject to extensive regulation by similar governmental authorities in other countries in which we operate. In the United States, the Federal Food, Drug, and Cosmetic Act ("FDCA") and the Public Health Service Act ("PHSA") and their implementing regulations set forth, among other things, requirements for the research, testing, development, manufacture, quality control, safety, effectiveness, approval, post-approval monitoring and reporting, labeling, storage, record keeping, distribution, import, export, advertising and promotion of our product candidates. Although the discussion below focuses on regulation in the United States, we anticipate seeking approval to market our products in other countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope to that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in the E.U. are addressed in a centralized way through the European Commission following the opinion of the EMA, but country-specific regulation in the individual European Union Member States ("E.U. Member States") remains essential in many respects. The process of obtaining regulatory marketing approvals and the subsequent compliance with appropriate supranational, federal, state, provincial, local and foreign statutes and regulations require the expenditure of substantial time and financial resources, and we may not be successful in any given jurisdiction.

U.S. Government Regulation

In the United States, drug products are regulated by the FDA under the FDCA and other laws, including, in the case of biologics, the PHSA. Drug products are also subject to other federal, state and local statutes and regulations. A failure to comply with any applicable requirements during the product development, approval, or post-approval periods may lead to administrative or judicial sanctions, including, among other things, the imposition by the FDA or an institutional review board ("IRB") of a hold on clinical trials, refusal to approve pending marketing applications or supplements, withdrawal of approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, or administrative, civil and/or criminal investigation, penalties or prosecution.

In the United States, all of our product candidates are regulated by the FDA as biologics. Biologics require the submission of a BLA and approval by the FDA prior to being marketed in the United States. Manufacturers of biologics may also be subject to state and local regulation.

The steps required before a biologic may be marketed in the United States generally include:

- completion of pre-clinical studies, animal studies and formulation studies, some in compliance with the FDA's current Good Laboratory Practices ("cGLP") regulations, and the Animal Welfare Act administered and enforced by the United States Department of Agriculture;
- submission to the FDA of an IND to support human clinical testing, which must become effective before human clinical trials may commence;
- approval by an IRB before each trial may be initiated at each clinical site;
- performance of adequate and well-controlled clinical trials under protocols submitted to the FDA and reviewed and approved by each IRB, conducted in accordance with federal regulations and current Good Clinical Practices ("cGCP") to establish the safety, purity and potency of the biologic for each targeted indication;
- submission of a BLA to the FDA;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the biologic is produced to assess compliance with current Good Manufacturing Practices ("cGMP") and to assure that the facilities, methods and controls are adequate; and
- FDA review and approval of the BLA.

Pre-clinical Studies

Pre-clinical studies include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product candidate. The conduct of the pre-clinical studies must comply with federal regulations and requirements, including, as applicable, cGLP and the Animal Welfare Act. The results of the pre-clinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. The FDA evaluates the IND to determine whether there is an adequate basis for starting the product candidate in initial clinical trials, and the IND must become effective before human clinical trials may be commenced. Additional pre-clinical studies may continue after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If during this 30-day period the FDA does not raise any concerns or issues that must be addressed prior to the commencement of clinical trials or does not impose a clinical hold, the IND becomes effective 30 days following the FDA's receipt of the IND and the clinical trial proposed in the IND may begin.

Clinical Trials

Clinical trials involve the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators. Clinical trials are subject to extensive regulation and must be conducted in compliance with (i) federal regulations, (ii) cGCP standards, which set safeguards to protect the rights and health of patients and establish standards for conducting, recording data from, and reporting results of clinical trials, and (iii) protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if any. Foreign studies conducted under an IND generally must meet the same requirements that apply to studies being conducted in the United States. The informed written consent of each study patient must be obtained before the patient may begin participation in the clinical trial. The study protocol, study plan, and informed consent forms for each clinical trial must be reviewed and approved by an IRB for each clinical site, and the study must be conducted under the auspices of an IRB for each trial site. Investigators and IRBs must also comply with FDA regulations and guidelines, including those regarding oversight of study patient informed consent, complying with the study protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting of adverse events.

The clinical trial program for a product candidate is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The three phases are as follows:

- *Phase 1.* Phase 1 involves the initial introduction of a product candidate into humans. Phase 1 clinical trials are typically conducted in healthy human subjects, but in some situations are conducted in patients with the target disease

or condition. These clinical trials are generally designed to evaluate the safety, metabolism, pharmacokinetic ("PK") properties and pharmacologic actions of the product candidate in humans, the side effects associated with increasing doses and, if possible, to gain early evidence of effectiveness. During Phase 1 clinical trials, sufficient information about the product candidate's PK properties and pharmacological effects may be obtained to inform and support the design of Phase 2 clinical trials. The total number of participants included in Phase 1 clinical trials varies, but is generally in the range of 20 to 80;

- *Phase 2.* Phase 2 includes the controlled clinical trials conducted to obtain initial evidence of effectiveness of the product candidate for a particular indication(s) in patients with the target disease or condition, to determine dosage tolerance and optimal dosage, and to gather additional information on possible adverse side effects and safety risks associated with the product candidate. Phase 2 clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population, usually involving no more than several hundred participants; and
- *Phase 3.* Phase 3 clinical trials are clinical trials conducted in an expanded patient population at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the product candidate has been obtained and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the product candidate and to provide an adequate basis for regulatory approval. Phase 3 clinical trials usually involve several hundred to several thousand participants. In most cases, the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the product candidate, although a single Phase 3 clinical trial with other confirmatory evidence may be sufficient in certain instances.

The decision to suspend or terminate development of a product candidate may be made by either a health authority body, such as the FDA, by an IRB, or by a company for various reasons and during any phase of clinical trials. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. In some cases, clinical trials are overseen by a data safety monitoring board ("DSMB"), which is an independent group of qualified experts organized by the trial sponsor to evaluate at designated points in time whether or not a trial may move forward and/or should be modified. These decisions are based on unblinded access to data from the ongoing trial and generally involve determinations regarding the benefit-risk ratio for study patients and the scientific integrity and validity of the clinical trial.

In addition, there are requirements for the registration of certain clinical trials of product candidates on public registries, such as www.clinicaltrials.gov, and the submission of certain information pertaining to these trials, including clinical trial results, after trial completion.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, a sponsor submits extensive information about the product candidate to the FDA in the form of a BLA to request marketing approval for the product candidate in specified indications.

Biologics License Applications

In order to obtain approval to market a biologic in the United States, a marketing application must be submitted to the FDA that provides data establishing the safety and effectiveness of the product candidate for the proposed indication. The application includes all relevant data available from pertinent pre-clinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a product candidate, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the product candidate to the satisfaction of the FDA. For example, in November 2016, the FDA issued a draft guidance document on developing new drugs and biologics for treating BCG-unresponsive NMIBC, and finalized this guidance in February 2018. Our BLA for Vicinium for the treatment of high-risk NMIBC may have to meet the expectations set forth in this guidance document to obtain approval.

Under the Prescription Drug User Fee Act ("PDUFA"), as amended, the fees payable to the FDA for reviewing an original BLA, as well as annual program fees for approved products, can be substantial, subject to certain limited deferrals, waivers and reductions that may be available. The FDA has 60 days from receipt of a BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may refuse to accept for filing any BLA that it deems incomplete or not properly reviewable at the time of submission, in which case the BLA will have to be updated and resubmitted. The FDA's PDUFA review goal is to review 90% of priority BLA applications within six months of filing and 90% of standard applications within 10 months of filing, but the FDA can and frequently does extend this review timeline to consider certain later-submitted information or information intended to clarify or supplement information provided in the initial submission. The FDA may not complete its review or approve a BLA within these established goal review times. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure, and potent for its intended use, and whether the product is being manufactured in compliance with cGMP. The FDA may also refer

applications for novel product candidates which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will inspect the facilities at which the product candidate is manufactured or the facilities that are significantly involved in the product development and distribution process, and will not approve the product candidate unless cGMP compliance is satisfactory. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCP. Under the Pediatric Research Equity Act, certain BLAs must include an assessment, generally based on clinical trial data, of the safety and effectiveness of the biological product in relevant pediatric populations. The FDA may waive or defer the requirement for a pediatric assessment, either at a company's request or by its own initiative, including waivers for certain products not likely to be used in a substantial number of pediatric patients. Products with orphan drug designation are exempt from these requirements for orphan-designated indications with no formal waiver process required.

After the FDA evaluates the BLA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA may issue an approval letter. The FDA's PDUFA review goal is to review such resubmissions within two or six months of receipt, depending on the type of information included. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval and deny approval of a resubmitted BLA. FDA approval of any application may include many delays or never be granted. An approval letter authorizes commercial marketing of the product candidate with specific prescribing information for specific indications. As a condition of BLA approval, the FDA may require a risk evaluation and mitigation strategy ("REMS") to help ensure that the benefits of the product outweigh the potential risks. REMS can include Medication Guides, communication plans for healthcare professionals, and also may include elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the biologic. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the biologic's safety, purity, or potency, which can be costly.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new BLA or a supplemental BLA before the change can be implemented. A supplemental BLA for a new indication typically requires clinical data similar to that in the original application, and the FDA generally uses the same procedures and actions in reviewing a supplemental BLA as it does in reviewing a new BLA.

Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if safety or manufacturing problems occur following initial marketing. For example, quality control and manufacturing procedures must conform, on an ongoing basis, to cGMP requirements, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to spend time, money and effort to maintain cGMP compliance. In addition, new or modified government requirements, including from new legislation, may be established that could delay or prevent regulatory approval of our product candidates under development or affect our ability to maintain product approvals we have obtained.

Biosimilars and Market Exclusivity

Under the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), the FDA can approve products that are biosimilar to (but not generic copies of) innovative biologics on the basis of less extensive data than is required by a full BLA. To be biosimilar, a biological product must be highly similar to the reference product and can have no clinically meaningful differences in safety, purity and potency from the reference product. An interchangeable biosimilar product must meet additional standards for interchangeability and, if approved, may be substituted for the reference product. At this juncture, it is unclear whether any product deemed ‘‘interchangeable’’ by the FDA, in fact, will be readily substituted by pharmacies, which are governed by state pharmacy law.

After an innovator has marketed its product for four years, a manufacturer may file an application for approval of a ‘‘biosimilar’’ version of the innovator product. However, although an application for approval of a biosimilar may be filed four years after approval of the innovator product, qualified innovative biological products receive 12 years of regulatory exclusivity, meaning that the FDA may not approve a biosimilar version until 12 years after the innovative biological product was first approved by the FDA under the PHSA. The BPCIA also provides a mechanism for innovators to enforce the patents that protect innovative biological products and for biosimilar applicants to challenge the patents. Such patent litigation may begin as early as four years after the innovative biological product is first approved by the FDA. Although the patents for the reference biologic may be challenged by the biosimilar applicant during that time period pursuant to the BPCIA statutory patent challenge framework, no

biosimilar or interchangeable product will be licensed by the FDA until the end of the exclusivity period. The first biologic product candidate submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against any other determinations of interchangeability to the reference product for the lesser of (i) one year after first commercial marketing of the interchangeable biosimilar product, (ii) 18 months after approval of the interchangeable biosimilar product if there is no legal challenge, (iii) 18 months after the resolution in the interchangeable biosimilar product applicant's favor of a lawsuit challenging the reference product's patents, and (iv) 42 months after approval of the interchangeable biosimilar product if a lawsuit is ongoing within the 42-month period.

The objectives of the BPCIA are conceptually similar to those of the Hatch-Waxman Act, which established abbreviated pathways for the approval of generic drugs. The FDA has published several guidance documents providing direction on developing and obtaining approval of biosimilar product candidates. The guidance documents to date explain, among other things, that the FDA will approve a biosimilar product if there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency. A determination of biosimilarity may be based upon: (1) analytical studies showing that the biological product is highly similar to, with no clinically meaningful differences from, the reference product, (2) animal studies, including toxicity assessments, and/or (3) a clinical trial or trials (including assessment of immunogenicity and PKs) that are sufficient to demonstrate safety, purity and potency. The FDA recommends that sponsors use a stepwise approach to developing the data and information needed to support biosimilarity. At each step, the sponsor should evaluate the extent of residual uncertainty of biosimilarity that remains and incorporate the FDA's advice for additional studies to address remaining uncertainty. To meet the higher standard for interchangeability the sponsor must demonstrate, in addition to biosimilarity, that the proposed biological product can be expected to produce the same clinical result and, if administered more than once to any given patient, the safety risk and potential for diminished efficacy associated with switching between the proposed biological product and the reference product is not greater than continuing to use the reference product. A biological product that is determined to be interchangeable may be substituted for the reference product without the intervention of the prescribing healthcare provider. In March 2015, the FDA approved the first biosimilar product under the BPCIA, and it has approved other biosimilar products since then. If any of our product candidates is approved by the FDA, the approval of a biosimilar to one of our products could have a material impact on our business. In particular, a biosimilar could be significantly less costly to bring to market and priced significantly lower than our products, if approved by the FDA.

The ‘‘Purple Book,’’ first published by the FDA in September 2014, lists biological products, including any biosimilar and interchangeable biological products licensed by the FDA under the PHSA. The lists include the date a biological product was licensed under Section 351(a) of the PHSA and whether the FDA evaluated the biological product for reference product exclusivity under Section 351(k)(7) of the PHSA. The Purple Book will also enable a user to see whether a biological product licensed under Section 351(k) of the PHSA has been determined by the FDA to be biosimilar to or interchangeable with a reference biological product (an already-licensed FDA biological product). Biosimilar and interchangeable biological products licensed under Section 351(k) of the PHSA will be listed under the reference product to which biosimilarity or interchangeability was demonstrated.

Advertising and Promotion

The FDA and other federal regulatory agencies closely regulate the marketing and promotion of biologics through standards and regulations for, among other things, direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the internet. A biologic cannot be promoted before it is approved. After approval, promotion of a biologic can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA.

Healthcare providers are permitted, however, to prescribe products for unapproved uses (also known as ‘‘off-label’’ uses) – that is, uses not approved by the FDA and therefore not described in the product's labeling – because the FDA does not regulate the practice of medicine. However, FDA restricts manufacturers' communications regarding unapproved uses. Broadly speaking, a manufacturer may not promote a product for an unapproved use, but may engage in non-promotional, balanced communication regarding unapproved uses under specified conditions. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the United States Department of Justice ("DOJ"), or the Office of Inspector General of the United States Department of Health and Human Services ("HHS"), as well as state authorities. Such enforcement action could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes products.

Post-approval Regulation

After regulatory approval of a product is obtained, a company is required to comply with a number of post-approval requirements. For example, as a condition of BLA approval, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. Regulatory approval of oncology products often requires that patients in clinical trials be followed for long periods to determine the overall survival benefit of the product. In addition, as a holder of an approved BLA, a company would be required to report adverse

reactions and production problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling for any of its products.

The manufacturing of our product candidates is required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. Our product candidates were manufactured at our production plant in Winnipeg, Manitoba, Canada. In September 2017, we completed the manufacturing of all Vicinium necessary for our ongoing Phase 3 VISTA Trial and for our CRADA with the NCI. In conjunction with this achievement, we ended our manufacturing activities in Winnipeg and have redirected our resources toward completing the technology transfer process necessary to outsource commercial scale drug supply manufacturing in the event we obtain approval from the FDA to market Vicinium for the treatment of high-risk NMIBC. In October 2018, we entered into the Fujifilm MSA for the manufacturing process and technology transfer of Vicinium drug substance production. In April 2019, the first full, commercial-scale cGMP run was completed at Fujifilm. Full quality release testing has been completed and all Phase 3 release specifications were met, supporting Fujifilm's ability to produce the bulk drug substance form of Vicinium for commercial purposes if we receive regulatory approval to market Vicinium for the treatment of high-risk NMIBC. In February 2020, the manufacturing of an additional commercial-scale cGMP lot (pre-PPQ) was completed and quality release testing is currently ongoing. Quality control and manufacturing procedures must continue to conform to cGMP after approval to assure and preserve the long-term stability of the biological product. Biologic manufacturers and other entities involved in the manufacture and distribution of approved biologics are also required to register their establishments and list any products they make with the FDA and to comply with related requirements in certain states. The FDA and certain state agencies periodically inspect manufacturing facilities to assess compliance with cGMP and other laws.

Discovery of problems with a product after approval may result in serious and extensive restrictions on a product or the manufacturer or holder of an approved BLA, as well as lead to potential market disruptions. These restrictions may include suspension of product manufacturing until the FDA is assured that quality standards can be met, continuing oversight of manufacturing by the FDA under a ''consent decree,'' which frequently includes the imposition of costs and continuing inspections over a period of many years, as well as possible withdrawal of the product from the market. Other potential consequences include interruption of production, issuance of warning letters or other enforcement letters, refusal to approve pending BLAs or supplements to approved BLAs, product seizure or detention, and injunctions or imposition of civil and/or criminal penalties.

In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation, correction, and reporting of any deviations from cGMP and impose reporting and documentation requirements upon a company and any third-party manufacturers that a company may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures, such as additional post-market clinical trials to assess new safety risks or distribution-related or other restrictions under a REMS.

Patent Term Extension

Depending upon the timing, duration and specifics of the FDA approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension. The provisions of the Hatch-Waxman Act permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The United States Patent and Trademark Office ("USPTO"), in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

Many other countries also provide for patent term extensions or similar extensions of patent protection for biologic products. For example, in Japan, it may be possible to extend the patent term for up to five years and in Europe, it may be possible to obtain a supplementary patent certificate that would effectively extend patent protection for up to five years.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act ("FCPA") prohibits any United States individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting

provisions requiring such companies to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Canadian Government Regulation

In Canada, Health Canada is responsible for the regulation of pharmaceuticals under the authority of the Food and Drugs Act and the Food and Drug Regulations. Any compound that fits under the definition of ‘‘drug’’ as defined in the Food and Drugs Act must undergo a series of trials (for example, Phase 1, 2 and 3, similar to the United States) to demonstrate it is both safe and effective before it can be marketed in Canada. Approval is based on a risk-benefit assessment, in which the therapeutic benefits are weighed against the risks associated with taking the drug.

All clinical drug trials taking place in Canada are regulated through the Food and Drug Regulations, which is supplemented by the Good Clinical Practice: Consolidated Guidelines. A failure to comply with any requirements during product development, approval, or post-approval periods may lead to administrative or judicial sanctions. These sanctions could include fines, suspension or cancellation of regulatory approvals, closure of a clinical trial, product recalls, seizure of products, operating restrictions, injunctions, criminal penalties, and criminal prosecution. Our product candidates are biologics and therefore come under the purview of the Biologics and Genetic Therapies Directorate of Health Canada. To receive approval from Health Canada, biologics, like all drugs, must be shown to be safe and effective. In addition, biologics must be shown to be of suitable quality in terms of both chemistry and manufacturing. This latter requirement increases the regulatory burden, requiring additional submissions and mandatory inspections with respect to the method of manufacture, similar to that in the United States. Health Canada also has rules relating to the approval of subsequent entry biologics in Canada, following the expiry of an innovator biologic’s data exclusivity and/or patent protection.

The Canadian drug approval process requires submission and approval of a CTA as well as approval by a Research Ethics Board before each phase of human clinical trials is commenced. Canadian clinical trial development is similar to the clinical trial phases of the United States.

Exclusivity

Under the Food and Drug Regulations there are data exclusivity provisions for ‘‘innovative drugs’’ that have not been previously approved in a drug by the relevant Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, or polymorph. The term of data exclusivity is presently eight years from the date of first market approval which can be extended to an additional six months for pediatric indications if an innovator includes, in its new drug submission, or any supplement to that new drug submission filed within the first five years of the eight-year data protection period, results of clinical trials which were designed and conducted with the purpose of increasing knowledge about the use of the drug in pediatric populations and which will lead to a health benefit for children.

Also, provided certain requirements are met, the newly implemented Certificate of Supplementary Protection regime in Canada (intended to partly compensate for time spent in research and obtaining marketing authorization) can provide for up to two years of additional protection from the expiry of a patent, for drugs containing a new medicinal ingredient, or a combination thereof, protected by an eligible patent.

In addition, Canada, similar to the United States, has patent/regulatory linkage provisions. The Patented Medicines (Notice of Compliance) Regulations enable a patent with claims to the medicinal ingredient, formulation, dosage form or use to be listed on the Patent Register. A second person who files a drug submission that directly or indirectly compares itself to a drug wherein there is a patent on the Patent Register will not obtain market authorization for their product until the patent term has expired, it is determined that they will not be infringing the patent, the patent is held invalid or the inclusion of the patent on the Patent Register is found to have been made through certain false statements. Although a stay pending the outcomes of any associated proceedings (up to two years) may be obtained, it can be costly, and success is not guaranteed. If a company is not successful in any such proceeding, they may be liable for damages and also may result in a competitor’s product receiving market authorization.

Advertising, Promotion and Compliance

Advertising and promotion of health products, particular prescription drugs/biologics is regulated primarily by Health Canada pursuant to the Food and Drugs Act and Regulations, by standards set by the Pharmaceutical Advertising Advisory Board, Advertising Standards Canada and industry associations, such as Innovative Medicines Canada, the national association representing Canadians who work for Canadian research-based pharmaceutical companies, and their Code of Ethical Practices. In addition, Canada has the Competition Act and the Corruption of Foreign Public Officials Act. All of these define how drugs can be advertised and what are or are not permitted activities and interactions with public officials, healthcare professionals, the public and other stakeholders. For example, in Canada direct to consumer advertising of prescription drugs is generally prohibited. Failure to comply can result in sanctions, fines, suspension or cancellation of regulatory approvals, closure of a clinical trial, product recalls, seizure of products, operating restrictions, injunctions, criminal penalties, and criminal prosecution.

European Union and other International Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our product candidates. Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of a product in those countries. Some countries outside of the United States have a similar process that requires the submission of a CTA much like the IND prior to the commencement of human clinical trials. In the E.U., for example, a CTA must be submitted to the competent authorities of the E.U. Member States where the clinical trial is conducted and to an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

Marketing Authorization Application for Biologic Medicinal Products

To obtain regulatory approval to commercialize a new drug under E.U. regulatory systems, we must submit a marketing authorization application.

In the E.U., a marketing authorization for a medicinal product can be obtained through a centralized, mutual recognition, decentralized procedure, or national procedure (single country). The centralized procedure is mandatory for certain medicinal products, including orphan medicinal products and certain biologic products and optional for certain other products, including medicinal products that are a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public or animal health.

In accordance with the centralized procedure, the applicant can submit a single application for marketing authorization to the EMA which will provide a positive opinion regarding the application if it meets certain quality, safety, and efficacy requirements. Based on the opinion of the EMA, the European Commission takes a final decision to grant a centralised marketing authorization which permits the marketing of a product in all 27 E.U. Member States and three of the four European Free Trade Association States - Iceland, Liechtenstein and Norway. Under the centralized procedure in the E.U., the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the EMA Committee for Medicinal Products for Human Use ("CHMP")).

For other countries outside of the E.U., such as the United Kingdom and countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Internationally, clinical trials are generally required to be conducted in accordance with cGCPs, applicable regulatory requirements of each jurisdiction and the medical ethics principles that have their origin in the Declaration of Helsinki. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Advertising, Promotion and Compliance

In the E.U., the advertising and promotion of our products will also be subject to E.U. laws and E.U. Member States' national laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. Other E.U. Member State national legislation may also apply to the advertising and promotion of medicinal products. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics ("SmPC"), as approved by the competent authorities. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. The SmPC forms an intrinsic and integral part of the marketing authorization granted for the medicinal product. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion and is prohibited in the E.U. The applicable laws at the E.U. level and in the individual E.U. Member States also prohibit the direct-to-consumer advertising of prescription-only medicinal products. Violations of the rules governing the promotion of medicinal products in the E.U. could be penalized by administrative measures, fines and imprisonment.

During all phases of development (pre- and post-marketing), failure to comply with applicable regulatory requirements may result in administrative or judicial sanctions. These penalties could include the imposition of a clinical hold on trials, refusal to approve pending applications, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, product detention or refusal to permit the import or export of products, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

Orphan Drug Designation

The FDA may grant Orphan Drug Designation to biologics intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States or a disease or condition that affects more than 200,000 individuals in the United States but there is no reasonable expectation that the cost of developing and making the biologic would be recovered from sales in the United States.

In the United States, Orphan Drug Designation entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax credits for certain research and user fee waivers under certain circumstances. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to seven years of market exclusivity, which means the FDA may not approve any other application for a biologic for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. The FDA can revoke a product's orphan drug exclusivity under certain circumstances, including when the product sponsor is unable to assure the availability of sufficient quantities of the product to meet patient needs. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same biologic for a different disease or condition.

In the E.U., medicinal products: (a) that are used to diagnose, treat or prevent life-threatening or chronically debilitating conditions that affect no more than five in 10,000 people in the E.U.; or (b) that are used to treat or prevent life-threatening, seriously debilitating or serious and chronic conditions and that, for economic reasons, would be unlikely to be developed without incentives; and (c) where no satisfactory method of diagnosis, prevention or treatment of the condition concerned exists, or, if such a method exists, the medicinal product would be of significant benefit to those affected by the condition, may be granted an orphan designation in the E.U. The application for orphan designation must be submitted to the EMA and approved by the European Commission before an application is made for marketing authorization for the product. Once designated, Orphan medicinal product designation also entitles a party to financial incentives such as reduction of fees or fee waivers. Moreover, ten years of market exclusivity is granted following biologic approval, if the product continues to be designated as an orphan medicinal product upon grant of the marketing authorization. During this ten-year period, with a limited number of exceptions, neither the competent authorities of the E.U. Member States, the EMA, or the European Commission are permitted to accept applications or grant marketing authorization for other similar medicinal products with the same therapeutic indication. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the ten-year period with the consent of the marketing authorization holder for the original orphan medicinal product or if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if this latter product is demonstrated to be safer, more effective or otherwise clinically superior to the original orphan medicinal product. This period of market exclusivity may be reduced to six years, at the end of the fifth year, if the orphan designation criteria are no longer met, including where it can be demonstrated on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity.

There is currently no orphan drug designation in Canada.

Orphan drug designation must be requested before submission of an application for marketing approval or marketing authorization. Orphan drug designation does not convey any advantage in, or shorten the duration of the regulatory review and approval process.

Vicinium for the treatment of SCCHN has received Orphan Drug Designation from the FDA and the EMA.

Expedited Programs in the United States and Other Jurisdictions

In the United States, a product may be granted Fast Track designation if it is intended for the treatment of a serious or life-threatening condition and demonstrates the potential to address unmet medical needs for such condition. With Fast Track designation, the sponsor may be eligible for more frequent opportunities to obtain the FDA's feedback, and the FDA may initiate review of sections of a BLA before the application is complete. This Rolling Review is available if the applicant provides and the FDA approves a schedule for the remaining information. Even if a product receives Fast Track designation, the designation can be rescinded and provides no assurance that a product will be reviewed or approved more expeditiously than would otherwise have been the case, or that the product will be approved at all.

FDA may designate a product candidate as a breakthrough therapy if it finds that the product candidate is intended, alone or in combination with one or more other product candidates or approved products, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For product candidates designated as breakthrough therapies, more frequent interaction and communication between the FDA and the sponsor can help to identify the most efficient path for clinical development. Product candidates designated as breakthrough therapies by the FDA may also be eligible for priority review. We may apply for breakthrough therapy designation for some of our product candidates. However, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and, in any event, does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidates no longer meet the conditions for designation.

Accelerated approval under FDA regulations allows a product designed to treat a serious or life-threatening disease or condition that provides a meaningful therapeutic advantage over available therapies to be approved on the basis of either an intermediate clinical endpoint or a surrogate endpoint that is reasonably likely to predict clinical benefit. Approvals of this kind typically include requirements for confirmatory clinical trials to be conducted with due diligence to validate the surrogate endpoint or otherwise confirm clinical benefit and for all promotional materials to be submitted to the FDA for review prior to dissemination.

The FDA may grant priority review designation to a product candidate, which sets the target date for FDA action on the application at six months from FDA filing, or eight months from the sponsor's submission. Priority review may be granted where a product is intended to treat a serious or life-threatening disease or condition and, if approved, has the potential to provide a safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in safety or efficacy compared to available therapy. If criteria are not met for priority review, the standard FDA review period is ten months from FDA filing or 12 months from sponsor submission. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

In Canada, Health Canada has a Priority Review Process, allowing for shortened review targets of eligible drug submissions. Eligibility for Priority Review is similar to that of the United States. The drug submission must be for a serious, life-threatening or severely debilitating disease or condition for which there is substantial evidence of clinical effectiveness that the drug provides (a) effective treatment, prevention or diagnosis of a disease or condition for which no drug is presently marketed in Canada or (b) a significant increase in efficacy and/or significant decrease in risk such that the overall benefit/risk profile is improved over existing therapies, preventatives or diagnostic agents for a disease or condition that is not adequately managed by a drug marketed in Canada. Priority Review does not change the quality, safety, or efficacy requirements of the submission; it just shortens Health Canada's target review timeline from 300 days down to 180 days.

Under the Centralized Procedure in the E.U., the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding ‘‘clock stops,’’ when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Accelerated evaluation might be granted by CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, which should be justified and assessed on a case-by-case basis. In this circumstance, EMA ensures that the opinion of CHMP is given within 150 days.

Vicinium has received Fast Track designation from the FDA for the treatment of SCCHN and NMIBC.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any collaborators, to profitably sell any products for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "Medicare Modernization Act") established the Medicare Part D program and generally authorized prescription drug plan sponsors to impose limits on the number of covered drugs under their plans in a therapeutic class. The Medicare Modernization Act, including its cost reduction initiatives, could decrease the coverage and reimbursement rate that we may receive for any of our product candidates, if approved. The Centers for Medicare & Medicaid Services ("CMS"), the agency that administers the Medicare program, also may revise reimbursement and implement coverage restrictions. Cost reduction initiatives and changes in coverage could decrease utilization of and reimbursement for any approved products, which would then affect the price we can receive. Private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement from federal legislation or regulation may lead to similar reductions in private payor reimbursement.

In addition, in March 2010, President Obama signed one of the most significant healthcare reform measures in decades. The Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA") substantially changed the way healthcare is financed by both governmental and private insurers and significantly impacts the pharmaceutical industry. The ACA has impacted existing government healthcare programs and has resulted in the development of new programs. For example, the ACA provides for Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Among the ACA's provisions of importance to the pharmaceutical industry are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription products and biological products;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program ("MDRP") to 23.1% for innovator drugs and 13% for non-innovator drugs of the average manufacturer price ("AMP");

- a new methodology by which AMP is calculated and reported by manufacturers for products that are inhaled, infused, instilled, implanted or injected and not generally dispensed through retail community pharmacies;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new partial prescription drug benefit for Medicare recipients ("Medicare Part D") coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand products to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient products to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service's 340B drug pricing program;
- new requirements to report to CMS annually specifying financial arrangements with physicians and teaching hospitals, as defined in the ACA and its implementing regulations, including reporting any ''payments or other transfers of value'' made or distributed to prescribers, teaching hospitals, and other healthcare providers and reporting any ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations during the preceding calendar year;
- a new requirement to annually report product samples that manufacturers and distributors provide to physicians;
- a mandatory non-deductible payment for employers with 50 or more full-time employees (or equivalents) who fail to provide certain minimum health insurance coverage for such employees and their dependents;
- establishment of the Center for Medicare and Medicaid Innovation within CMS to test innovative payments and service delivery models; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012, which, among other things, led to aggregate reductions in Medicare payments for all items and services, including prescription drugs and biologics, to service providers of, on average, 2% per fiscal year beginning April 1, 2013 and, due to subsequent legislation, will continue until 2029. The American Taxpayer Relief Act of 2012 also, among other things, reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additional legislative changes, FDA or CMS regulation, or guidance could be adopted, which may impact the marketing approvals and reimbursement for our product candidates. For example, there have been several Congressional inquiries and proposed bills and regulatory initiatives designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. In November 2015, the United States House of Representatives formed an Affordable Drug Pricing Task Force to advance legislation intended to control pharmaceutical drug costs and investigate pharmaceutical drug pricing, and the United States Senate has requested information from certain pharmaceutical companies in connection with an investigation into pharmaceutical drug pricing practices.

Certain provisions of the ACA have been subject to judicial and Congressional challenges, as well as efforts to repeal or replace them or to alter their interpretation or implementation. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017 eliminated the tax-based shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, as amended (the "Code"), commonly referred to as the "individual mandate," effective January 1, 2019. Further, the Bipartisan Budget Act of 2018 among other things, amended the Medicare statute, effective January 1, 2019, to reduce the coverage gap in most Medicare drug plans, commonly known as the "donut hole," by raising the manufacturer discount under the Medicare Part D coverage gap discount program to 70%. Additional legislative changes, regulatory changes and judicial challenges related to the ACA remain possible. It is unclear how the ACA and its implementation, as well as efforts to repeal or replace, or invalidate, the ACA, or portions thereof, will affect our business. It is possible that the ACA, as currently enacted or may be amended in the future, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, and new payment methodologies and in additional downward pressure on coverage and payment and the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we obtain regulatory approval. In the United States and in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a biologic may be separate from the process for setting the price or reimbursement rate that the payor will pay for the biologic. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the products approved by the FDA, Health Canada or comparable foreign regulatory authorities for a particular indication or if a product is included it may not be listed on the formulary for all the indications or it may be listed on a narrower basis than what is approved by the FDA, Health Canada or comparable foreign regulatory authorities. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA, Health Canada or other comparable foreign regulatory authorities' approvals. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

In 2003, the United States Congress enacted legislation providing Medicare Part D, which became effective at the beginning of 2006. Government payment for some of the costs of prescription drugs may increase demand for any products for which we receive marketing approval. However, to obtain payments under this program, we would be required to sell products to Medicare recipients through prescription drug plans operating pursuant to this legislation. These plans will likely negotiate discounted prices for our products. Federal, state and local governments in the United States continue to consider legislation to limit the growth of healthcare costs, including the cost of prescription drugs. Future legislation could limit payments for pharmaceuticals such as the product candidates that we are developing.

Different pricing and reimbursement schemes exist in other countries. In Canada, the Patented Medicines Prices Review Board evaluates and controls excessive pricing of patented products. Further, there are national, provincial and territorial formularies funded by government healthcare systems, in addition to formularies for private payors (private insurers) and hospitals or hospital groups. Listing on the formularies and price depend on evidence and submissions regarding the cost-benefit of the drug and comparison of the cost-effectiveness of a particular product candidate to currently available therapies and is often subject to negotiations.

In the E.U., once a marketing authorization is granted for a medicinal product the applicant is required to engage in pricing and reimbursement discussions and negotiate with a separate pricing authority in each of the E.U. Member States. The E.U. Member States governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed upon. To obtain reimbursement or pricing approval, some of the E.U. Member States may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other E.U. Member States allow companies to fix their own prices for medicinal products but monitor and control company profits. The downward pressure on healthcare costs in general, particularly pharmaceuticals, has become more intense. As a result, increasingly high barriers are being erected to the entry of new products. Furthermore, many E.U. Member States and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere. The E.U. Member States have discretion to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. We may face competition for our products, if approved, from lower priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

Health Technology Assessment ("HTA") of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some E.U. Member States. These E.U. Member States include France, Germany, Ireland, Italy and Sweden. The HTA process in European Economic Area ("EEA") countries is governed by the national laws of these countries. HTA is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual medicinal products as well as their potential implications for the healthcare system. Those elements of medicinal products are compared with other treatment options available on the market.

The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual E.U. Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product vary between E.U. Member States.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on managed care in the United States has increased and will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time.

Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

American Society of Clinical Oncology ("ASCO") Value Assessment for Cancer Treatments

On May 31, 2016, ASCO published a framework to assess the value of cancer treatment options. The framework was developed in response to concern that new, expensive cancer treatments may not be supported by adequate medical evidence. The purpose of the framework is to provide a standardized quantification of cancer treatments and assist oncologists and patients in deciding between new cancer treatments and the standard of care. The framework takes into account a medication's (i) efficacy, (ii) safety and (iii) cost, to derive an overall treatment value.

While we believe that the safety and efficacy profiles of our product candidates are potentially better than that of the standard of care and, if approved, we intend to price our products competitively, we do not know how the data will be assessed by ASCO. It is also unknown whether use of this application could adversely affect the assessment of any of our product candidates. If this framework were adopted and utilized by payors and physicians, and if Vicinium for the treatment of high-risk NMIBC were to receive low ratings, this could adversely affect the price and reimbursement of Vicinium, if approved, reduce prescriptions and harm our business.

Other Healthcare Laws and Compliance Requirements

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

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting some business arrangements from prosecution, the exemptions and safe harbors are drawn narrowly and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from federal Anti-Kickback Statute liability. Liability may be established under the federal Anti-Kickback Statute without proving actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below).

The federal civil False Claims Act prohibits, among other things, any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds; knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government; or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. The False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the statute and to share in any monetary recovery. Pharmaceutical and other healthcare companies have faced enforcement actions under the federal civil False Claims Act for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product and for allegedly causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses. In addition, a claim can be deemed to be false due to failure to comply with legal or regulatory requirements material to the government's payment decision. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble

damages and significant mandatory penalties per false claim or statement. Pharmaceutical and other healthcare companies also are subject to other federal false claims laws, including, among others, federal criminal healthcare fraud and false statement statutes.

The fraud provisions of the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), among other things, impose criminal and civil liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

The federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives.

Many states have adopted analogous laws and regulations, including state anti-kickback and false claims laws, which may apply to items or services reimbursed under Medicaid and other state programs or, in several states, regardless of the payor. Several states have enacted legislation requiring pharmaceutical companies to, among other things, establish marketing compliance programs; file periodic reports with the state, including reports on gifts and payments to individual health care providers; make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities; and/or register their sales representatives. Some states prohibit pharmacies and other healthcare entities from providing specified physician prescribing data to pharmaceutical companies for use in sales and marketing. Some states prohibit other specified sales and marketing practices, including the provision of gifts, meals, or other items to certain health care providers, and/or offering co-pay support to patients for certain prescription drugs. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws. In addition, in order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in some states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state.

In addition, we may be subject to data privacy and security laws and regulations by both the federal government and the states in which we conduct our business. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. Numerous federal and state laws and regulations, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, including the California Consumer Privacy Act, govern the collection, use, disclosure, and protection of health-related and other personal information. Failure to comply with such laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant civil or criminal penalties), private litigation and/or adverse publicity that could negatively affect our business. HIPAA, and its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. HIPAA also includes several tiers of civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gives state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. We may obtain health information from third parties, such as research institutions, that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA other than with respect to providing certain employee benefits, we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Other jurisdictions, including Canada, have corresponding laws and regulations governing the handling of personal information and third-party communications that may be more or less stringent than those of the United States. In Canada, such laws include the Personal Information Protection and Electronic Documents Act, similar provincial legislation regarding privacy and personal health information and anti-spam legislation, wherein the failure to comply or breaches can result in notification requirements or corrective action, including civil and criminal fines and sanctions.

In the United States, our activities are potentially subject to additional regulation by various federal, state and local authorities in addition to the FDA, including CMS, other divisions of HHS (for example, the Office of Inspector General), the DOJ and individual United States Attorney offices within the DOJ, and state and local governments.

If we participate in the MDRP, we will have certain price reporting obligations to the MDRP, and we may have obligations to report average sales price ("ASP") figures to the Medicare program. Under the MDRP, we would be required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and

Medicare Part B. Those rebates would be based on pricing data reported by us on a monthly and quarterly basis to CMS. These data would include AMP and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the United States in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions.

Federal law also requires that a company that participates in the MDRP report ASP information each quarter to CMS for certain categories of drugs that are paid under Part B of the Medicare program. Manufacturers calculate ASP based on a statutorily defined formula and interpretations of the statute by CMS. CMS uses these submissions to determine payment rates for drugs under Medicare Part B and the resulting Medicare payment rate.

Federal law requires that any company that participates in the MDRP also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. The Health Resources and Services Administration ("HRSA"), which administers the 340B drug pricing program, issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. HRSA also has implemented a ceiling price reporting requirement, pursuant to which manufacturers must report the 340B ceiling prices for their covered outpatient drugs to HRSA on a quarterly basis.

In addition, in order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, a manufacturer also must participate in the Department of Veterans Affairs Federal Supply Schedule ("FSS") pricing program, established by Section 603 of the Veterans Health Care Act of 1992. Under this program, the manufacturer is obligated to make its "covered drugs" (biologics or innovator drugs) available for procurement on an FSS contract and charge a price to four federal agencies - Department of Veterans Affairs, Department of Defense, Public Health Service and Coast Guard - that is no higher than the statutory federal ceiling price. The requirements under the 340B and FSS programs could reduce the revenue we may generate from any products that are commercialized in the future and could adversely affect our business and operating results.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by manufacturers, governmental or regulatory agencies, and the courts. The Medicaid rebate amount for each covered outpatient drug is computed each quarter based on the manufacturer's submission to CMS of its current AMP and, in the case of innovator products, best price figures, for the quarter. If we participate in the MDRP and become aware that our reporting for a prior quarter was incorrect, or has changed, we will be obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due. Such restatements and recalculations would increase our costs for complying with the laws and regulations governing the MDRP. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the ceiling price at which we would be required to offer our products to certain covered entities, such as safety-net providers, under the 340B drug pricing program, and we may be obligated to issue refunds to covered entities.

If we participate in the MDRP or our products are covered under Medicare Part B, we will be liable for errors associated with our submission of pricing data. We cannot assure you that our submissions, if we participate in these programs, will not be found by CMS to be incomplete or incorrect. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted false AMP, ASP or best price information to the government, we may be liable for civil monetary penalties per item of false information. If we are found to have made a misrepresentation in the reporting of our ASP, the Medicare statute provides for civil monetary penalties for each misrepresentation for each day in which the misrepresentation was applied. Civil monetary penalties also can be applied if we are found to have intentionally charged 340B covered entities more than the statutorily mandated ceiling price. Our failure to submit monthly/quarterly AMP, ASP and best price data on a timely basis could result in a civil monetary penalty per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we would participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs that we are able to successfully commercialize.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including (depending on the applicable law) criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private "*qui tam*" actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign

laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and more extensive reporting of payments or transfers of value to healthcare professionals.

In the E.U., interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct in the individual E.U. Member States. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of the E.U. Member States and by the United Kingdom's Bribery Act 2010.

The national laws of certain E.U. Member States require payments made to physicians to be publicly disclosed. Moreover, the European Federation of Pharmaceutical Industries and Associations ("EFPIA") Code on disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organizations imposes a general obligation on members of EFPIA or related national industry bodies to disclose transfers of value to healthcare professionals. In addition, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her competent professional organization, and/or the competent authorities of the individual E.U. Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the individual E.U. Member States.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, warning letters or untitled letters, injunctions, civil, administrative, or criminal penalties, monetary fines or imprisonment, suspension or withdrawal of regulatory approvals, suspension of ongoing clinical studies, refusal to approve pending applications or supplements to applications filed by us, suspension or the imposition of restrictions on operations, product recalls, the refusal to permit the import or export of our products or the seizure or detention of products.

Environmental and Safety laws

We are subject to a variety of federal, provincial and local regulations relating to the use, handling, storage and disposal of hazardous materials, including chemicals and radioactive and biological materials. Our operations involve such hazardous materials and produce such hazardous waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by federal, provincial and local regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. Radioactive materials in Canada come under federal jurisdiction. Canada's Nuclear Safety and Control Act 1997 c.9 contains a general prohibition against any activity, including possession of radioactive material, except in accordance with the terms and conditions set out in a federal license issued by the Canadian Nuclear Safety Commission. The Nuclear Substances and Radiation Devices Regulation does however, exempt licensing requirements for small quantities of radioactive substances that either meet concentrations set out in a schedule to the Regulation or, for radioactive substances not set out in the schedule, that meet certain regulatory criteria. Our operations do not currently require a federal license issued by the Canadian Nuclear Safety Commission. Our operations in Canada may be subject to license approvals, notification requirements and investigation and enforcement for air and water and waste matters.

Corporate History and Acquisition of Viventia

We were incorporated under the laws of the State of Delaware in 2008. We were formerly known as Denovo Therapeutics, Inc. and Newco LS14, Inc. before changing our name to Eleven Biotherapeutics, Inc. in February 2010 and again to Sesen Bio, Inc. in May 2018.

In September 2016, we entered into a Share Purchase Agreement with Viventia, the shareholders of Viventia named therein (collectively, the "Selling Shareholders") and, solely in its capacity as seller representative, Clairmark, an affiliate of Leslie L. Dan, one of our former directors, pursuant to which we agreed to and simultaneously completed the acquisition of all of the outstanding capital stock of Viventia from the Selling Shareholders (the "Viventia Acquisition"). In connection with the closing of the Viventia Acquisition, we issued 4.0 million shares of our common stock to the Selling Shareholders according to their pro rata share of Viventia's then-outstanding shares of common stock, which represented approximately 19.9% of our voting power as of immediately prior to the issuance of such shares of common stock.

In connection with the Viventia Acquisition, we are obligated to pay to the Selling Shareholders certain post-closing contingent cash payments upon the achievement of specified milestones and based upon net sales, in each case subject to the terms and conditions set forth in the acquisition agreement, including: (i) a one-time milestone payment of $12.5 million payable upon the first sale of Vicinium (referred to herein as the "Purchased Product"), in the United States; (ii) a one-time milestone payment of $7.0 million payable upon the first sale of the Purchased Product in any one of certain specified European countries; (iii) a one-time milestone payment of $3.0 million payable upon the first sale of the Purchased Product in Japan; and (iv) and quarterly earn-out payments equal to two percent (2%) of net sales of the Purchased Product during specified earn-out periods. Such earn-out payments are payable with respect to net sales in a country beginning on the date of the first sale in such country and ending on

the earlier of (i) December 31, 2033 and (ii) fifteen years after the date of such sale, subject to early termination in certain circumstances if a biosimilar product is on the market in the applicable country.

Under the Share Purchase Agreement, we, our affiliates, licensees and subcontractors are required to use commercially reasonable efforts, for the first seven years following the closing of the Viventia Acquisition, to achieve marketing authorizations throughout the world and, during the applicable earn-out period, to commercialize the Purchased Product in the United States, France, Germany, Italy, Spain, United Kingdom, Japan, China and Canada.

Employees

As of December 31, 2019, we had 25 full-time employees and no part-time employees, ten hold Ph.D. degrees and one is a veterinary doctor. This number consists of eight employees engaged in administration, five employees engaged in clinical and regulatory activities, five employees engaged in research and development, five employees engaged in operations (three in manufacturing and two in facility/engineering) and two employees engaged in quality and support. Two of our employees are located in our corporate headquarters in Boston, twelve of our employees are located in our Winnipeg facility, and eleven of our employees are located in our Philadelphia office. We have no collective bargaining agreements with our employees and none are represented by labor unions. We have not experienced any work stoppages. We believe our relationship with our employees is satisfactory.

Corporate Information and Access to SEC Reports

Our principal executive offices are located at 245 First Street, Suite 1800, Cambridge, Massachusetts 02142, our telephone number is (617) 444-8550 and our website address is www.sesenbio.com. We make our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports, available free of charge in the “Investors” section of our website as soon as reasonably practicable after we file these reports with the SEC. We routinely post these reports, recent news and announcements, financial results and other important information about our business on our website at www.sesenbio.com. Information contained on our website is not a part of this Annual Report on Form 10-K.

In addition, the United States Securities and Exchange Commission ("SEC") maintains an Internet website at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

Item 1A. Risk Factors.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.

We are a specialty pharmaceutical company with a limited operating history. Over the past few years, we have focused primarily on developing our lead product candidate, Vicinium for the treatment of high-risk NMIBC. Since our inception, we have received no revenues from sales of our products, have incurred significant operating losses and expect to continue to incur operating losses for the foreseeable future as we continue our ongoing Phase 3 VISTA Trial of Vicinium for the treatment of high-risk NMIBC and seek marketing approval from the FDA. We had a net losses of $107.5 million, $33.7 million and $29.0 million for the years ended December 31, 2019, 2018 and 2017, respectively. We incurred negative cash flows from operating activities of $37.5 million, $22.8 million and $17.8 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, we had cash and cash equivalents of $48.1 million, net working capital (current assets less current liabilities) of $45.9 million and an accumulated deficit of $293.5 million. We have financed our operations to date primarily through private placements of our common stock, preferred stock, common stock warrants and convertible bridge notes, venture debt borrowings, our initial public offering ("IPO"), our follow-on public offerings, sales effected in "at-the-market" ("ATM") offerings, our License Agreement with Roche and, to a lesser extent, from a collaboration. The majority of our revenue to date has been from milestone payments received under our License Agreement with Roche and collaboration revenue. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year.

We expect to incur losses for the foreseeable future, and we expect these losses to increase as we:

- seek marketing approval for Vicinium for the treatment of high-risk NMIBC in the United States, including a meeting with the FDA's ODAC;
- establish a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize Vicinium for the treatment of high-risk NMIBC, if approved;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed drugs;
- continue our clinical development activities for Vicinium for the treatment of high-risk NMIBC, including a post-marketing confirmatory trial;
- seek and conduct combination trials of one or more of our product candidates;
- seek to discover and develop additional product candidates;
- in-license or acquire the rights to other products, product candidates or technologies;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- maintain, expand and protect our intellectual property portfolio;
- add equipment and physical infrastructure to support our research and development;
- complete the technology transfer of Vicinium bulk drug substance manufacturing to Fujifilm;
- hire additional clinical, quality control, scientific and management personnel, including personnel to support our commercialization efforts; and
- expand our operational, financial and management systems and personnel.

Because of the numerous risks and uncertainties associated with drug development and commercialization, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those expected or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase.

With the exception of specified regulatory, development and commercial milestones under our License Agreement with Roche, we currently have no source of product revenue and may never become profitable.

Our ability to become and remain profitable depends on our ability to generate revenue. Although we may be entitled to certain licensing fees related to specific regulatory, development and commercial milestones for EBI-031 under our License Agreement with Roche, we have not commercialized any of our product candidates. We do not expect to generate significant revenue from the development of our product candidates unless and until we obtain marketing approval for, and commercialize, Vicinium for the treatment of high-risk NMIBC. Our ability to generate revenue from Vicinium for the treatment of high-risk NMIBC, if approved, will depend on a number of factors, including:

- our ability to obtain regulatory approval for, and successfully commercialize, Vicinium for the treatment of high-risk NMIBC;
- our ability to complete and submit our BLA for Vicinium to the FDA and obtain regulatory approval for indications for which there is a commercial market;

- our ability to complete and submit applications to, and obtaining regulatory approval from, foreign regulatory authorities, including Health Canada and the European Commission;
- the size of the markets in the territories for which we gain regulatory approval;
- our ability to find a suitable contract sales organization ("CSO") to help us market and promote Vicinium, if approved;
- our ability to develop a commercial organization capable of sales, marketing and distribution for Vicinium, if approved;
- our ability to enter into and maintain commercially reasonable agreements with wholesalers, distributors and other third parties in our supply chain;
- our success in establishing a commercially viable price for Vicinium, if approved;
- our success in defending against potential competition and other developments in our market generally;
- our ability to manufacture commercial quantities of Vicinium at acceptable cost levels;
- our ability to obtain coverage and adequate reimbursement from third-party payors, including government payors; and
- our ability to successfully complete development activities, including the necessary clinical trials, for Vicinium for the treatment of high-risk NMIBC.

Even if Vicinium for the treatment of high-risk NMIBC is approved for commercial sale, Vicinium may not gain market acceptance or achieve commercial success. If our addressable market is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect or the treatment population is narrowed by competition, physician choice or clinical practice guidelines, we may not generate significant revenue from sales of Vicinium. In addition, we would anticipate incurring significant costs associated with commercializing Vicinium, if approved. We may not achieve profitability soon after generating product sales from Vicinium, if ever. If we are unable to generate product revenues from Vicinium, we will not become profitable and may be unable to continue operations without continued funding.

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

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

We are devoting substantial financial resources to our ongoing and planned activities including functions associated with operating as a public company. We expect to continue to spend substantial amounts to commercialize Vicinium for the treatment of high-risk NMIBC, if approved. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

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

- the success of our commercialization of Vicinium for the treatment of high-risk NMIBC, if approved;
- the outcome, timing and cost of the regulatory approval process for Vicinium for the treatment of high-risk NMIBC by the FDA, including the potential for the FDA to require that we perform more studies and clinical trials than those we currently expect;
- the costs and timing of the implementation of commercial-scale manufacturing activities;
- our ability to establish commercial arrangements on favorable terms, if at all, particularly manufacturing, marketing and distribution arrangements for Vicinium for the treatment of high-risk NMIBC;
- the costs and timing associated with our manufacturing process and technology transfer to Fujifilm;
- 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 effect of competing technological and market developments; and
- the extent to which we in-license or acquire other products, product candidates or technologies.

We cannot be certain that additional funding will be available when needed on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts, when required or on acceptable terms, we also could be required to:

- seek strategic collaborations to assist in the commercialization of Vicinium for the treatment of high-risk NMIBC in the United States and other markets;
- relinquish or license on unfavorable terms our rights to Vicinium for the treatment of high-risk NMIBC or our other product candidates that we otherwise would seek to develop and commercialize ourselves;

- delay, limit, reduce or terminate the drug development of our product candidates, or seek collaborators for one or more of our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or
- significantly curtail our operations.

Based on our current operating plan, we believe that our cash and cash equivalents of $48.1 million as of December 31, 2019 will be sufficient to fund our operations into 2021; however, we have based this estimate on assumptions that may prove to be wrong, and our capital resources may be utilized faster than we currently expect.

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

Our report from our independent registered public accounting firm for the year ended December 31, 2019 includes an explanatory paragraph stating that our recurring losses from operations and insufficient cash resources raise substantial doubt about our ability to continue as a going concern. If we are unable to obtain adequate financing or engage in another strategic transaction on acceptable terms and when needed, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. While we believe that our cash and cash equivalents of $48.1 million at December 31, 2019 will be sufficient to fund our operations into 2021, given our planned expenditures for the next several years, we and our independent registered public accounting firm have concluded that there is still a substantial doubt regarding our ability to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or a part of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms, or at all.

Future sales and issuances of shares of our common stock or rights to purchase shares of our common stock, including common stock purchase warrants and stock options, could result in additional dilution of the percentage ownership of our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or other third-party funding, collaborations, strategic alliances, licensing arrangements, other commercial arrangements and marketing and distribution arrangements. We do not have any committed external source of funds other than the amounts payable under the License Agreement with Roche. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights as holders of our common stock. For example, as of December 31, 2019, and subject to adjustment upon certain corporate events, including stock dividends, stock splits and distributions of cash, up to 22,894,704 shares of our common stock could be issuable by us, with a weighted-average exercise price of $1.43 per share, in connection with the exercise of our outstanding warrants to purchase our common stock.

We have also adopted the 2014 Stock Incentive Plan ("2014 Plan") to enable us and our subsidiaries to recruit and retain highly qualified employees, directors and consultants, provide those individuals with an incentive for productivity, and provide those individuals with an opportunity to share in our growth and value. As of December 31, 2019, we had an aggregate of 6,236,384 stock options outstanding under the 2014 Plan, our prior equity plan and inducement awards granted outside of our equity plans. In addition, as of December 31, 2019, we had 8,753,022 shares of common stock available for grant under our 2014 Plan. Future equity incentive grants and issuances of shares of common stock under the 2014 Plan, or other grants outside of the 2014 Plan pursuant to inducement equity awards, may have an adverse effect on the market price of shares of our common stock.

Further, debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through government or other third-party funding, collaborations, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Our business and operations would suffer in the event of computer system failures, cyberattacks or a deficiency in our cybersecurity or those of any business partner.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures, cyberattacks or cyber-intrusions over the Internet, loss of funds or information from phishing or other fraudulent schemes, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risks of a security breach or disruption, particularly through cyberattacks or cyber-intrusions, including by computer hackers, foreign governments and cyberterrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Such an event could cause interruption of our operations or loss of Company funds and have a negative financial consequence on our business. For example, the loss of data from completed or ongoing clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data, or inappropriate disclosure of confidential, proprietary or personal information, we could incur material legal claims and liability and damage to our reputation and the development and commercialization of Vicinium for the treatment of high-risk NMIBC could be delayed.

Public health epidemics or outbreaks, including the recent COVID-19 coronavirus pandemic, could adversely affect our business.

Broad-based business or economic disruptions could adversely affect our ongoing or planned development and operational activities, as well as our ability to raise capital. For example, in December 2019 an outbreak of a novel strain of coronavirus (COVID-19) was identified in Wuhan, China. This virus continues to spread globally, has been declared a pandemic by the World Health Organization and has spread to over 100 countries, including the United States. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to businesses and capital markets around the world.

The extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the pandemic, new information that may emerge concerning the severity of COVID-19 and public and private actions to contain COVID-19 or treat its impact. COVID-19 has and will likely continue to result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate. While we cannot presently predict the scope and severity of any potential business shutdowns or disruptions, if we or any of the third parties with whom we engage, including the suppliers, manufacturers and other third parties in our global supply chain, clinical trial sites, regulators, potential business development partners and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

Risks Related to Clinical Development and Regulatory Approval of Vicinium

We are dependent on our lead product candidate, Vicinium for the treatment of high-risk NMIBC. If we are unable to obtain marketing approval for or successfully commercialize our lead product candidate, either alone or through a collaboration, or experience significant delays in doing so, our business could be materially harmed.

We currently have no products approved for sale and have invested a significant portion of our efforts and financial resources in the development of Vicinium for the treatment of high-risk NMIBC. Our prospects are substantially dependent on our ability to obtain marketing approval for and successfully commercialize Vicinium for the treatment of high-risk NMIBC. The success of Vicinium will depend on several factors, including the following:

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

If we are unable to develop, receive marketing approval for, or successfully commercialize Vicinium for the treatment of high-risk NMIBC or experience delays as a result of any of these factors or otherwise, our business could be materially harmed.

If clinical trials of Vicinium fail to demonstrate safety and efficacy to the satisfaction of the FDA, Health Canada, the EMA or other regulatory authorities or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be delayed or unable to complete, the development and commercialization of Vicinium for the treatment of high-risk NMIBC.

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

Many compounds that initially showed promise in early-stage testing for treating cancer have later been found to not be effective treatments or to cause side effects that prevented further development of the compound. The therapeutic efficacy and safety profile of Vicinium for the treatment of high-risk NMIBC has not been demonstrated in humans, and we may not be able to successfully develop and commercialize Vicinium.

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

We may expend our limited resources to pursue development of Vicinium for the treatment of high-risk NMIBC and fail to capitalize on product candidates or indications that have a greater likelihood of clinical success or commercial potential.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater likelihood of clinical success or commercial potential. For example, we previously invested a significant portion of our efforts and financial resources in the development of isunakinra for the treatment of patients with dry eye disease and allergic conjunctivitis. Notwithstanding this significant investment, based on the results from our completed Phase 3 clinical trials in dry eye disease and allergic conjunctivitis, we do not plan to pursue further development of isunakinra. Additionally, in September 2017, we 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 high-risk NMIBC.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on research and development programs and product candidates for specific indications may not yield any commercially viable products. In addition, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

If we experience any of a number of possible unforeseen events in connection with our clinical trials, potential marketing approval or commercialization of Vicinium for the treatment of high-risk NMIBC could be delayed or prevented.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize Vicinium for the treatment of high-risk NMIBC that we may develop, including:

- clinical trials of Vicinium may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon the development of Vicinium for the treatment of high-risk NMIBC;

- the number of patients required for clinical trials of Vicinium for the treatment of high-risk NMIBC may be larger than we anticipate, enrollment in these clinical trials may be slower or more challenging than we anticipate or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements, including cGCP or meet their contractual obligations to us in a timely manner, or at all;
- inspection of the clinical trial operations, trial sites or manufacturing facilities by the FDA or other comparable foreign regulatory authorities such as Health Canada, or the competent authorities of the E.U. Member States, could result in findings of non-compliance and the imposition of a clinical suspension or termination;
- regulators or IRBs/Ethics Committees may delay or not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays or fail to reach agreement with the FDA or a comparable foreign regulatory authority, including Health Canada or the competent authorities of the E.U. Member States, on a trial design that we are able to execute;
- we may be unable to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including for the same indications as our clinical trials;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- trial sites and investigators may deviate from clinical trial protocols or otherwise fail to conduct the trial in accordance with regulatory requirements, and investigators may drop out of the clinical trial;
- trial sites may withdraw from our clinical trials, including as a result of changing standards of care or ineligibility of a site to participate in our clinical trials;
- we may decide, or regulators or IRBs/Ethics Committees or other reviewing entities, including comparable foreign regulatory authorities such as Health Canada or the competent authorities of the E.U. Member States, may require us to suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements including cGCP or a finding that the patients are being exposed to unacceptable health risks;
- the cost of clinical trials of Vicinium for the treatment of high-risk NMIBC may be greater than we anticipate;
- we may receive feedback from DSMBs or the FDA, or a comparable foreign regulatory authority, including Health Canada or the competent authorities of the E.U. Member States, that might require modification to the protocol for the clinical trial or performance of additional studies before clinical trials may continue;
- as a clinical trial proceeds, or as the results of earlier stage studies or concurrent studies become available, we may determine that we need to modify the protocol and/or other aspects of the clinical trial before it may continue;
- the FDA, a comparable foreign regulatory authority, including Health Canada, or the competent authorities of the E.U. Member States, or we may decide to, or a DSMB may recommend to, suspend or terminate clinical trials at any time for safety issues or for any other reason;
- the supply or quality of Vicinium or other materials necessary to conduct clinical trials of Vicinium may be insufficient or inadequate;
- Vicinium may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs/Ethics Committees to suspend or terminate the trials;
- lack of adequate funding to continue a clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical trials or increased expenses associated with the services of our CROs and other third parties; and
- changes in applicable laws, governmental regulations or administrative actions.

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

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

If we are required to conduct additional clinical trials or other testing of Vicinium for the treatment of high-risk NMIBC beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of Vicinium or other testing, if the results of these trials or tests are not favorable or are only modestly favorable or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for Vicinium for the treatment of high-risk NMIBC;

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

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

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

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States, including Health Canada or the EMA. We have previously experienced difficulties with clinical trial enrollment and retention, which led to the early termination of our Phase 3 trial of Vicinium for the treatment of SCCHN in 2008, and we may experience difficulties in patient enrollment in our clinical trials in the future for a variety of reasons.

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

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

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

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

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

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

Vicinium for the treatment of high-risk NMIBC may cause undesirable side effects, serious adverse events or have other properties that could delay or halt clinical trials, delay or prevent its regulatory approval, limit the commercial profile of its labeling, if approved, or result in significant negative consequences following any marketing approval.

Undesirable side effects or serious adverse events caused by Vicinium for the treatment of high-risk NMIBC could cause us or regulatory authorities to interrupt, delay or halt respective clinical trials and could result in a restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities, including Health Canada or the European Commission.

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

As of the May 29, 2019 data cutoff date, in patients across all cohorts (n=133) of our Phase 3 VISTA Trial of Vicinium for the treatment of high-risk NMIBC, 88% experienced at least one adverse event, with 95% of adverse events being Grade 1 or 2. The most commonly reported treatment-related adverse events were dysuria (14%), hematuria (13%) and urinary tract infection (12%) - all of which are consistent with the profile of bladder cancer patients and the use of catheterization for treatment delivery. These adverse events were determined by the clinical investigators to be manageable and reversible, and only four patients (3%) discontinued treatment due to an adverse event. Serious adverse events, regardless of treatment attribution, were reported in 14% of patients. There were four treatment-related serious adverse events reported in three patients including acute kidney injury (Grade 3), pyrexia (Grade 2), cholestatic hepatitis (Grade 4) and renal failure (Grade 5). There were no age-related increases in adverse events observed in the VISTA Trial.

In addition, side effects and serious adverse events or further safety or toxicity issues that we may experience in our clinical trials or in post-marketing experience could lead to the FDA's imposition of a REMS or other post-marketing obligations, which could hinder us from generating revenues or achieving profitability. Results of our clinical trials could reveal an unacceptably high severity and prevalence of side effects or serious adverse events. As a result, our clinical trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities, including Health Canada, the EMA and the European Commission, could order us to cease further development or deny approval of Vicinium for the treatment of high-risk NMIBC. The related drug-side effects or serious adverse events in our clinical trials could affect clinical trial patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims.

Additionally, if Vicinium for the treatment of high-risk NMIBC receives marketing approval, and we or others later identify undesirable side effects or serious adverse events caused by Vicinium, a number of potentially significant negative consequences could result, including:

- we may suspend or be forced to suspend marketing of Vicinium for the treatment of high-risk NMIBC;
- we may be obliged to conduct a product recall or product withdrawal;
- regulatory authorities may suspend, vary, or withdraw their approvals of Vicinium for the treatment of high-risk NMIBC;
- regulatory authorities may order the seizure or recall of Vicinium;
- regulatory authorities may require additional warnings on the label or a REMS that could diminish the usage or otherwise limit the commercial success of Vicinium for the treatment of high-risk NMIBC;
- we may be required to conduct post-marketing studies;
- we could be sued and held liable for harm caused to patients;
- we could be required to pay fines and face other administrative, civil and criminal penalties; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of Vicinium for the treatment of high-risk NMIBC, if approved.

We will need to obtain FDA approval of any proposed names for Vicinium for the treatment of high-risk NMIBC, and any failure or delay associated with such naming approval may adversely impact our business.

On October 30, 2019, we submitted our proposed proprietary name request for Vicinium for the treatment of high-risk NMIBC to the FDA. We have not yet submitted our proprietary name request for Vicinium to any foreign regulatory authority, including Health Canada or the European Commission, for provisional approval. Any proprietary name we propose to use with Vicinium for the treatment of high-risk NMIBC in the United States will be subject to review by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA reviews any proposed product name, including an evaluation of potential for confusion with other product names. The FDA may also object to a product name if it believes the name

inappropriately implies medical claims or contributes to an overstatement of efficacy. If the FDA objects to any proposed proprietary product name, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable laws, not infringe the existing rights of third parties and be acceptable to the FDA. However, this approval is subject to further and final review by the FDA at the time of BLA review.

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

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

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

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

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

Our product candidate, Vicinium for the treatment of high-risk NMIBC, has been produced in our own manufacturing facility for all clinical trials for Vicinium to date, including our ongoing Phase 3 VISTA Trial. In September 2017, we completed the manufacturing of all Vicinium necessary for our ongoing Phase 3 VISTA Trial and for our CRADA with the NCI. We intend to utilize a third-party manufacturer to produce the commercial supply of Vicinium, if approved, and have had discussions with the FDA regarding the criteria for demonstrating comparability of Vicinium produced by our third-party manufacturer to Vicinium produced in our own manufacturing facility. In October 2018, we entered into the Fujifilm MSA for the manufacturing process and technology transfer of Vicinium drug substance production. In April 2019, the first full, commercial-scale cGMP run was completed at Fujifilm. Full quality release testing has been completed and all Phase 3 release specifications were met, supporting Fujifilm's ability to produce the bulk drug substance form of Vicinium for commercial purposes if we receive regulatory approval to market Vicinium for the treatment of high-risk NMIBC.

Although we do not anticipate changes to the raw materials, formulations or properties nor do we anticipate changes to the Vicinium manufacturing process or finished product specifications as a result of this transfer, because this manufacturing change is being introduced at an advanced stage of development of Vicinium, the FDA may require a comprehensive comparability assessment, potentially including additional nonclinical studies or clinical trials utilizing Vicinium produced by our third-party manufacturer, and/or a modification of our ongoing Phase 3 VISTA Trial to include Vicinium produced by our third-party manufacturer. Such requirements could result in lengthy delays and significantly higher costs for the clinical development, acceptance of a BLA, and potential commercialization of Vicinium for the treatment of high-risk NMIBC. If we are unable to demonstrate comparability of Vicinium produced in our own manufacturing to Vicinium produced by our third-party manufacturer, we may not be able to obtain approval of a BLA for Vicinium for the treatment of high-risk NMIBC.

If we are unable to effectively transfer our manufacturing process to our third-party manufacturer, we may be unable to continue the clinical development of or continue to seek marketing approval of Vicinium for the treatment of high-risk NMIBC. If we are able to effectively complete the transfer of certain of our manufacturing processes and technologies to FujiFilm, the manufacturing facilities used by Fujifilm to manufacture the bulk drug substance form of Vicinium will be subject to inspections by the FDA, and we will depend on Fujifilm's ability to comply with cGMP or other applicable regulatory standards. If they cannot successfully manufacture material in compliance with these strict regulatory requirements, we and they will not be able to secure or maintain regulatory approval for their manufacturing facilities. If the FDA does not approve the manufacturing facilities of Fujifilm with respect to the manufacture of the materials covered under the Fujifilm MSA, Fujifilm's ability to produce the bulk drug substance form of Vicinium on a commercial-scale could be delayed which could adversely affect our ability to commercialize Vicinium for the treatment of high-risk NMIBC. We and Fujifilm also may be subject to penalties and sanctions from the FDA for any violations of applicable regulatory requirements.

Risks Related to the Commercialization of Vicinium

Our commercial success depends upon attaining significant market acceptance of Vicinium for the treatment of high-risk NMIBC, if approved, among physicians, patients, third-party payors and the medical community.

Even if we obtain regulatory approval for Vicinium for the treatment of high-risk NMIBC, Vicinium may not gain market acceptance among physicians, patients, third-party payors or the medical community. Vicinium based on our TFPT platform, which is a new technology and therapeutic approach. Market participants with significant influence over acceptance of new treatments, such as physicians and third-party payors, may not adopt a product or treatment based on our TFPT platform and technologies, and we may not be able to convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, Vicinium for the treatment of high-risk NMIBC. Market acceptance of Vicinium for the treatment of high-risk NMIBC, if approved, depends on a number of factors, including:

- the perceived quality, efficacy and safety of Vicinium;
- clinical indications for which Vicinium is approved;
- availability of alternative effective treatments for high-risk NMIBC and the relative risks, benefits and costs of those treatments;
- acceptance by physicians, major operators of cancer clinics and patients of Vicinium as a safe and effective treatment for high-risk NMIBC;
- the success of our physician education programs;
- potential and perceived advantages of Vicinium over alternative treatments;
- safety of Vicinium seen in a broader patient group, potentially including its use outside the approved indication should physicians choose to prescribe them for such uses;
- prevalence and severity of any side effects;
- any new or unexpected results from additional clinical trials or further analysis of clinical data of completed clinical trials by us or our competitors;
- product labeling or patient information requirements imposed by the FDA;
- timing of market introduction of Vicinium as well as competitive products;
- the pricing of our treatments, particularly in relation to alternative treatments, and willingness and ability of patients to pay for Vicinium;
- availability of coverage and adequate reimbursement and pricing by third-party payors and government authorities;
- maintaining compliance with all applicable regulatory requirements;
- relative convenience and ease of administration; and
- effectiveness of our sales, marketing and distribution efforts and operations.

If Vicinium for the treatment of high-risk NMIBC is approved but fails to achieve market acceptance among physicians, patients, third-party payors or the medical community, we may not be able to generate significant revenues, which would compromise our ability to become profitable.

The market opportunity for Vicinium may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small.

Cancer therapies are sometimes characterized as first-line, second-line or third-line. When cancer is detected early enough, first-line therapy, usually chemotherapy, hormone therapy, surgery, radiotherapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second-line and third-line therapies are administered to patients when prior therapy is not effective. We are seeking approval of Vicinium for the treatment of high-risk NMIBC after prior therapies have failed.

Our projections of both the number of people who have high-risk NMIBC, as well as the subset of people with this cancer who have previously failed prior treatments, and who have the potential to benefit from treatment with Vicinium, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers and the number of patients may turn out to be lower than expected. Even if we receive regulatory approval for Vicinium for the treatment of high-risk NMIBC and obtain significant market share, because the potential target population is small, we may never achieve profitability without obtaining regulatory approval for additional indications, including the use of Vicinium as a first-line therapy.

Our commercial success could depend upon the continued marketing of another company's approved product, or the approval of another company's product candidate, that is administered with our product candidates.

Some of our future clinical trials and some of the indications for which we are developing our product candidates may involve the use of our product candidates in combination with other companies' marketed products or product candidates. These marketed products or product candidates may be administered in a clinical trial in combination with one or more of our product candidates. In the event that any of these pharmaceutical companies has unforeseen issues that negatively impacts the clinical development, marketing approval or availability of its product or product candidate or otherwise opts to discontinue clinical development or marketing of its product or product candidate, our ability to complete our applicable clinical trials and/or evaluate clinical results for our product candidate in combination with the other company's marketed product or product candidate may be negatively impacted. As a result, this could adversely affect our ability to file for, obtain, or maintain regulatory approval for our product candidate on a timely basis, or at all. For example, under the terms of the CRADA, the NCI will conduct a Phase 1 clinical trial in patients with high-risk NMIBC to evaluate the safety, efficacy and biological correlates of Vicinium in combination with durvalumab.

If we are unable to establish sales, marketing and distribution capabilities, we may not be successful in commercializing Vicinium for the treatment of high-risk NMIBC, if and when it is approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of therapeutic products. To achieve commercial success for Vicinium for the treatment of high-risk NMIBC, if approved, we will need to establish sales, marketing and distribution capabilities, either ourselves or through collaborations or other arrangements with third parties.

There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of Vicinium for the treatment of high-risk NMIBC for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize Vicinium for the treatment of high-risk NMIBC, if approved, on our own include:

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

We may enter into arrangements with third parties to perform sales, marketing and distribution services in markets outside the United States. We may also enter into arrangements with third parties to perform these services in the United States if we do not establish our own sales, marketing and distribution capabilities in the United States or if we determine that such third-party arrangements are otherwise beneficial. Our product revenues and our profitability, if any, under any such third-party sales, marketing or distribution arrangements are likely to be lower than if we were to market, sell and distribute Vicinium for the treatment of high-risk NMIBC ourselves. In addition, we may not be successful in entering into arrangements with third parties

to sell, market and distribute Vicinium for the treatment of high-risk NMIBC, if approved, or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market Vicinium for the treatment of high-risk NMIBC, if approved, effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing Vicinium for the treatment of high-risk NMIBC, if approved.

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

The development and commercialization of new biologics products is highly competitive. We face competition with respect to Vicinium for the treatment of high-risk NMIBC from both large and small pharmaceutical, biopharmaceutical and biotechnology companies, academic institutions and other research organizations. There are a number of large pharmaceutical, biopharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of high-risk NMIBC. For instance, in January 2020, the FDA approved Merck & Co., Inc.'s Keytruda (pembrolizumab) as a systemic monotherapy to treat patients with BCG-unresponsive, high-risk NMIBC with CIS with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy. In addition, FerGene Inc. is developing Adstiladrin (nadofaragene firadenovec (rAd-IFN/Syn3) for high-grade BCG-unresponsive NMIBC for the United States market and presented Phase 3 data in December 2019, and its BLA has been accepted by the FDA for review. There is intense and rapidly evolving competition in the biotechnology, biopharmaceutical and antibody fragment and immuno-oncology therapeutics fields. Some of these competitive products and therapies are based on scientific approaches that are similar to our approach, and others are based on entirely different approaches.

We also face substantial competition with respect to our EBI-031 program. The current standard of care for diabetic macular edema ("DME") includes anti-VEGF therapies and corticosteroids. Some patients with DME are effectively treated by the current standard of care therapies. Approved anti-VEGF therapies for treating DME include Lucentis (ranibizumab) and Eylea® (aflibercept). Off-label use of Avastin (bevacizumab) is also seen in DME. Approved corticosteroid therapies include Ozurdex (dexamethasone implant) and Iluvien (fluocinolone implant). Laser photocoagulation was historically the standard of care for treating DME, in particular for a subcategory of DME called clinically significant macular edema, and is still used to treat some DME patients. However, anti-VEGF therapy has been proven in clinical trials to have superior efficacy over laser photocoagulation. Our competitors for treating DME include, but are not limited to, Novartis (Brolucizumab), Opthea Limited (OPT-302 in combination with aflibercept), Roche (Faricimab) and Kodiak Sciences Inc. (KSI-301).

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

In addition, our ability to compete may be affected in many cases by insurers or other third-party payors, particularly Medicare, seeking to encourage the use of generic drug products. Generic products are currently being used as part of the standard of care for the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If any product candidate that we may develop achieves marketing approval, we expect that it will be priced at a significant premium over competitive generic products.

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

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

On May 31, 2016, ASCO published a framework to assess the value of cancer treatment options. The framework was developed in response to concern that new, expensive cancer treatments may not be supported by adequate medical evidence. The purpose of the framework is to provide a standardized quantification of cancer treatments and assist oncologists and patients in deciding between new cancer treatments and the standard of care. The framework takes into account a medication’s (i) efficacy, (ii) safety and (iii) cost, to derive an overall treatment value.

While we believe that the safety and efficacy profiles of our product candidates are potentially better than that of the standard of care and, if approved, we intend to price our products competitively, we do not know how the data will be assessed by ASCO. It is also unknown whether use of this application could adversely affect the assessment of any of our product candidates. If this framework were adopted and utilized by payors and physicians, and if Vicinium for the treatment of high-risk NMIBC were to receive low ratings, this could adversely affect the price and reimbursement of Vicinium, if approved, reduce prescriptions and harm our business.

Even if we are able to commercialize Vicinium for the treatment of high-risk NMIBC, it may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business.

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

Inadequate reimbursement may adversely affect the demand for, or the price of, Vicinium for the treatment of high-risk NMIBC, if approved. Obtaining and maintaining adequate reimbursement for Vicinium for the treatment of high-risk NMIBC may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize Vicinium for the treatment of high-risk NMIBC, if approved.

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

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

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

or regulation relating to the health care industry or third-party coverage and reimbursement may be enacted in the future and how such legislation or regulation could impact our business. See the risk factor entitled “Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of Vicinium for the treatment of high-risk NMIBC and affect the prices we, or they, may obtain” in this Annual Report on Form 10-K for more information, including with respect to the ACA.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of Vicinium for the treatment of high-risk NMIBC, if approved.

We face an inherent risk of product liability exposure related to the use of Vicinium for the treatment of high-risk NMIBC and will face an even greater risk if Vicinium for the treatment of high-risk NMIBC receives marketing approval and is commercialized. If we cannot successfully defend ourselves against claims that Vicinium for the treatment of high-risk NMIBC caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for Vicinium for the treatment of high-risk NMIBC;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial patients;
- significant costs to defend the related litigation;
- substantial monetary awards to trial patients;
- loss of revenue;
- reduced time and attention of our management to pursue our business strategy; and
- the inability to commercialize Vicinium for the treatment of high-risk NMIBC.

We currently hold $10.0 million CAD in product liability insurance coverage in the aggregate, with a per incident limit of $10.0 million CAD, which may not be adequate to cover all liabilities that we may incur. We would need to increase our insurance coverage if we expand our clinical development activities beyond historical levels. We would need to further increase our insurance coverage if Vicinium for the treatment of high-risk NMIBC is approved and we commence commercialization. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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

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

Risks Related to the License Agreement with Roche

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

In June 2016, we entered into the License Agreement with Roche, pursuant to which we granted Roche an exclusive, worldwide license, including the right to sublicense, to the Licensed Intellectual Property. Under the License Agreement, Roche is required to continue developing, at its cost, EBI-031 and any other product made from the Licensed Intellectual Property that contains a Licensed Product and pursue ongoing patent prosecution, 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 received from Roche an upfront license fee of $7.5 million in August 2016 upon the effectiveness of the License Agreement with Roche following approval by our stockholders, and Roche agreed to pay up to an additional $262.5 million upon the achievement of specified regulatory, development and commercial milestones with respect to up to two unrelated indications. Specifically, an aggregate amount of up to $197.5 million is payable to 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. In September 2016, Roche paid us the first development milestone of $22.5 million as a result of the IND application for EBI-031 becoming effective on or before September 15, 2016. Additional amounts of up to $65.0 million are payable upon the achievement of specified development and regulatory milestones in a second indication.

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

The License Agreement with Roche provides for two “option periods” during which Roche may elect to make a one-time payment to us and, in turn, terminate its diligence, milestone and royalty payment obligations under the License Agreement. Specifically, (i) Roche may exercise a buy-out option following the first dosing ("Initiation") in the first Phase 2 study for a Licensed Product until the day before Initiation of the first Phase 3 study for a Licensed Product, in which case Roche is required to pay us $135.0 million within 30 days after Roche’s exercise of such buy-out option and receipt of an invoice from us, or (ii) Roche may exercise a buy-out option following the day after Initiation of the first Phase 3 study for a Licensed Product until the day before the acceptance for review by the FDA or other regulatory authority of a BLA or similar application for marketing approval for a Licensed Product in either the United States or in the E.U., in which case Roche is required to pay us, within 30 days after Roche’s exercise of such buy-out option and receipt of an invoice from us, $265.0 million, which amount would be reduced to $220.0 million if none of our patent rights containing a composition of matter claim covering any compound or Licensed Product has issued in the E.U.

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

We may seek third-party collaborators or licensees for development and commercialization of our product candidates, including Vicinium for the treatment of high-risk NMIBC. Our likely collaborators or licensees for any sales, marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We are not currently party to any such arrangement, other than the License Agreement with Roche. Our ability to generate revenues from these arrangements will depend on our collaborators’ or licensee's abilities and efforts to successfully perform the functions assigned to them in these arrangements.

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

- collaborators or licensees have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations or licenses;
- collaborators or licensees may not perform their obligations as expected;
- collaborators or licensees may not pursue development and commercialization of our product candidates that receive marketing approval or may elect not to continue or renew development or commercialization programs based on

clinical trial results, changes in the collaborators' or licensees' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;

- collaborators or licensees may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators or licensees could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators or licensees believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered under the collaboration or license with us may be viewed by our collaborators or licensees as competitive with their own product candidates or products, which may cause collaborators or licensees to cease to devote resources to the commercialization of our product candidates;
- a collaborator or licensee with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators or licensees, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would divert management attention and resources, be time-consuming and expensive;
- collaborators or licensees may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators or licensees may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations or licenses may be terminated for the convenience of the collaborator or licensee and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements and licenses may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If any collaborations or licenses that we enter into, do not result in the successful development and commercialization of products or if one of our collaborators or licensees terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration or license. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10-K would also apply to the activities of any collaborators and licensees.

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

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

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

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other

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

We rely on third parties to conduct our pre-clinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates.

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

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

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

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

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

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

We lease a 31,100 square foot manufacturing, laboratory, warehouse and office facility in Winnipeg, Manitoba. We have three 15-liter fermenters, one 30-liter fermenter, one 150-liter fermenter, one 500-liter fermenter and one 1,500-liter fermenter. Our classified fermentation suite and post-production processing capabilities were dedicated to producing our pre-clinical study and clinical trial batches of Vicinium. In September 2017, we completed the manufacturing of all Vicinium necessary for our ongoing Phase 3 VISTA Trial and for our CRADA with the NCI. In conjunction with this achievement, we ended our manufacturing activities in Winnipeg and have redirected our resources toward completing the technology transfer process necessary to outsource commercial scale drug supply manufacturing in the event we obtain approval from the FDA to market Vicinium for the treatment of high-risk NMIBC.

In October 2018, we entered into the Fujifilm MSA for the manufacturing process and technology transfer of Vicinium drug substance production. In April 2019, the first full, commercial-scale cGMP run was completed at Fujifilm. Full quality release testing has been completed and all Phase 3 release specifications were met, supporting Fujifilm's ability to produce the bulk drug substance form of Vicinium for commercial purposes if we receive regulatory approval to market Vicinium for the treatment of high-risk NMIBC.

Our manufacturing facility was audited by a third party in July 2018 to assess our commercial manufacturing capabilities. It was concluded from the audit that facility upgrades would be required for commercial manufacturing. Our manufacturing facility was also audited by a third party for compliance with cGMP in January 2014 and it did not identify any major impediments to the cGMP manufacturing of product candidates up to and including Phase 3 production. Manufacturing of drugs and product candidates, including Vicinium and VB6-845d, must comply with cGMP standards and other regulations. Methods of manufacture as well as validation of manufacturing procedures and quality control systems are reviewed by regulatory authorities, such as the FDA, Health Canada and the competent authorities of the E.U. Member States, to determine their effect on the quality, purity and potency of product candidates. All such manufacturing procedures, validation programs and quality assessment activities must be properly documented in accordance with regulatory requirements. The FDA, Health Canada and the competent authorities of the E.U. Member States conduct inspections to determine compliance with cGMP to ensure that product candidates used in human testing are adequately characterized in terms of identity, potency and purity. In general, the cGMP standards expected for marketed drugs also apply to the supply of product candidates evaluated in most stages of clinical testing.

The facilities used by Fujifilm and any other CMO we may utilize to manufacture Vicinium must be the subject of a satisfactory inspection before the FDA and other applicable regulatory authorities approve a BLA or marketing authorization for Vicinium manufactured at that facility. We will depend on these third-party manufacturing partners for compliance with the FDA's, E.U.'s and comparable foreign regulatory authorities', including Health Canada's, requirements for the manufacture of Vicinium, if approved.

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

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

Changes in United States patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. For example, the United States previously enacted and is currently implementing wide-ranging patent reform legislation. Specifically, on September 16, 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") was signed into law and included a number of significant changes to United States patent law, and many of the provisions became effective in March 2013. However, it may take the courts years to interpret the provisions of the Leahy-Smith Act, and the implementation of the statute could increase the uncertainties and costs surrounding the prosecution of our licensed and future patent applications and the enforcement or defense of our licensed and future patents, all of which could have a material adverse effect on our business, financial condition and results of operations.

In addition, the United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the United States Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we might obtain in the future.

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

Filing, prosecuting and defending patents on all of our product candidates and technologies throughout the world would be prohibitively expensive, and our or our licensors' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws and practices of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Moreover, the intellectual property laws of the United States change over time. For example, several United States Supreme Court cases have redefined what is considered to be patentable subject matter. Consequently, we and our licensors may not be able to prevent third parties from practicing our and our licensors' inventions in all countries inside or outside the United States, or from selling or importing products made using our and our licensors' inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export infringing products to territories where we or our licensors have patent protection, but where enforcement is not as strong as in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

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

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

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

Many countries, including E.U. countries, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which

could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

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

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

We depend on our License Agreements with Zurich, Micromet and XOMA, and if we cannot meet the requirements under the agreements we could lose important rights to Vicinium, which could have material adverse effect on our business.

We have an exclusive License Agreement with Zurich. Pursuant to the agreement, we were granted an exclusive license, with the right to sublicense, under certain patents primarily relating, in part, to our targeting agents, EpCAM chimera and immunoconjugates (including aspects of Vicinium for the treatment of high-risk NMIBC and Vicinium for the treatment of SCCHN) and methods of use, to make, use, sell and import products that would otherwise infringe such patents in the field of the treatment, stasis and palliation of disease in humans. If we fail to meet our obligations under the license agreement, Zurich may have the right to terminate our license, and upon the effective date of such termination, our right to use the licensed Zurich patent rights would end. To the extent such licensed technology or patent rights relate to our product candidates, we would expect to exercise all rights and remedies available to us, including attempting to cure any breach by us, and otherwise seek to preserve our rights under the patent rights licensed to us, but we may not be able to do so in a timely manner, at an acceptable cost to us or at all. Any uncured, material breach under the license agreement could result in our loss of rights to practice the patent rights licensed to us under the license agreement, and to the extent such patent rights and other technology relate to our product candidates or other of our compounds, it could have a material adverse effect on our commercialization efforts for our product candidates, including Vicinium for the treatment of high-risk NMIBC and Vicinium for the treatment of SCCHN.

We also have a License Agreement with Micromet, which grants us non-exclusive rights, with certain sublicense rights, for know-how and patents allowing exploitation of certain single chain antibody products. If we fail to meet our obligations under the license agreement, Micromet may have the right to terminate our license, and upon the effective date of such termination, our right to use the licensed Micromet patent rights would end. To the extent such licensed technology or patent rights relate to our product candidates, we would expect to exercise all rights and remedies available to us, including attempting to cure any breach by us, and otherwise seek to preserve our rights under the patent rights licensed to us, but we may not be able to do so in a timely manner, at an acceptable cost to us or at all. Any uncured, material breach under the license agreement could result in our loss of rights to practice the patent rights licensed to us under the license agreement, and to the extent such patent rights and other technology relate to our product candidates or other of our compounds, it could have a material adverse effect on our commercialization efforts for our product candidates, including Vicinium for the treatment of high-risk NMIBC and Vicinium for the treatment of SCCHN.

We also have a License Agreement with XOMA, which grants us non-exclusive rights to certain XOMA patent rights and know-how related to certain expression technology, including plasmids, expression strains, plasmid maps and production systems. If we fail to meet our obligations under the license agreement, XOMA may have the right to terminate our license, and upon the effective date of such termination, our right to use the licensed XOMA patent rights and related know-how would end. To the extent such licensed technology or patent rights relate to our product candidates, we would expect to exercise all rights and remedies available to us, including attempting to cure any breach by us, and otherwise seek to preserve our rights under the patent rights licensed to us, but we may not be able to do so in a timely manner, at an acceptable cost to us or at all. Any uncured, material breach under the license agreement could result in our loss of rights to practice the patent rights licensed to us under the license agreement, and to the extent such patent rights and other technology relate to our product candidates or other of our compounds, it could have a material adverse effect on our commercialization efforts for our product candidates, including Vicinium for the treatment of high-risk NMIBC and Vicinium for the treatment of SCCHN.

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

Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, trademarks or other intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. In a trademark infringement proceeding, we could be enjoined from continued use of a trademark deemed to be infringing and forced to rebrand product packaging, product inserts, market and advertising materials, resulting in a loss of sales and established goodwill in that name or mark. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a trademark. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

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

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

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

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

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

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

Many of our employees and our licensors' employees, including our senior management, were previously employed at universities, medical institutions or other biotechnology or pharmaceutical companies, including our competitors or potential

competitors. Some of these employees, including members of our senior management, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

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

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

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

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

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

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

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

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

- others may be able to make product candidates that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have licensed;
- biosimilar product manufacturers may develop, seek approval for, and launch biosimilar versions of our products, which could be significantly less costly to bring to market and priced significantly lower than our products;
- we or our licensors might not have been the first inventor to file patent applications covering certain of our inventions;
- others may design around our intellectual property rights or independently develop similar or alternative technologies or duplicate any of our technologies without infringing or misappropriating our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents with claims that cover our products or even issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;

- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies or product candidates that are patentable; and
- the intellectual property rights of others may have an adverse effect on our business.

Risks Related to Regulatory and Marketing Approval of Vicinium for the Treatment of High-Risk NMIBC and Other Legal Compliance Matters

If we are not able to obtain regulatory approval, or there are delays in obtaining approval, we will not be able to commercialize Vicinium for the treatment of high-risk NMIBC or any other product candidate that we may develop, and our ability to generate revenue will be materially impaired. The marketing approval process is expensive, time-consuming and uncertain. As a result, we cannot predict when or if we, or any licensees or collaborators, will obtain marketing approval to commercialize Vicinium for the treatment of high-risk NMIBC or any other product candidate.

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

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

The regulatory process can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Moreover, changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable regulatory authorities in other countries, including Health Canada and the European Commission, have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional pre-clinical, clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. In February 2018, the FDA issued finalized guidance on developing drugs and biologics for treating BCG-unresponsive NMIBC, which sets forth certain expectations for our development of Vicinium for the treatment of high-risk NMIBC. We may be unable to satisfy all recommendations contained in the FDA guidance and, even if we do, it is not guaranteed that meeting all such recommendations will be sufficient to obtain marketing approval.

The different requirements and expectations of the EMA and Health Canada compared with the FDA may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these product candidates or lead to significant post approval limitations or restrictions. If we experience delays in obtaining regulatory approvals, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

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

With the enactment of the BPCIA, abbreviated pathways for approval of biosimilar and interchangeable biological products were created. The BPCIA establishes legal authority for the FDA to review and approve biosimilars for marketing, as well as

biosimilars that have been designated as “interchangeable” with a previously approved biologic, or reference product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a full BLA. This period of regulatory exclusivity runs concurrently with, but is independent of, periods of patent protection for the reference product.

We believe that any of our product candidates, including Vicinium for the treatment of high-risk NMIBC, approved as a biological product under a full BLA should qualify for a 12-year period of exclusivity. However:

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

The BPCIA is complex and its provisions continue to be interpreted and implemented by the FDA and United States courts. As a result, the ultimate impact, implementation and implications of the BPCIA are subject to uncertainty and could compromise the future commercial prospects for our biological products. Moreover, it is not yet clear the extent to which a biosimilar, once approved, may be substituted for any one of our reference products in a way that is similar to traditional generic substitution for pharmaceutical products; this will depend on a number of marketplace and regulatory factors that are still developing at both the federal and state levels of government.

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

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

Even if we, or our third-party licensees or collaborators, obtain marketing approvals for our product candidates, the terms of those approvals, ongoing regulations and post-marketing restrictions may limit how we, or they, manufacture and market our products, which could materially impair our ability to generate revenue.

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

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

Accordingly, assuming we receive marketing approval for one or more of our product candidates, we and our contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any

future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Thus, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

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

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical trials, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other federal and state regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. The respective safety and efficacy profiles of our product candidates will continue to be closely monitored by the FDA and comparable foreign regulatory authorities, including Health Canada, if they are approved. If new safety information becomes available after approval of our product candidates, the FDA may require labeling changes or establishment of a REMS, and the FDA or comparable foreign regulatory authorities, including Health Canada, may require a similar strategy, impose significant restrictions on our product candidates' indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

The FDA and other federal and state agencies, including the DOJ closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. Violations of such requirements may lead to investigations alleging violations of the FDCA and other statutes, including the False Claims Act and other federal and state health care fraud and abuse laws as well as state consumer protection laws. In the United States, engaging in impermissible promotion of approved products for off-label uses can also subject us to false claims litigation under federal and state statutes, and other litigation and/or investigation, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which we promote or distribute our drug products. These false claims statutes include the federal civil False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. These False Claims Act lawsuits against pharmaceutical companies have led to several substantial civil and criminal settlements. These lawsuits have increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, or may be excluded from the Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully market our approved products, we may become subject to such litigation and/or investigation and, if we are not successful in defending against such actions, those actions could compromise our ability to become profitable. Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:

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

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

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

Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

We are subject to United States data protection laws and regulations (i.e., laws and regulations that address privacy and data security) at both the federal and state levels. The legislative and regulatory landscape for data protection continues to evolve, and in recent years there has been an increasing focus on privacy and data security issues. Numerous federal and state laws, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, and disclosure of health-related and other personal information. In addition, we may obtain health information from third parties (e.g., healthcare providers who prescribe our products) that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA-other than potentially with respect to providing certain employee benefits-we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. Finally, a data breach affecting sensitive personal information, including health information, could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

E.U. Member States, Switzerland and other countries have also adopted data protection laws and regulations, which impose significant compliance obligations. For example, the collection and use of personal health data in the E.U. is governed by the E.U. General Data Protection Regulation ("GDPR"). The GDPR imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern the legal basis for processing personal data, which may include consent of the individuals to whom the personal data relates, the information provided to the individuals and the security and confidentiality of the personal data.

The GDPR prohibits the transfer of personal data to countries outside of the European Economic Area ("EEA") that are not considered by the European Commission to provide an adequate level of data protection. These countries include the United States. Transfer of personal data from the EEA to the United States is only permitted if there is an appropriate legal basis for the transfer of personal data, such as the existence of certain agreements in compliance with the model contractual clauses as issued by the European Commission, or if the recipient of the personal data in the United States is "Privacy Shield" certified, or if there is another appropriate legal basis i accordance with the GDPR for the transfer of personal data from the EEA to the United States.

The E.U. Data Protection Regulation has introduced new data protection requirements in the E.U. and substantial fines for breaches of the data protection rules.

Our failure to comply with these laws, or changes in the way in which these laws are implemented, could lead to government enforcement actions and significant penalties against us, and adversely impact our business.

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government,

with potential liability including mandatory treble damages and significant per-claim penalties, set at $10,781 to $21,563 per false claim for violations occurring after November 2, 2015;

- HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry relating to the delivery of or payment for healthcare benefits, items or services;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered products to report payments and other transfers of value to physicians and teaching hospitals;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which imposes obligations, including mandatory contractual terms, on covered healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws and transparency statutes, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that prohibit certain marketing-related activities, including the provision of gifts, meals, or other items to certain health care providers, and restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; state laws that require identification or licensing of sales representatives; and state and foreign laws governing the privacy, security, collection, use and disclosure of health information, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the FTC Act), many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of our product candidates, including Vicinium for the treatment of high-risk NMIBC, and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been, and continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any collaborators, to profitably sell any products for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

In the United States, the Medicare Modernization Act established the Medicare Part D program and generally authorized prescription drug plan sponsors to impose limits on the number of covered drugs under their plans in a therapeutic class. The Medicare Modernization Act, including its cost reduction initiatives, could decrease the coverage and reimbursement rate that we may receive for any of our product candidates, if approved. CMS, the agency that administers the Medicare program, also may revise reimbursement and implement coverage restrictions. Cost reduction initiatives and changes in coverage could decrease utilization of and reimbursement for any approved products, which would then affect the price we can receive. Private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement from federal legislation or regulation may lead to similar reductions in private payor reimbursement.

In addition, in March 2010, President Obama signed into law the ACA. Among the provisions of the ACA of potential importance to our business and our product candidates are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription products and biological products;
- an increase in the statutory minimum rebates a manufacturer must pay under the MDRP to 23.1% for innovator drugs and 13% for non-innovator drugs of the AMP;
- a new methodology by which AMP is calculated and reported by manufacturers for products that are inhaled, infused, instilled, implanted or injected and not generally dispensed through retail community pharmacies;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand products to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient products to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service's 340B drug pricing program;
- new requirements to report to CMS annually specifying financial arrangements with physicians and teaching hospitals, as defined in the ACA and its implementing regulations, including reporting any ''payments or other transfers of value'' made or distributed to prescribers, teaching hospitals, and other healthcare providers and reporting any ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations during the preceding calendar year;
- a new requirement to annually report product samples that manufacturers and distributors provide to physicians;
- a mandatory non-deductible payment for employers with 50 or more full-time employees (or equivalents) who fail to provide certain minimum health insurance coverage for such employees and their dependents;
- establishment of the Center for Medicare and Medicaid Innovation within CMS to test innovative payments and service delivery models; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012, which, among other things, led to aggregate reductions in Medicare payments for all items and services, including prescription drugs and biologics, to service providers of, on average, 2% per fiscal year beginning April 1, 2013 and, due to subsequent legislation, will continue until 2029. The American Taxpayer Relief Act of 2012 also, among other things, reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which regulatory approval is obtained, including Vicinium for the treatment of high-risk NMIBC, which could have a material adverse effect on our financial operations.

Additional legislative changes, FDA or CMS regulation, or guidance could be adopted, which may impact the marketing approvals and reimbursement for our product candidates. For example, there have been several Congressional inquiries and proposed bills and regulatory initiatives designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. In November 2015, the United States House of Representatives formed an Affordable Drug Pricing Task Force to advance legislation intended to control pharmaceutical drug costs and investigate pharmaceutical drug pricing, and the United States Senate has requested information from certain pharmaceutical companies in connection with an investigation into pharmaceutical drug pricing practices. If healthcare policies or reforms intended to curb healthcare costs are adopted or if we experience negative publicity with respect to pricing of our products or the pricing of pharmaceutical drugs generally, the prices that we charge for any approved products may be limited, our commercial opportunity may be limited and/or our revenues from sales of our products may be negatively impacted.

Certain provisions of the ACA have been subject to judicial and Congressional challenges, as well as efforts to repeal or replace them or to alter their interpretation or implementation. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017 eliminated the tax-based shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Code, commonly referred to as the "individual mandate," effective January 1, 2019. Further, the Bipartisan Budget Act of 2018 among other things, amended the Medicare statute, effective January 1, 2019, to reduce the coverage gap in most Medicare drug plans, commonly known as the "donut hole," by raising the manufacturer discount under

the Medicare Part D coverage gap discount program to 70%. Additional legislative changes, regulatory changes and judicial challenges related to the ACA remain possible. It is unclear how the ACA and its implementation, as well as efforts to repeal or replace, or invalidate, the ACA, or portions thereof, will affect our business. It is possible that the ACA, as currently enacted or may be amended in the future, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, and new payment methodologies and in additional downward pressure on coverage and payment and the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. Moreover, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted in the United States or outside of the United States, or whether the FDA or CMS regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be.

If we participate in the MDRP and fail to comply with our reporting and payment obligations under that or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

If we participate in the MDRP, we will have certain price reporting obligations to the MDRP, and we may have obligations to report average sales price ASP figures to the Medicare program. Under the MDRP, we would be required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates would be based on pricing data reported by us on a monthly and quarterly basis to CMS. These data would include AMP and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the United States in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions.

Federal law also requires that a company that participates in the MDRP report ASP information each quarter to CMS for certain categories of drugs that are paid under Part B of the Medicare program. Manufacturers calculate ASP based on a statutorily defined formula and interpretations of the statute by CMS. CMS uses these submissions to determine payment rates for drugs under Medicare Part B and the resulting Medicare payment rate.

Federal law requires that any company that participates in the MDRP also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. The HRSA, which administers the 340B drug pricing program, issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. HRSA also has implemented a ceiling price reporting requirement, pursuant to which manufacturers must report the 340B ceiling prices for their covered outpatient drugs to HRSA on a quarterly basis.

In addition, in order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, a manufacturer also must participate in the Department of Veterans Affairs FSS pricing program, established by Section 603 of the Veterans Health Care Act of 1992. Under this program, the manufacturer is obligated to make its "covered drugs" (biologics or innovator drugs) available for procurement on an FSS contract and charge a price to four federal agencies - Department of Veterans Affairs, Department of Defense, Public Health Service and Coast Guard - that is no higher than the statutory federal ceiling price. The requirements under the 340B and FSS programs could reduce the revenue we may generate from any products that are commercialized in the future and could adversely affect our business and operating results.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by manufacturers, governmental or regulatory agencies, and the courts. The Medicaid rebate amount for each covered outpatient drug is computed each quarter based on the manufacturer's submission to CMS of its current AMP and, in the case of innovator products, best price figures, for the quarter. If we participate in the MDRP and become aware that our reporting for a prior quarter was incorrect, or has changed, we will be obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due. Such restatements and recalculations would increase our costs for complying with the laws and regulations governing the MDRP. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the ceiling price at which we would be required to offer our products to certain covered entities, such as safety-net providers, under the 340B drug pricing program, and we may be obligated to issue refunds to covered entities.

If we participate in the MDRP or our products are covered under Medicare Part B, we will be liable for errors associated with our submission of pricing data. We cannot assure you that our submissions, if we participate in these programs, will not be found by CMS to be incomplete or incorrect. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted false AMP, ASP or best price information to the government, we may be liable for civil monetary penalties per item of false information. If we are found to have made a misrepresentation in the reporting of our ASP, the Medicare statute provides for civil monetary penalties for each misrepresentation for each day in which the misrepresentation was applied. Civil monetary penalties also can be applied if we are found to have intentionally charged 340B covered entities more than the statutorily mandated ceiling price. Our failure to submit monthly/quarterly AMP, ASP and best price data on a timely basis could result in a civil monetary penalty per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we would participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs that we are able to successfully commercialize.

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

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

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

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

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

The consequences of the United Kingdom’s withdrawal from the E.U. may have a negative effect on global economic conditions, financial markets and our business.

In June 2016, a majority of voters in the United Kingdom elected to withdraw from the E.U. in a national referendum. In March 2017, the government of the United Kingdom formally initiated the withdrawal procedure. The United Kingdom left the E.U. on January 31, 2020 and is no longer an E.U. Member State. The United Kingdom and the E.U. have reached an agreement which will govern the United Kingdom's relationship with the E.U. until the end of 2020. It is uncertain low the legal relationship between the United Kingdom and the E.U. will be governed after 2020. The legal frameworks and regulatory requirements applicable to medicinal products may diverge and separate marketing authorizations and other regulatory approvals may be required to place medicinal products on the market and to manufacture, distribute, import and export medicinal products in the United Kingdom and in the E.U. These developments, or the perception that any of them could occur, have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these factors could significantly increase the complexity of our activities in the E.U. and in the United Kingdom, could depress our economic activity and restrict our access to capital, which could have a material adverse effect on our business, financial condition and results of operations and reduce the price of our securities.

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

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

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

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

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

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

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

Risks Related to Employee Matters and Managing Growth

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

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

that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2019, we had 25 full-time employees and no part-time employees, ten hold Ph.D. degrees and one is a veterinary doctor. This number consists of eight employees engaged in administration, five employees engaged in clinical and regulatory activities, five employees engaged in research and development, five employees engaged in operations (three in manufacturing and two in facility/engineering) and two employees engaged in quality and support. Two of our employees are located in our corporate headquarters in Boston, twelve of our employees are located in our Winnipeg facility, and eleven of our employees are located in our Philadelphia office. As our development and commercialization plans and strategies develop, or as a result of any future acquisitions, we will need additional managerial, operational, sales, marketing, financial and other resources. Our management, personnel and systems that are currently in place may not be adequate to support this future growth. Future growth would impose significant added responsibilities on members of management, including:

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

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

We may acquire other assets or businesses, or form collaborations or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, incur debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of assets or businesses, or strategic alliances and collaborations, to expand our existing technologies and operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any such transaction, any of which could have a detrimental effect on our financial condition, results of operations and cash flows. We may not be able to find suitable acquisition candidates, and if we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business. We may incur debt or assume unknown or contingent liabilities in connection therewith. Integration of an acquired company or assets may also disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, especially the acquisition of commercial assets, and require management resources that would otherwise focus on developing our existing business. We may not be able to find suitable collaboration partners or identify other investment opportunities, and we may experience losses related to any such investments.

To finance any acquisitions or collaborations, we may choose to issue debt or shares of our common stock as consideration. Any such issuance of shares would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other assets or companies or fund a transaction using our stock as consideration. Alternatively, it may be necessary for us to raise additional capital for acquisitions through public or private financings. Additional capital may not be available on terms that are favorable to us, or at all.

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

To manage future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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

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

Risks Related to Ownership of Our Common Stock

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

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

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

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

If we are unable to regain compliance with the listing requirements of the Nasdaq Global Market, our common stock may be delisted from the Nasdaq Global Market which could have a material adverse effect on our financial condition and could make it more difficult for you to sell your shares.

Our common stock is listed on the Nasdaq Global Market, and we are therefore subject to its continued listing requirements, including requirements with respect to the market value of publicly-held shares, market value of listed shares, minimum bid price per share, and minimum stockholders' equity, among others, and requirements relating to board and committee independence. If we fail to satisfy one or more of the requirements, we may be delisted from the Nasdaq Global Market.

On March 2, 2020, we received notice (the "Notice") from the Nasdaq Stock Market LLC ("Nasdaq") that we are not currently in compliance with the $1.00 minimum bid price requirement for continued listing on the Nasdaq Global Market, as set forth in Nasdaq Listing Rule 5450(a)(1). The Notice indicated that, consistent with Nasdaq Listing Rule 5810(c)(3)(A), we have until August 31, 2020 to regain compliance with the minimum bid price requirement by having the closing bid price of our common stock meet or exceed $1.00 per share for at least ten consecutive business days. The notification had no immediate effect on the

listing of our common stock, and our common stock will continue to trade on the Nasdaq Global Market under the symbol “SESN” at this time.

If we do not regain compliance by August 31, 2020, we may be eligible for an additional 180 calendar day grace period if we meet the continued listing requirement for market value of publicly held shares ($1.0 million) and all other Nasdaq initial listing standards which require, among other things, that we have at least $5.0 million of stockholders’ equity or at least $4.0 million of stockholders’ equity and $50.0 million market value of listed shares. If we fail to regain compliance during the applicable period, we will receive notification from Nasdaq that our common stock is subject to delisting. At that time, we may then appeal the delisting determination to a Hearings Panel. Such notification will have no immediate effect on our listing on the Nasdaq Global Market, nor will it have an immediate effect on the trading of our common stock pending such hearing. There can be no assurance, however, that we will be able to regain compliance with Nasdaq’s minimum bid price requirement. If we regain compliance with the Nasdaq’s minimum bid price requirement, there can be no assurance that we will be able to maintain compliance with the continued listing requirements for the Nasdaq Global Market or that our common stock will not be delisted from the Nasdaq Global Market in the future. In addition, we may be unable to meet other applicable listing requirements of the Nasdaq Global Market, including maintaining minimum levels of stockholders’ equity or market values of our common stock in which case, our common stock could be delisted notwithstanding our ability to demonstrate compliance with the minimum bid price requirement.

Delisting from the Nasdaq Global Market may adversely affect our ability to raise additional financing through the public or private sale of equity securities, may significantly affect the ability of investors to trade our securities and may negatively affect the value and liquidity of our common stock. Delisting also could have other negative results, including the potential loss of employee confidence, the loss of institutional investors or interest in business development opportunities.

If we are delisted from Nasdaq and we are not able to list our common stock on another exchange, our common stock could be quoted on the OTC Bulletin Board or in the “pink sheets.” As a result, we could face significant adverse consequences including, among others:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a “penny stock” which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and little or no analyst coverage for us;
- we would no longer qualify for exemptions from state securities registration requirements, which may require us to comply with applicable state securities laws; and
- a decreased ability to issue additional securities (including pursuant to short-form Registration Statements on Form S-3) or obtain additional financing in the future.

If our common stock becomes subject to the penny stock rules, it would become more difficult to trade our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not retain our listing on the Nasdaq Global Market and if the price of our common stock is less than $5.00, our common stock may be deemed a penny stock. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser’s written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stockholders may have difficulty selling their shares.

The price of our common stock has been volatile and may fluctuate in the future, which could result in substantial losses for our stockholders.

The price of our common stock is highly volatile and may be affected by developments directly affecting our business, as well as by developments out of our control or not specific to us. The pharmaceutical and biotechnology industries, in particular, and the stock market generally, are vulnerable to abrupt changes in investor sentiment. Prices of securities and trading volumes of companies in the pharmaceutical and biotechnology industries, including ours, can swing dramatically in ways unrelated to, or that bear a disproportionate relationship to, our performance. The price of our common stock and their trading volumes may fluctuate based on a number of factors including, but not limited to:

- the success of competitive products or technologies;
- results of clinical trials of Vicinium for the treatment of high-risk NMIBC or any other product candidate that we may develop;
- our ability to complete the BLA submission for Vicinium, whether or not the FDA will accept such submission and whether or not the FDA will approve Vicinium for marketing;
- if approved, the success of commercialization of Vicinium;
- results of clinical trials of, or regulatory approvals for, product candidates of our competitors;
- the success of commercialization of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key scientific or management personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional products, product candidates or technologies, the costs of commercializing any such products and the costs of development of any such product candidates or technologies;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

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

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

As of February 29, 2020, we had outstanding 109,988,768 shares of common stock. Of these shares, 4,058,596 shares are restricted securities under Rule 144 under the Securities Act of 1933, as amended ("Securities Act"). Any of our remaining shares that are not restricted securities under Rule 144 under the Securities Act may be resold in the public market without restriction unless purchased by our affiliates.

Moreover, a holder of 3,582,328 shares of our common stock issued in connection with the acquisition of Viventia has the right, subject to specified conditions, to require us to file a registration statement covering such shares or to include such shares in registration statements that we may file for ourselves or other stockholders. We have filed registration statements on April 9, 2014, March 12, 2015, March 31, 2016, May 5, 2017, May 16, 2018 (as amended on August 10, 2018), May 21, 2019 and November 14, 2019 registering all shares of common stock that we may issue under our equity compensation plans or outside of our equity compensation plans pursuant to inducement equity awards.

As of February 29, 2020, we had outstanding options to purchase an aggregate of 9,468,484 shares of our common stock with a weighted-average exercise price of $1.30, of which options to purchase 2,245,002 shares were vested; warrants to purchase 20,410,000 shares of our common stock at an exercise price of $1.47 per share; warrants to purchase 1,943,017 share of our common stock at an exercise price of $0.95 per share; warrants to purchase 486,687 shares of our common stock at an exercise price of $0.55 per share; warrants to purchase 27,500 shares of our common stock at an exercise price of $11.83 per share; and warrants to purchase 27,500 shares of our common stock at an exercise price of $11.04 per share.

Shares issuable upon exercise of these options and warrants can be freely sold in the public market upon issuance, subject to volume, notice and manner of sale limitations applicable to affiliates.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock and could impair our ability to raise capital through the sale of additional equity or equity-linked securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

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

As of December 31, 2019, we had United States federal net operating loss ("NOL") carryforwards of $160.1 million, state NOL carryforwards of $131.2 million and United States federal and state research and development credit ("R&D credit")

carryforwards of $2.2 million and $0.9 million, respectively. $118.9 million of the United States federal NOL carryforwards and $131.2 million of the state NOL carryforwards expire beginning 2030 through 2039. $41.2 million of the United States federal NOL carryforwards will be carried forward indefinitely. The United States federal and state R&D credit carryforwards expire at various dates beginning in 2027 through 2039, if not utilized. Utilization of these NOL and R&D credit carryforwards may be subject to a substantial limitation under Sections 382 and 383 of the Code and comparable provisions of state, local and foreign tax laws due to changes in ownership of our company that have occurred previously or that could occur in the future. Under Section 382 of the Code and comparable provisions of state, local and foreign tax laws, if a corporation undergoes an “ownership change,” generally defined as a greater than 50% change by value in its equity ownership over a three year period, the corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes, such as research and development tax credits, to reduce its post-change income may be limited. We have determined that it is more likely than not that our NOL and R&D credit carryforward amounts disclosed are subject to a material limitation under Section 382. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we generate taxable income, our ability to use our pre-change NOL and R&D credit carryforwards to reduce United States federal and state taxable income may be subject to limitations, which could result in increased future tax liability to us.

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

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

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

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

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

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

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

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

We are no longer an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 and, as a result, can no longer rely on exemptions from certain disclosure requirements which are available to emerging growth companies. Among other things, we are now required to comply with the auditor attestation requirements in the assessment of our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002 ("SOX 404(b)").

We were previously required to furnish only a report by our management on our internal control over financial reporting. We are now required to also include, beginning with this Annual Report on Form 10-K and included elsewhere herein, an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with SOX 404(b), we completed a process to document and evaluate our internal control over financial reporting, which was both costly and challenging. In this regard, we will continue to dedicate internal resources, potentially

engage outside consultants and adopt detailed work plans to continue to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting.

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

We are subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

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

We have never declared or paid, and for the foreseeable future do not expect to declare or pay, cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain.

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

The trading market for shares of our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. Although we have obtained analyst coverage, if one or more of the analysts who cover us downgrade shares of our common stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We lease a 31,100 square foot manufacturing, laboratory, warehouse and office facility in Winnipeg, Manitoba. We have three 15-liter fermenters, one 30-liter fermenter, one 150-liter fermenter, one 500-liter fermenter and one 1,500-liter fermenter. Our classified fermentation suite and post-production processing capabilities were dedicated to producing our pre-clinical study and clinical trial batches of Vicinium. In September 2017, we completed the manufacturing of all Vicinium necessary for our ongoing Phase 3 VISTA Trial and for our CRADA with the NCI. In conjunction with this achievement, we ended our manufacturing activities in Winnipeg and have redirected our resources toward completing the technology transfer process necessary to outsource commercial scale drug supply manufacturing in the event we obtain approval from the FDA to market Vicinium for the treatment of high-risk NMIBC. We operate our Winnipeg facility under a five-year renewable lease expiring in September 2020, and we have a right to renew the lease for one subsequent five-year term.

Our corporate headquarters is located in Cambridge, MA, where we occupy office space under a lease that was executed in October 2016. The initial term of the lease expired in July 2017, with the lease now continuing on a renewable four-month term unless terminated by either party with the requisite notice. The lease is currently extended through August 2020.

We also have office space in Philadelphia, PA, where we occupy office space under a lease executed in December 2017. The initial term of the lease expired in May 2018, which now continues on renewable six-month terms unless terminated by either party with the requisite notice. The lease has been extended through October 2020.

We believe that our existing facilities are adequate to meet our current needs and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Stock Price

Our common stock trades under the symbol "SESN" on the Nasdaq Global Market.

Holders

As of February 29, 2020, there were 31 holders of record of our common stock. This number does not include beneficial owners whose shares were held in street name.

Dividends

We have never declared or paid, and for the foreseeable future do not expect to declare or pay, cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business.

Unregistered Sales of Securities

None.

Purchases of Equity Securities by the Issuer

None.

Securities Authorized for Issuance under Equity Compensation Plans

The information required by this item regarding our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Item 6. Selected Financial Data.

The information under this item is not required to be provided by smaller reporting companies.

Item 7. 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 consolidated financial statements and related notes thereto and other financial information included elsewhere in this Annual Report on Form 10-K. In addition to historical information, some of the information contained in the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. You should review the "Risk Factors" section of this Annual Report on Form 10-K for a discussion of important factors that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a late-stage clinical company advancing targeted fusion protein therapeutics ("TFPTs") for the treatment of patients with cancer. We genetically fuse the targeting antibody fragment and the cytotoxic protein payload into a single molecule which is produced through our proprietary one-step, microbial manufacturing process. We target tumor cell surface antigens with limited expression on normal cells. Binding of the target antigen by the TFPT allows for rapid internalization into the targeted cancer cell. We have designed our targeted proteins to overcome the fundamental efficacy and safety challenges inherent in existing antibody-drug conjugates ("ADCs") where a payload is chemically attached to a targeting antibody.

Our most advanced product candidate, Vicinium, also known as VB4-845, is a locally-administered targeted fusion protein composed of an anti-epithelial cell adhesion molecule ("EpCAM") antibody fragment tethered to a truncated form of *Pseudomonas exotoxin A* for the treatment of high-risk NMIBC. On December 6, 2019, we initiated our BLA submission for Vicinium to the FDA under Rolling Review. "Rolling Review" of the BLA enables individual modules to be submitted and reviewed on an ongoing basis, rather than waiting for all sections to be completed before submission. The submission consisted of Modules 1, 2, 4 and 5, with information amendments to be submitted to these modules throughout 2020. We anticipate completing Module 3 (CMC) to finalize the BLA submission in the second half of 2020.

In August 2019, we reported updated preliminary efficacy data from our ongoing single-arm, multi-center, open-label Phase 3 clinical trial of Vicinium as a monotherapy in patients with high-risk, bacillus Calmette-Guérin ("BCG")-unresponsive NMIBC (the "VISTA Trial"). As of the May 29, 2019 data cutoff date, the data reported the preliminary complete response rates ("CRRs") in evaluable carcinoma *in situ* ("CIS") patients following three, six, nine and 12 months of treatment in the clinical trial. The results were consistent with the results observed in the previously completed Phase 1 and Phase 2 clinical trials of Vicinium for the treatment of high-risk NMIBC. The VISTA Trial completed enrollment in April 2018 with a total of 133 patients across three cohorts based on histology and time to disease recurrence after adequate BCG treatment (under 2018 FDA guidance on treatment of NMIBC, adequate BCG is defined as at least two courses of BCG with at least five doses in an initial induction course of treatment, plus at least two doses in a second course of treatment):

- Cohort 1 (n=86): Patients with CIS with or without papillary disease that recurred within six months of their last course of adequate BCG;
- Cohort 2 (n=7): Patients with CIS with or without papillary disease that was determined to be refractory or recurred after six months, but less than 11 months, after their last course of adequate BCG; and
- Cohort 3 (n=40): Patients with high-risk (Ta or T1) papillary disease without CIS that was determined to be refractory or recurred within six months of their last course of adequate BCG.

The primary endpoints of the VISTA Trial are CRR at 3 months in patients with CIS (with or without papillary disease) whose disease is BCG-unresponsive and duration of response ("DoR") for BCG-unresponsive CIS patients who experience a complete response ("CR").

As of the May 29, 2019 data cutoff date, preliminary primary and secondary endpoint data for each of the trial cohorts were as follows:

Cohort 1 (n=86) Evaluable Population (n=82) Complete Response Rate, for CIS:

Time Point	Evaluable Patients*	Complete Response Rate (95% Confidence Interval)
3-months	n=82	39% (28%-50%)
6-months	n=82	26% (17%-36%)
9-months	n=82	20% (12%-30%)
12-months	n=82	17% (10%-27%)

**Response-evaluable population includes any modified intention-to-treat ("mITT") subject who completed the induction phase.*

Cohort 2 (n=7) Evaluable Population (n=7) Complete Response Rate, for CIS:

Time Point	Evaluable Patients*	Complete Response Rate (95% Confidence Interval)
3-months	n=7	57% (18%-90%)
6-months	n=7	57% (18%-90%)
9-months	n=7	43% (10%-82%)
12-months	n=7	14% (0%-58%)

**Response-evaluable population includes any mITT subject who completed the induction phase.*

Pooled Cohorts 1 and 2 Evaluable Population (n=89) Complete Response Rate, for CIS:

Time Point	Evaluable Patients*	Complete Response Rate (95% Confidence Interval)
3-months	n=89	40% (30%-51%)
6-months	n=89	28% (19%-39%)
9-months	n=89	21% (13%-31%)
12-months	n=89	17% (10%-26%)

**Response-evaluable population includes any mITT subject who completed the induction phase.*

Phase 3 Pooled Complete Response Rate vs. Phase 2 Pooled Complete Response Rate:

Time Point	Preliminary Phase 3 Pooled CRR (95% Confidence Interval)	Phase 2 Pooled CRR (95% Confidence Interval)
3-months	40% (30%-51%)	40% (26%-56%)
6-months	28% (19%-39%)	27% (15%-42%)
9-months	21% (13%-31%)	18% (8%-32%)
12-months	17% (10%-26%)	16% (7%-30%)

Cohort 3 (n=40) Evaluable Population (n=38) Recurrence-Free Rate†:

Time Point	Evaluable Patients*	Recurrence-Free Rate (95% Confidence Interval)
3-months	n=38	71% (54%-85%)
6-months	n=38	58% (41%-74%)
9-months	n=38	45% (29%-62%)
12-months	n=38	42% (26%-59%)

†Recurrence-free rate is defined as the percentage of patients that are recurrence-free at the given assessment time point.

**Response-evaluable population includes any mITT subject who completed the induction phase.*

Duration of Response: The median DoR for patients in Cohort 1 and Cohort 2 combined (n=93) is 287 days (lower 95% confidence interval ("CI") = 154 days, upper 95% confidence interval is not estimable ("NE") due to the limited number of events occurring beyond the median), using the Kaplan-Meier method. The Kaplan-Meier method is a non-parametric statistical analysis used to estimate survival times and times to event when incomplete observations in data exist. Additional *ad hoc* analysis of pooled data for all patients with CIS (Cohorts 1 and 2, n=93) shows that among patients who achieved a complete response at 3 months, 52%

remained disease-free for a total of 12 months or longer after starting treatment, using the Kaplan-Meier method. DoR is defined as the time from first occurrence of complete response to documentation of treatment failure or death.

We have conducted additional analyses for secondary endpoints based on the May 29, 2019 data cutoff date. These additional preliminary data include the following:

- ***Time to Cystectomy:*** Across all 133 patients treated with Vicinium in the VISTA Trial, greater than 75% of all patients are estimated to remain cystectomy-free at 2.5 years, using the Kaplan-Meier method. Additional *ad hoc* analysis shows that approximately 88% of responders are estimated to remain cystectomy-free at 3 years. Time to cystectomy is defined as the time from the date of first dose of study treatment to surgical bladder removal. The first 2018 FDA guidance on treatment of BCG-unresponsive NMIBC patients states that the goal of therapy in such patients is to avoid cystectomy. Therefore, time to cystectomy is a key secondary endpoint in the VISTA Trial.
- ***Time to Disease Recurrence:*** High-grade papillary (Ta or T1) NMIBC is associated with higher rates of progression and recurrence. The median time to disease recurrence for patients in Cohort 3 (n=40) is 402 days (95% CI, 170-NE), using the Kaplan-Meier method. Time to disease recurrence is defined as the time from the date of the first dose of study treatment to the first occurrence of treatment failure or death on or prior to treatment discontinuation.
- ***Progression-Free Survival ("PFS"):*** 90% of all 133 patients treated with Vicinium in the VISTA Trial are estimated to remain progression-free for 2 years or greater, using the Kaplan-Meier method. PFS is defined as the time from the date of first dose of study treatment to the first occurrence of disease progression (e.g. T2 or more advanced disease) or death on or prior to treatment discontinuation.
- ***Event-Free Survival:*** 29% of all 133 patients treated with Vicinium in the VISTA Trial are estimated to remain event-free at 12 months, using the Kaplan-Meier method. Event-free survival is defined as the time from the date of first dose of study treatment to the first occurrence of disease recurrence, progression or death on or prior to treatment discontinuation.
- ***Overall Survival ("OS"):*** 96% of all 133 patients treated with Vicinium in the VISTA Trial are estimated to have an overall survival of 2 years or greater, using the Kaplan-Meier method. OS is defined as the time from the date of first dose of study treatment to death from any cause.

Preliminary Safety Results

As of the May 29, 2019 data cutoff date, in patients across all cohorts (n=133) of our Phase 3 VISTA Trial of Vicinium for the treatment of high-risk NMIBC, 88% experienced at least one adverse event, with 95% of adverse events being Grade 1 or 2. The most commonly reported treatment-related adverse events were dysuria (14%), hematuria (13%) and urinary tract infection (12%) - all of which are consistent with the profile of bladder cancer patients and the use of catheterization for treatment delivery. These adverse events were determined by the clinical investigators to be manageable and reversible, and only four patients (3%) discontinued treatment due to an adverse event. Serious adverse events, regardless of treatment attribution, were reported in 14% of patients. There were four treatment-related serious adverse events reported in three patients including acute kidney injury (Grade 3), pyrexia (Grade 2), cholestatic hepatitis (Grade 4) and renal failure (Grade 5). There were no age-related increases in adverse events observed in the VISTA Trial.

Other Vicinium Activity

In August 2018, we received Fast Track designation from the FDA for Vicinium for the treatment of high-risk NMIBC.

In May 2019, we met with the FDA for a Type C meeting for CMC and reached agreement with the FDA on the analytical comparability plan to be used to assess comparability between the drug supply used in clinical trials and the potential commercial drug supply to be produced by Fujifilm. We also confirmed with the FDA that, subject to final comparability data to be provided in the BLA submission, no additional clinical trials were deemed necessary to establish comparability.

In June 2019, we met with the FDA for a Type B Pre-BLA meeting regarding the approval pathway for Vicinium for the treatment of patients with high-risk, BCG-unresponsive NMIBC. At the meeting, we reached alignment with the FDA on an accelerated approval pathway for Vicinium along with Rolling Review. The FDA also indicated that the clinical data, nonclinical data, clinical pharmacology data, and the safety database were sufficient to support a BLA submission, and that no additional clinical trials were necessary for a BLA submission. Per the official FDA minutes received post-meeting, the FDA stated that the pre-licensing inspection may be completed at the time of process performance qualification manufacturing, which we believe will benefit the overall review timeline for the BLA. In addition, the FDA communicated that they expect that a meeting with the FDA's Oncologic Drugs Advisory Committee ("ODAC") will be required as part of the accelerated approval pathway. If Vicinium receives marketing approval for treatment of NMIBC, a post-marketing confirmatory trial will also be required.

In November 2019, we met with the FDA for a Type C meeting to discuss the details of a post-marketing confirmatory trial for Vicinium for the treatment of high-risk NMIBC. At that meeting, we reached agreement with the FDA that the post-marketing

confirmatory trial for Vicinium will enroll BCG-refractory patients who have received less-than-adequate BCG, which is especially important in light of the ongoing BCG shortage. This represents a broader patient population than the BCG-intolerant population originally proposed. We anticipate that, if Vicinium is approved by the FDA, the initial indication will be for BCG-unresponsive patients who have received adequate BCG. If the post-marketing confirmatory trial is successful, it could result in an expanded label to include this additional population of patients who have received less-than-adequate BCG.

On December 4, 2019, we met with the FDA for a Type B pre-BLA meeting for CMC. At that meeting, we reached agreement with the FDA on the final content for Module 3 (CMC) of the BLA.

On December 6, 2019, we initiated our BLA submission for Vicinium to the FDA under Rolling Review. The submission consisted of Modules 1, 2, 4 and 5, with information amendments to be submitted to these modules throughout 2020. We anticipate completing Module 3 (CMC) to finalize the BLA submission in the second half of 2020.

Manufacturing

In October 2018, we entered into a Master Bioprocessing Services Agreement with Fujifilm (the "Fujifilm MSA") for the manufacturing process and technology transfer of Vicinium drug substance production. In April 2019, the first full, commercial-scale cGMP run was completed at Fujifilm. Full quality release testing has been completed and all Phase 3 release specifications were met, supporting Fujifilm’s ability to produce the bulk drug substance form of Vicinium for commercial purposes if we receive regulatory approval to market Vicinium for the treatment of high-risk NMIBC.

Joint Development

In June 2017, we entered into a Cooperative Research and Development Agreement ("CRADA") with the National Cancer Institute ("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-risk NMIBC to evaluate the safety, efficacy and biological correlates of Vicinium in combination with durvalumab. This Phase 1 clinical trial is open and is actively recruiting patients.

Vicinium has also been evaluated for the treatment of squamous cell carcinoma of the head and neck ("SCCHN"). Vicinium for the treatment of SCCHN had previously been designated as Proxinium™ to indicate its different fill volume and vial size as well as its different route for local administration via intratumoral injection. In addition to our locally-administered TFPTs, our pipeline also includes systemically-administered TFPTs that are built around our proprietary de-immunized variant of the plant-derived cytotoxin bouganin ("deBouganin"). One of these product candidates, VB6-845d, is a TFPT consisting of an EpCAM-targeting fragment antigen binding domain ("Fab") genetically linked to deBouganin, a novel plant derived cytotoxic payload that we have optimized for minimal immunogenic potential and is administered by intravenous infusion. 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-risk NMIBC. We are also exploring collaborations for Vicinium for the treatment of SCCHN and for VB6-845d.

We maintain global development, marketing and commercialization rights for all of our TFPT-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-risk NMIBC, we intend to build a North American specialty urology sales force to market the product in the United States and Canada. Outside the United States and Canada, we will seek commercialization partners with urology expertise. We also own or exclusively license worldwide intellectual property rights for all of our TFPT-based product candidates, covering our key patents with protection into 2036.

License Agreement with Roche

In June 2016, we entered into the License Agreement with Roche, pursuant to which we granted Roche an exclusive, worldwide license, including the right to sublicense, to our patent rights and know-how related to our monoclonal antibody EBI-031 and all other IL-6 anti-IL antagonist monoclonal antibody technology owned by us (collectively, the "Licensed Intellectual Property"). Under the License Agreement, Roche is required to continue developing, at its cost, EBI-031 and any other product made from the Licensed Intellectual Property that contains an IL-6 antagonist anti-IL monoclonal antibody ("Licensed Product") and pursue ongoing patent prosecution, 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.

Through December 31, 2019, we have received a total of $30.0 million in payments from Roche pursuant to the License Agreement, including a $7.5 million upfront payment in August 2016 and a $22.5 million milestone payment in September 2016 as a result of the investigational new drug ("IND") application for EBI-031 becoming effective. We are also entitled to receive up to an additional $240.0 million upon the achievement of other specified regulatory, development and commercial milestones, as well as royalty payments in accordance with a tiered royalty rate scale, with rates ranging from 7.5% to 15% of net sales of potential future products containing EBI-031 and up to 50% of these rates for net sales of potential future products containing other IL-6 compounds, with each of the royalties subject to reduction under certain circumstances and to the buy-out options of Roche.

Liquidity and Going Concern

As of December 31, 2019, we had cash and cash equivalents of $48.1 million, net working capital (current assets less current liabilities) of $45.9 million and an accumulated deficit of $293.5 million. The Company incurred negative cash flows from operating activities of $37.5 million, $22.8 million and $17.8 million for the years ended December 31, 2019, 2018 and 2017, respectively. Since our inception, we have received no revenue from sales of our products, and we anticipate that operating losses will continue for the foreseeable future as we continue our ongoing Phase 3 VISTA Trial of Vicinium for the treatment of high-risk NMIBC and seek marketing approval from the FDA. We have financed our operations to date primarily through private placements of our common stock, preferred stock, common stock warrants and convertible bridge notes, venture debt borrowings, our initial public offering ("IPO"), follow-on public offerings, sales effected in "at-the-market" ("ATM") offerings, our License Agreement with Roche and, to a lesser extent, from a collaboration.

Under Accounting Standards Codification Topic 205-40, *Presentation of Financial Statements - Going Concern*, we are required at each reporting period to evaluate whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of our plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists, we evaluate whether the mitigating effect of our plans sufficiently alleviates the substantial doubt about our ability to continue as a going concern. The mitigating effect of our plans, however, is only considered if both (i) it is probable that our plans will be effectively implemented within one year after the date that our financial statements are issued and (ii) it is probable that our plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about our ability to continue as a going concern within one year after the date that our financial statements are issued. Generally, to be considered probable of being effectively implemented, our plans must have been approved by our board of directors before the date that our financial statements are issued.

Our future success is dependent on our ability to develop our product candidates, including Vicinium for the treatment of high-risk NMIBC, and ultimately upon our ability to attain profitable operations. In order to commercialize our product candidates, including Vicinium for the treatment of high-risk NMIBC, we need to complete clinical development and comply with comprehensive regulatory requirements. We are subject to a number of risks similar to other late-stage clinical companies, including, but not limited to, successful discovery and development of our product candidates, raising additional capital, development and commercialization by our competitors of new technological innovations, protection of proprietary technology and market acceptance of our products. The successful discovery and development of product candidates, including Vicinium for the treatment of high-risk NMIBC, requires substantial working capital, and we expect to seek additional funds through equity or debt financings or through additional collaboration, licensing transactions or other sources. We may be unable to obtain equity or debt financings or enter into additional collaboration or licensing transactions at favorable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include liens or other restrictive covenants limiting 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, strategic collaborations and alliances or licensing 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. If we are unable to raise additional funds when needed, we may be required to implement cost reduction strategies and 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. In December 2019 an outbreak of a novel strain of coronavirus (COVID-19) was identified in Wuhan, China. This virus continues to spread globally, has been declared a pandemic by the World Health Organization and has spread to over 100 countries, including the United States. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to businesses and capital markets around the world. We are proactively executing risk mitigation strategies to attenuate the impact of COVID-19 on us, and at this time, we have not yet experienced any business disruptions as a result of the pandemic.

We do not believe that our cash and cash equivalents of $48.1 million as of December 31, 2019 is sufficient to fund our current operating plan for at least twelve months after the issuance of our consolidated financial statements. Based on our current operating plan, we anticipate having sufficient cash to fund our operations into 2021; however, we have based this estimate on assumptions that may prove to be wrong, and our capital resources may be utilized faster than we currently expect. Given our history of significant losses, negative cash flows from operations, limited cash resources currently on hand and dependence on our ability - about which there can be no certainty - to obtain additional financing to fund our operations after the current cash resources are exhausted, substantial doubt exists about our ability to continue as a going concern. The consolidated financial statements beginning on page F-1 of this Annual Report on Form 10-K were prepared under the assumption that we will continue as a going concern and do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Components of Our Results of Operations

Research and Development

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 share-based compensation expense;
- expenses incurred under agreements with contract research organizations ("CROs") and investigative sites that conduct our clinical trials;
- expenses associated with developing manufacturing capabilities and manufacturing clinical study materials;
- expenses associated with transferring manufacturing capabilities to contract manufacturing organizations ("CMOs") for commercial-scale production;
- facilities, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, and other supplies; and
- expenses associated with pre-clinical and regulatory activities.

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

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

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

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

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 and technology transfer, 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-risk NMIBC 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 high-risk NMIBC. We expect our research and development expenses for Vicinium for the treatment of high-risk 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 (in thousands):

	Year ended December 31,		
	2019	**2018**	**2017**
Programs:			
Vicinium for the treatment of high-risk NMIBC	$ 16,023	$ 8,942	$ 6,974
Total direct program expenses	16,023	8,942	6,974
Personnel and other expenses:			
Employee and contractor-related expenses	6,513	3,913	3,871
Platform-related lab expenses	513	250	455
Facility expenses	442	363	398
Other expenses	1,172	609	812
Total personnel and other expenses	8,640	5,135	5,536
Total Research and Development	**$ 24,663**	**$ 14,077**	**$ 12,510**

General and Administrative

General and administrative expenses consist primarily of salaries and related costs for personnel, including share-based compensation, in executive, operational, finance, business development and human resource functions. Other general and administrative expenses include facility-related costs, professional fees for legal, patent, consulting and accounting services, commercial market research and United States pre-launch market readiness.

Change in Fair Value of Contingent Consideration

In connection with the Viventia Acquisition 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 and are based on regulatory approval in certain markets and future revenue levels. The fair value of contingent consideration is assessed at each balance sheet date and changes, if any, to the fair value are recognized in earnings (or loss) for the period.

Other Income, Net

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

Results of Operations

Comparison of the Years ended December 31, 2019 and 2018

	Year ended December 31,		Increase/(Decrease)	
	2019	2018	Dollars	Percentage
	(in thousands, except percentages)			
Operating expenses:				
Research and development	$ 24,663	$ 14,077	$ 10,586	75%
General and administrative	12,208	11,623	585	5%
Change in fair value of contingent consideration	71,620	8,800	62,820	714%
Total operating expenses	108,491	34,500	73,991	214%
Loss from Operations	(108,491)	(34,500)	(73,991)	214%
Other income (expense):				
Other income, net	991	807	184	23%
Net Loss and Comprehensive Loss	**$ (107,500)**	**$ (33,693)**	**$ (73,807)**	**219%**

Research and Development

Research and development expenses were $24.7 million for the year ended December 31, 2019 compared to $14.1 million for the year ended December 31, 2018. The increase of $10.6 million was due primarily to increased costs associated with technology transfer and manufacturing scale-up for commercial supply, professional fees in support of regulatory activities and employee-related compensation, partially offset by lower clinical trial expenses as a result of our Phase 3 VISTA trial winding down.

General and Administrative

General and administrative expenses were $12.2 million for the year ended December 31, 2019 compared to $11.6 million for the year ended December 31, 2018. The increase of $0.6 million was due primarily to increases in employee-related compensation and professional and audit fees, partially offset by lower external legal fees and commercial expenses.

Change in Fair Value of Contingent Consideration

The non-cash change in fair value of contingent consideration was $71.6 million for the year ended December 31, 2019 compared to $8.8 million for the year ended December 31, 2018. The change in fair value of $71.6 million for the year ended December 31, 2019 was primarily driven by second and fourth quarter of 2019 events. During the second quarter of 2019, we reassessed the total addressable global market for NMIBC and determined that both the global market size and estimated potential Vicinium commercial net sales within the global NMIBC market were likely higher than our previous estimates. Specific drivers of the increased revenue estimates include our expectations that Vicinium for the treatment of high-risk NMIBC could achieve peak market penetration earlier than previously estimated and that Vicinium sales outside the United States could be two to three times our expected sales volumes in the United States, resulting in a $44.0 million increase in the estimated fair value of contingent consideration. The $25.0 million increase in the estimated fair value of contingent consideration during the fourth quarter of 2019 was primarily attributable to increases in our assumptions for both the estimated United States market share for Vicinium for the treatment of high-risk NMIBC, if approved, and the probability of success for achieving marketing approval by the FDA, based on expert commentary from a December 2019 public hearing of the FDA's Oncologic Drugs Advisory Committee during a review a competitor's product. As contingent consideration incorporates a royalty rate of 2% on all commercial net sales reported through December 2033, any increase in expected future net sales correlates to an increase in the estimated fair value of our contingent consideration liability. Changes in forecast assumptions, including the probability of regulatory approvals and Vicinium pricing and sales volumes, as well as changes in the discount rate utilized based on prevailing market conditions, could result in materially different fair value estimates.

The non-cash change in fair value of contingent consideration of $8.8 million for the year ended December 31, 2018 was primarily attributable to changes in discount rates and assumptions related to the development and commercialization timelines and estimated sales projections.

Other income, net

Other income, net was $1.0 million for the year ended December 31, 2019 compared to $0.8 million for the year ended December 31, 2018. The change of $0.2 million was due primarily to the increase in interest income on higher cash balances as a result of the equity financing completed in June 2019.

Comparison of the Years ended December 31, 2018 and 2017

For a comparison of our results of operations for the years ended December 31, 2018 and 2017, see "Part II - Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the United States Securities and Exchange Commission ("SEC") on March 1, 2019.

Liquidity and Capital Resources

Overview

As of December 31, 2019, we had cash and cash equivalents of $48.1 million, net working capital of $45.9 million and an accumulated deficit of $293.5 million. We incurred negative cash flows from operating activities of $37.5 million, $22.8 million and $17.8 million for the years ended December 31, 2019, 2018 and 2017, respectively. Since our inception, we have received no revenue from sales of our products, and we anticipate that operating losses will continue for the foreseeable future as we continue our ongoing Phase 3 VISTA Trial of Vicinium for the treatment of high-risk NMIBC and seek marketing approval from the FDA. We have financed our operations to date primarily through private placements of our common stock, preferred stock, common stock warrants and convertible bridge notes, venture debt borrowings, our IPO, follow-on public offerings, sales effected in ATM offerings, our License Agreement with Roche and, to a lesser extent, from a collaboration.

In November 2019, we entered into an Open Market Sale Agreement [SM] (the "Sales Agreement") with Jefferies LLC ("Jefferies"), under which we may issue and sell shares of our common stock from time to time for an aggregate sales price of up to $35.0 million through Jefferies (the "ATM Offering"). Sales of common stock under the Sales Agreement are made by any method that is deemed to be an ATM offering as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended, including but not limited to sales made directly on or through the Nasdaq Global Market or any other existing trading market for our common stock. We have no obligation to sell any of our common stock and may at any time suspend offers under the Sales Agreement or terminate the Sales Agreement. Subject to the terms and conditions of the Sales Agreement, Jefferies will use its commercially reasonable efforts to sell common stock from time to time, as the sales agent, based upon our instructions, which include a prohibition on sales below a floor of $1.00 per share. We have provided Jefferies with customary indemnification rights, and Jefferies is entitled to a commission at a fixed rate equal to 3.0% of the gross proceeds for each sale of common stock. We incurred $0.2 million in legal, accounting and printing costs related to the Prospectus Supplement filed with the SEC in connection with the ATM Offering. Through December 31, 2019, we raised $1.9 million of net proceeds from the sale of 2.1 million shares of common stock under the ATM Offering.

In October 2019, we entered into transactions with holders of our outstanding 2018 Warrants and 2017 Warrants to modify certain provisions of their warrant agreements, specifically to provide lower exercise prices and anti-dilution protections in exchange for waiving a prohibition on variable rate transactions. As a result, some holders of each class exercised their warrants under Warrant Exercise Agreements, which lowered the per share exercise prices for the 2018 Warrants from $1.20 to $0.60 and for the 2017 Warrants from $0.80 to $0.55, in exchange for immediate exercise. As a result of the Warrant Exercise Agreements, we received proceeds of $2.0 million during the fourth quarter of 2019. Unrelated to the Warrant Exercise Agreements, there were additional exercises by the holders of 2018 Warrants and 2017 Warrants during the second quarter of 2019, resulting in proceeds of $3.5 million. During the year ended December 31, 2019, we received aggregate proceeds of $5.5 million from the exercises of 5.3 million 2018 Warrants and 1.5 million 2017 Warrants.

In June 2019, we raised $27.8 million of net proceeds from the sale of 20.4 million shares of common stock and accompanying warrants to purchase an additional 20.4 million shares of common stock in an underwritten public offering (the "June 2019 Financing").

We do not believe that our cash and cash equivalents of $48.1 million as of December 31, 2019 is sufficient to fund our current operating plan for at least twelve months after the issuance of our consolidated financial statements. Based on our current operating plan, we anticipate having sufficient cash to fund our operations into 2021; however, we have based this estimate on assumptions that may prove to be wrong, and our capital resources may be utilized faster than we currently expect. Given our history of significant losses, negative cash flows from operations, limited cash resources currently on hand and dependence on our ability - about which there can be no certainty - to obtain additional financing to fund our operations after the current cash resources are exhausted, substantial doubt exists about our ability to continue as a going concern. The consolidated financial statements beginning on page F-1 of this Annual Report on Form 10-K were prepared under the assumption that we will continue as a going concern and do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

In December 2019 an outbreak of a novel strain of coronavirus (COVID-19) was identified in Wuhan, China. This virus continues to spread globally, has been declared a pandemic by the World Health Organization and has spread to over 100 countries, including

the United States. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to businesses and capital markets around the world. We are proactively executing risk mitigation strategies to attenuate the impact of COVID-19 on us, and at this time, we have not yet experienced any business disruptions as a result of the pandemic.

Funding Requirements

Our future success is dependent on our ability to develop our product candidates, including Vicinium for the treatment of high-risk NMIBC, and ultimately upon our ability to attain profitable operations. In order to commercialize our product candidates, including Vicinium for the treatment of high-risk NMIBC, we need to complete clinical development and comply with comprehensive regulatory requirements. We are subject to a number of risks similar to other late-stage clinical companies, including, but not limited to, successful discovery and development of our product candidates, raising additional capital, development and commercialization by our competitors of new technological innovations, protection of proprietary technology and market acceptance of our products. The successful discovery and development of product candidates, including Vicinium for the treatment of high-risk NMIBC, requires substantial working capital, and we expect to seek additional funds through equity or debt financings or through additional collaboration, licensing transactions or other sources. We may be unable to obtain equity or debt financings or enter into additional collaboration or licensing transactions at favorable terms, or at all, and, if necessary, we may be required to implement cost reduction strategies.

We will incur substantial expenses if and as we:

- continue our Phase 3 VISTA Trial for Vicinium for the treatment of high-risk NMIBC;
- seek marketing approvals for Vicinium for the treatment of high-risk NMIBC;
- establish sales, marketing and distribution capabilities and scale up and validate external manufacturing capabilities (including completing the manufacturing process and technology transfer to any third-party manufacturers) to commercialize Vicinium for the treatment of high-risk NMIBC, if approved;
- 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;
- expand our operational, financial and management systems and personnel;
- conduct research and pre-clinical and clinical development of Vicinium for the treatment of high-risk NMIBC and our other product candidates;
- seek to discover and develop additional product candidates; and
- in-license or acquire the rights to other products, product candidates or technologies.

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 Vicinium for the treatment of high-risk NMIBC and our other product candidates;
- the cost and timing of any new clinical trials or studies of Vicinium for the treatment of high-risk NMIBC;
- our ability to establish collaborations or licensing arrangements 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, including those associated with the manufacturing process and technology transfer to third-party manufacturers to facilitate such commercial-scale manufacturing of Vicinium;
- the costs and timing of establishing sales, marketing and distribution capabilities for Vicinium for the treatment of high-risk NMIBC, if approved;
- 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 for Vicinium for the treatment of high-risk NMIBC, 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 to perform;
- 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 Vicinium for the treatment of high-risk NMIBC, if approved.

Until such time, if ever, as we can generate substantial product revenues from commercial sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or other third-party funding, strategic collaborations and alliances, and licensing arrangements. We do not have any committed external source of funds other than the amounts payable

under the License Agreement with Roche. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include liens or other restrictive covenants limiting 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, strategic collaborations and alliances or licensing 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 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.

Cash Flows

The following table sets forth a summary of our cash flows for the years ended December 31, 2019, 2018 and 2017 (in thousands):

	Year ended December 31,		
	2019	**2018**	**2017**
Net Cash Used in Operating Activities	$ (37,521)	$ (22,829)	$ (17,765)
Net Cash (Used in) Provided by Investing Activities	(136)	(2)	98
Net Cash Provided by Financing Activities	35,356	58,583	7,005
Net Increase in Cash, Cash Equivalents and Restricted Cash	**$ (2,301)**	**$ 35,752**	**$ (10,662)**

Net Cash Used in Operating Activities

Net cash used in operating activities was $37.5 million for the year ended December 31, 2019 and consisted primarily of a net loss of $107.5 million, adjusted for non-cash items, including deprecation of $0.2 million, share-based compensation of $1.2 million, a change in the fair value of the contingent consideration of $71.6 million and a net decrease in operating assets and liabilities of $3.1 million.

Net cash used in operating activities was $22.8 million for the year ended December 31, 2018 and consisted primarily of a net loss of $33.7 million, adjusted for non-cash items, including depreciation of $0.2 million, share-based compensation of $1.3 million, a change in the fair value of the contingent consideration of $8.8 million and a net increase in operating assets and liabilities of $0.6 million.

Net cash used in operating activities was $17.8 million for the year ended December 31, 2017 and consisted primarily of a net loss of $29.0 million, adjusted for non-cash items, including depreciation of $0.3 million, share-based compensation of $1.4 million, a change in the fair value of contingent consideration of $9.1 million and a net increase in operating assets and liabilities of $0.6 million.

Net Cash (Used in) Provided by Investing activities

Net cash (used in) provided by investing activities consisted of de minimis purchases and sales or property and equipment during each of the years ended December 31, 2019, 2018 and 2017.

Net Cash Provided by Financing activities

Net cash provided by financing activities was $35.4 million for the year ended December 31, 2019 and consisted primarily of $27.8 million in net proceeds from our June 2019 Financing, $5.5 million from the exercise of outstanding warrants to purchase our common stock and $1.9 million in net proceeds from our ATM Offering.

Net cash provided by financing activities was $58.6 million for the year ended December 31, 2018 and consisted primarily of $51.0 million in net proceeds from our March 2018 and June 2018 financings and $7.3 million from the exercise of outstanding warrants to purchase our common stock.

Net cash provided by financing activities was $7.0 million for the year ended December 31, 2017 and consisted primarily of $6.9 million in net proceeds from our November 2017 financing.

Critical Accounting Policies and Use of Estimates

The preparation of our consolidated financial statements in accordance with GAAP and the rules and regulations of the SEC require the use of estimates and assumptions, based on complex judgments considered reasonable, and affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. Our critical accounting policies are those policies which require the most significant judgments and estimates in the preparation of our consolidated financial statements. Management has determined

that our most critical accounting policies are those relating to the fair value of intangible assets, goodwill and contingent consideration; income taxes (including the valuation allowance for deferred tax assets); research and development expenses; and going concern considerations.

Indefinite-Lived Intangible Assets

Our intangible assets consist of indefinite-lived, acquired in-process research and development ("IPR&D") worldwide product rights to Vicinium as a result of the Viventia Acquisition in 2016. IPR&D assets acquired in a business combination are considered indefinite-lived until the completion or abandonment of the associated research and development efforts. Amortization over the estimated useful life will commence at the time of Vicinium's launch in the respective markets, if approved. If regulatory approval to market Vicinium for the treatment of high-risk NMIBC is not obtained, we will immediately expense the related capitalized cost.

Indefinite-lived intangible assets are quantitatively tested for impairment at least annually during the fourth quarter of the fiscal year, or more often if indicators of impairment are present. Impairment testing of indefinite-lived intangible assets requires management to estimate the future discounted cash flows of an asset using assumptions believed to be reasonable, but which are unpredictable and inherently uncertain. Actual future cash flows may differ from the estimates used in impairment testing. We recognize an impairment loss when and to the extent that the estimated fair value of an intangible asset is less than its carrying value. In addition, on a quarterly basis, we perform a qualitative review of our business operations to determine whether events or changes in circumstances have occurred which could indicate that the carrying value of our intangible assets was not recoverable. Based on the annual testing and quarterly reviews performed, we concluded that the carrying value of our intangible assets was not impaired as of December 31, 2019 and 2018.

Goodwill

Goodwill on our consolidated balance sheet is the result of the Viventia Acquisition in September 2016 and represents the difference between the purchase price and the fair value of the identifiable tangible and intangible net assets acquired under the acquisition method of accounting. Goodwill is not amortized; rather than recording periodic amortization, goodwill is quantitatively tested for impairment at least annually during the fourth quarter of the fiscal year, or more often if indicators of impairment are present. Impairment testing of goodwill requires management to estimate the future discounted cash flows of a reporting unit using assumptions believed to be reasonable, but which are unpredictable and inherently uncertain. Actual future cash flows may differ from the estimates used in impairment testing. If the fair value of the equity of a reporting unit exceeds the reporting unit’s carrying value, including goodwill, then goodwill is considered not to be impaired. We recognize a goodwill impairment when and to the extent that the fair value of the equity of a reporting unit is less than the reporting unit's carrying value, including goodwill. We have only one reporting unit. In addition, on a quarterly basis, we perform a qualitative review of our business operations to determine whether events or changes in circumstances have occurred which could have a material adverse effect on the estimated fair value of each reporting unit and thus indicate a potential impairment of the goodwill carrying value. Based on the annual testing and quarterly reviews performed, we concluded that there was no goodwill impairment during the years ended December 31, 2019, 2018 and 2017.

Contingent Consideration

Contingent consideration on our consolidated balance sheet is the result of the Viventia Acquisition in September 2016 and represents the discounted present value of future launch milestones and net sales royalties due to the Selling Shareholders pursuant to the Share Purchase Agreement. For additional information, see "Note 1. Description of Business" in our consolidated financial statements, which begin on page F-1 of this Annual Report on Form 10-K. Contingent consideration is measured at its estimated fair value on a recurring basis at each reporting period, with fluctuations in value resulting in a non-cash charge to earnings (or loss) during the period. The estimated fair value measurement is based on significant unobservable inputs (Level 3 within the fair value hierarchy), including internally developed financial forecasts, probabilities of success and timing of certain milestone events and achievements, which are unpredictable and inherently uncertain. Actual future cash flows may differ from the assumptions used to estimate the fair value of contingent consideration. The valuation of contingent consideration requires the use of significant assumptions and judgments, which management believes are consistent with those that would be made by a market participant. Management reviews its assumptions and judgments on an ongoing basis as additional market and other data is obtained, and any future changes in the assumptions and judgments utilized by management may cause the estimated fair value of contingent consideration to fluctuate materially, resulting in earnings volatility.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and net operating loss ("NOL") and research and development credit ("R&D credit") carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change

in tax rates is recognized in operations in the period that includes the enactment date. A valuation allowance is recorded to the extent it is more likely than not that some portion or all of the deferred tax assets will not be realized.

Unrecognized income tax benefits represent income tax positions taken on income tax returns that have not been recognized in the financial statements. We recognize the benefit of an income tax position only if it is more likely than not (greater than 50%) that the tax position will be sustained upon tax examination, based solely on the technical merits of the tax position. Otherwise, no benefit is recognized. The tax benefits recognized are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. We recognize accrued interest and penalties related to uncertain tax positions as income tax expense in our consolidated statements of operations. As of December 31, 2019 and 2018, we did not have any uncertain tax positions.

Research and Development Costs

Research and development activities are expensed in the period incurred. Research and development expenses consist of both internal and external costs associated with all basic research activities, clinical development activities and technical efforts required to develop a product candidate. Internal research and development consist primarily of personnel costs, including salaries, benefits and share-based compensation, facilities leases, research-related overhead, pre-approval regulatory and clinical trial costs, manufacturing and other contracted services, license fees and other external costs.

In certain circumstances, we are required to make advance payments to vendors for goods or services that will be received in the future for use in research and development activities. In such circumstances, the advance payments are recorded as prepaid assets and expensed when the activity has been performed or when the goods have been received.

Recently Issued Accounting Standards

Recently issued accounting standards are discussed in "Part IV - Item 15. Exhibits and Financial Statements - Notes to Consolidated Financial Statements - Note 4. Recent Accounting Pronouncements" in our consolidated financial statements, which begin on page F-1 of this Annual Report on Form 10-K.

Commitments and Contractual Obligations

The information generally required by this item regarding our commitments and contractual obligations is not required to be provided by smaller reporting companies.

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 SEC.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

The information under this item is not required to be provided by smaller reporting companies.

Item 8. Financial Statements and Supplementary Data.

Our consolidated financial statements, together with the report of our independent registered public accounting firm, appear in the Index to Financial Statements beginning on page F-1 of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

There has been no change of accountants nor any disagreements with accountants on any matter of accounting principles or practices or financial disclosure required to be reported under this Item.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

We maintain disclosure controls and procedures, as defined in Exchange Act Rules 13a-15(f) and 15d-15(e), that are designed to ensure information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principle financial officer, to allow timely decisions regarding required disclosure. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are achieved. Further, the design of a control system must be balanced against resource constraints, and therefore, the benefits of controls must be considered relative to their costs. Given the inherent limitations in all systems of controls, no evaluation of controls can provide absolute assurance all control issues and instances of fraud, if any, within a company have been detected. These inherent limitations include the realities that judgments in decision making can be faulty and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions or the degree of compliance with the policies and procedures may deteriorate. Accordingly, given the inherent limitations in a cost-effective system of controls, financial statement misstatements due to error or fraud may occur and may not be detected. Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance of achieving their objectives. We conduct periodic evaluations of our system of controls to enhance, where necessary, our control policies 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 the end of the period covered by this Annual Report on Form 10-K. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2019.

Remediation of Previously Identified Material Weakness

We previously reported a material weakness, initially identified in 2016, in our controls over the financial reporting process related to business combinations. As a result of inexperience in our finance and accounting group related to the accounting for business combinations, we lacked sufficient review of the assumptions used and conclusions reached related to the projections of financial information used to value the intangible assets and goodwill for the 2016 Viventia Acquisition.

In October 2017, John J. McCabe resigned as our Chief Financial Officer, and Richard F. Fitzgerald was appointed our Chief Financial Officer in January 2018. Mr. Fitzgerald brought to us significant technical accounting knowledge and experience which he utilized to implement new processes and controls over the course of 2018 and until his departure in August 2019, which improvements have continued under Monica Forbes since her promotion from our Vice President of Finance to our Chief Financial Officer in August 2019, in order to remediate the identified material weakness.

Although we have not entered into any business combination transactions since September 2016, the annual impairment testing required for our in-process research and development intangible assets and goodwill resulting from the Viventia Acquisition necessitates similar valuation processes and controls. For example, both require the development of sophisticated long-range cash flow forecasts, by market and appropriately adjusted for the probability of success, which include but are not limited to: (i) revenues from product sales and/or royalties; (ii) expenses, including costs of goods sold, research and development, general and administrative and sales and marketing; (iii) expectations of long-term effective tax rates; (iv) consideration of capital expenditures which may be required in order to achieve revenue; and (v) working capital requirements. The resulting forecasts are then subjected to a discounted cash flow analysis in order to arrive at an estimate of fair value.

For the Company's annual impairment test performed as of October 1, 2019, cash flow forecasts were prepared and reviewed by individuals hired by the Company in 2019 that have significant prior work experience with financial planning and analysis. Based management's assessment, we have concluded that our disclosure controls and procedures were designed and operating effectively as of December 31, 2019 and, therefore, the previously identified material weakness was remediated.

Management Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting ("ICFR"), as defined in Exchange Act Rules 13a-15(f) and 15d-15(e), to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. ICFR includes our policies and procedures, such as our Code of Conduct, which (i) require our employees, officers and directors to adhere to certain ethical standards; (ii) require the maintenance of records, in reasonable detail, to help to ensure that our transactions, assets and liabilities are accurately and fairly recorded; (iii) provide reasonable assurance that transactions are authorized by our management and directors and are recorded as necessary to allow for the accurate preparation of financial statements in accordance with GAAP;

and (iv) provide reasonable assurance regarding the safeguarding of our assets and the prevention or timely detection of the unauthorized acquisition, use or disposition of our assets, which could have a material effect on the financial statements. ICFR includes the controls themselves, management's monitoring of those controls, actions taken to correct any deficiencies identified and oversight of our internal control environment by the audit committee of our board of directors. Any system of internal control has inherent limitations and therefore may not prevent or detect misstatements. Projections of any evaluation of the effectiveness of ICFR to future periods are subject to the risk that controls may become inadequate over time because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our ICFR as of the end of our fiscal year 2019 and has reviewed the results of this assessment with the audit committee of our board of directors. Management based its assessment on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management concluded that our ICFR was effective as of December 31, 2019 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP.

The effectiveness of our ICFR as of December 31, 2019 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included immediately below.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Sesen Bio, Inc.

Opinion on Internal Control over Financial Reporting

We have audited Sesen Bio, Inc.'s internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Sesen Bio, Inc. (the "Company") maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' (deficit) equity, and cash flows for each of the three years in the period ended December 31, 2019, and the related notes and our report dated March 16, 2020 expressed an unqualified opinion thereon that included an explanatory paragraph regarding the Company's ability to continue as a going concern.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, 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.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 16, 2020

Changes in Internal Control over Financial Reporting

Except as described above under *Remediation of Previously Identified Material Weakness*, during the quarter ended December 31, 2019, there were no changes in our ICFR, as defined in Exchange Act Rules 13a-15(f) and 15d-15(e), which materially affected, or are reasonably likely to materially affect, our ICFR.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Code of Conduct

Our Board has adopted a written Code of Business Conduct and Ethics applicable to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions. The Code of Business Conduct and Ethics covers fundamental ethical and compliance-related principles and practices such as accurate accounting records and financial reporting, avoiding conflicts of interest, the protection and use of our property and information and compliance with legal and regulatory requirements. A current copy of the code is posted on the Corporate Governance section of our website, which is located at www.sesenbio.com. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding any substantive amendment to, or waiver from, a provision of this Code and by posting such information on the website address and location specified above.

The additional information required by this item will be set forth in our 2020 Proxy Statement to be filed with the SEC within 120 days of December 31, 2019 and is incorporated by reference into this Annual Report on Form 10-K.

Item 11. Executive Compensation.

The information required by this item will be set forth in our 2020 Proxy Statement to be filed with the SEC within 120 days of December 31, 2019 and is incorporated by reference into this Annual Report on Form 10-K.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item will be set forth in our 2020 Proxy Statement to be filed with the SEC within 120 days of December 31, 2019 and is incorporated by reference into this Annual Report on Form 10-K.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be set forth in our 2020 Proxy Statement to be filed with the SEC within 120 days of December 31, 2019 and is incorporated by reference into this Annual Report on Form 10-K.

Item 14. Principal Accountant Fees and Services.

The information required by this item will be set forth in our 2020 Proxy Statement to be filed with the SEC within 120 days of December 31, 2019 and is incorporated by reference into this Annual Report on Form 10-K.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)(1) Consolidated Financial Statements

The consolidated financial statements listed in the Index to Financial Statements beginning on page F-1 are filed as part of this Annual Report on Form 10-K.

(a)(2) Financial Statement Schedules

The financial statement schedule listed in the Index to Financial Statements on page F-1 is filed as part of this Annual Report on Form 10-K.

(a)(3) Exhibits

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

Exhibit Index

Exhibit No.	Description
2.1	Share Purchase Agreement, effective as of September 20, 2016, by and between Eleven Biotherapeutics, Inc., Viventia Bio Inc. and Clairmark Investments Ltd., as representative of the selling shareholders (we hereby agree to furnish supplementally a copy of any omitted schedules to the SEC upon request). Incorporated herein by reference to Exhibit 2.1 to our Current Report on Form 8-K filed on September 21, 2016 (File No. 001-36296).
3.1	Restated Certificate of Incorporation of Eleven Biotherapeutics, Inc. Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed on February 18, 2014 (File No. 001-36296).
3.2	Amended and Restated By-laws of Eleven Biotherapeutics, Inc. Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed on April 16, 2015 (File No. 001-36296).
3.3	Certificate of Amendment of Certificate of Incorporation. Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed on May 17, 2018 (File No. 001-36296).
3.4	Amendment to Amended and Restated By-laws. Incorporated by reference to Exhibit 3.2 to our Current Report on Form 8-K filed on May 17, 2018 (File No. 001-36296).
4.0*	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.
4.1	Specimen Stock Certificate evidencing the shares of common stock. Incorporated by reference to Exhibit 4.1 to our Registration Statement on Form S-1/A filed on January 23, 2014 (Reg. No. 333-193131).
4.2	Registration Rights Agreement, dated as of September 20, 2016 by and among Eleven Biotherapeutics, Inc. and the shareholders named therein. Incorporated herein by reference to Exhibit 4.1 to our Current Report on Form 8-K filed on September 21, 2016 (File No. 001-36296).
4.3	Form of Warrant to Purchase Common Stock, by and between Eleven Biotherapeutics, Inc. and the persons party thereto. Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed on December 1, 2014 (File No. 001-36296).
4.4	Form of Warrant issued to Silicon Valley Bank and Life Science Loans, LLC dated November 25, 2014. Incorporated by reference to Exhibit 10.23 to our Registration Statement on Form S-1 filed with the SEC on December 19, 2014 (Reg. No. 333-201176).
4.5	Form of Common Warrant. Incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed with the SEC on November 3, 2017 (File. No. 001-36296).
4.6	Form of Warrant. Incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed with the SEC on March 23, 2018 (File. No. 001-36296).
4.7	Form of Common Stock Purchase Warrant. Incorporated herein by reference to Exhibit 4.1 to our Current Report on Form 8-K filed with the SEC on June 19, 2019 (File. No. 001-36296).
4.8	Form of 2017 Warrant Amendment Agreement. Incorporated by reference to Exhibit 4.2 to our Current Report on Form 8-K filed October 29, 2019 (File No. 001-36296).
4.9	Form of 2018 Warrant Amendment Agreement. Incorporated by reference to Exhibit 4.4 to our Current Report on Form 8-K filed October 29, 2019 (File No. 001-36296).
10.1+	Amended and Restated 2009 Stock Incentive Plan. Incorporated by reference to Exhibit 10.1 to our Registration Statement on Form S-1 filed on December 30, 2013 (Reg. No. 333-193131).

10.2+	Form of Incentive Stock Option Agreement under the Amended and Restated 2009 Stock Incentive Plan. Incorporated by reference to Exhibit 10.2 to our Registration Statement on Form S-1 filed on December 30, 2013 (Reg. No. 333-193131).
10.3+	Form of Non-statutory Stock Option Agreement under the Amended and Restated 2009 Stock Incentive Plan. Incorporated by reference to Exhibit 10.3 to our Registration Statement on Form S-1 filed on December 30, 2013 (Reg. No. 333-193131).
10.4+	Form of Restricted Stock Agreement under the Amended and Restated 2009 Stock Incentive Plan. Incorporated by reference to Exhibit 10.4 to our Registration Statement on Form S-1 filed on December 30, 2013 (Reg. No. 333-193131).
10.5+	2014 Stock Incentive Plan, as amended. Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on June 25, 2019 (File No. 001-36296).
10.6+	Form of Incentive Stock Option Agreement under 2014 Stock Incentive Plan. Incorporated by reference to Exhibit 10.6 to our Registration Statement on Form S-1/A filed on January 23, 2014 (Reg. No. 333-193131).
10.7+	Form of Non-statutory Stock Option Agreement under 2014 Stock Incentive Plan. Incorporated by reference to Exhibit 10.7 to our Registration Statement on Form S-1/A filed on January 23, 2014 (Reg. No. 333-193131).
10.8+	Form of Restricted Stock Unit Agreement under 2014 Stock Incentive Plan. Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on June 29, 2015 (File No. 001-36296).
10.9*	Form of Indemnification Agreement by and between Sesen Bio, Inc. and Each of its Directors and Executive Officers.
10.10+	2014 Employee Stock Purchase Plan. Incorporated by reference to Exhibit 10.13 to our Registration Statement on Form S-1/A filed with the SEC on January 23, 2014 (Reg. No. 333-193131).
10.11†	License Agreement, dated as of June 10, 2016, by and among Eleven Biotherapeutics, Inc., F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. Incorporated herein by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q filed on August 12, 2016 (File No. 001-36296).
10.12†	License Agreement, effective January 13, 2003, as amended and restated on October 14, 2015, by and between The University of Zurich and Viventia Bio Inc. Incorporated herein by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on September 21, 2016 (File No. 001-36296).
10.13†	Non-Exclusive Product License Agreement, effective as of October 18, 2005, by and between Micromet AG and Viventia Biotech Inc. Incorporated herein by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q filed on November 9, 2018 (File No. 001-36296).
10.14†	Non-Exclusive License Agreement, effective as of November 30, 2001, by and between XOMA Ireland Limited and Viventia Biotech Inc. Incorporated herein by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q filed on November 9, 2018 (File No. 001-36296).
10.15	Indenture, dated March 31, 2000, between 131-149 Hamelin Street Leaseholds Limited (successor in interest of Almad Investments Limited) and Viventia Bio Inc. (successor in interest of Viventia Biotech Inc.), as amended by Lease Amending Agreement, dated June 26, 2003, as further amended by Lease Amending Agreement, dated January 26, 2004, and as further amended by Letter Agreement, dated June 25, 2008, and as further amended by Lease Amending Agreement, September 16, 2015. Incorporated herein by reference to Exhibit 10.4 to our Current Report on Form 8-K filed on September 21, 2016 (File No. 001-36296).
10.16+	Employment Agreement, dated August 7, 2018, by and between Sesen Bio, Inc. and Thomas R. Cannell. Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on August 13, 2018 (File No. 001-36296).
10.17	Form of Securities Purchase Agreement. Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on March 23, 2018 (File. No. 001-36296).
10.18	Amendment to Securities Purchase Agreement, dated October 28, 2019, by and among Sesen Bio, Inc. and the undersigned parties thereto. Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed October 29, 2019 (File No. 001-36296).
10.19+	Stock Option Award Agreement, dated August 7, 2018, by and between Sesen Bio, Inc. and Thomas R. Cannell, D.V.M. Incorporated by reference to Exhibit 10.32 to our Annual Report on Form 10-K filed on March 1, 2019 (File. No. 001-36296).

10.20†	Master Bioprocessing Services Agreement, dated October 4, 2018, between Sesen Bio, Inc. and FUJIFILM Diosynth Biotechnologies U.S.A., Inc. Incorporated by reference to Exhibit 10.34 to our Annual Report on Form 10-K filed on March 1, 2019 (File. No. 001-36296).
10.21+	Employment Agreement, dated September 20, 2016, by and between Eleven Biotherapeutics, Inc. and Glen Macdonald, as amended on February 21, 2017. Incorporated herein by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q filed on May 10, 2019 (File No. 001-36296).
10.22+	Employment Agreement, dated August 26, 2019, by and between Monica Forbes and Sesen Bio, Inc. Incorporated herein by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on August 26, 2019 (File No. 001-36296).
10.23+	Employment Agreement, dated July 26, 2019, by and between Mark R. Sullivan and Sesen Bio, Inc. Incorporated herein by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q filed on November 12, 2019 (File No. 001-36296).
10.24+	Stock Option Award Agreement, dated August 1, 2019, by and between Sesen Bio, Inc. and Monica Forbes. Incorporated herein by reference to Exhibit 10.3 to our Quarterly Report on Form 10-Q filed on November 12, 2019 (File No. 001-36296).
21.1*	Subsidiaries of Sesen Bio, Inc.
23.1*	Consent of Ernst & Young LLP.
31.1*	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of the Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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.

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

† Portions of this exhibit have been omitted in compliance with Item 601 of Regulation S-K.

Item 16. Form 10-K Summary.

Not applicable.

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.
(Registrant)

Date: March 16, 2020

By: /s/ Thomas R. Cannell, D.V.M.
Name: Thomas R. Cannell, D.V.M.
Title: President and Chief Executive Officer
(Principal Executive Officer and Duly Authorized Officer)

Pursuant to the requirements of the Securities and Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Capacity	Date
/s/ Thomas R. Cannell, D.V.M. Thomas R. Cannell, D.V.M.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 16, 2020
/s/ Monica Forbes Monica Forbes	Chief Financial Officer (Principal Financial Officer)	March 16, 2020
/s/ Kirstin Anderson Kirstin Anderson	Corporate Controller (Principal Accounting Officer)	March 16, 2020
/s/ Jay S. Duker, M.D. Jay S. Duker, M.D.	Chair of the Board of Directors	March 16, 2020
/s/ Carrie L. Bourdow Carrie L. Bourdow	Director	March 16, 2020
/s/ Jane V. Henderson Jane V. Henderson	Director	March 16, 2020
/s/ Jason A. Keyes Jason A. Keyes	Director	March 16, 2020
/s/ Daniel S. Lynch Daniel S. Lynch	Director	March 16, 2020

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Sesen Bio, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Sesen Bio, Inc. (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' (deficit) equity and cash flows for each of the three years in the period ended December 31, 2019, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 16, 2020 expressed an unqualified opinion thereon.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company will require additional capital to fund its current operating plan and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2010.

Boston, Massachusetts
March 16, 2020

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

	December 31,	
	2019	**2018**
Assets		
Current assets:		
Cash and cash equivalents	$ 48,121	$ 50,422
Prepaid expenses and other current assets	6,326	1,334
Total current assets	54,447	51,756
Restricted cash	20	20
Property and equipment, net	238	321
Intangibles	46,400	46,400
Goodwill	13,064	13,064
Other assets	196	—
Total Assets	**$ 114,365**	**$ 111,561**
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	$ 1,902	$ 1,367
Accrued expenses	6,169	4,746
Other current liabilities	446	—
Total current liabilities	8,517	6,113
Contingent consideration	120,020	48,400
Deferred tax liability	12,528	12,528
Other liabilities	—	313
Total Liabilities	141,065	67,354
Commitments and contingencies		
Stockholders' (Deficit) Equity:		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized at December 31, 2019 and 2018; no shares issued and outstanding at December 31, 2019 and 2018	—	—
Common stock, $0.001 par value per share; 200,000,000 shares authorized at December 31, 2019 and 2018; 106,801,409 and 77,456,180 shares issued and outstanding at December 31, 2019 and 2018, respectively	107	77
Additional paid-in capital	266,717	230,154
Accumulated deficit	(293,524)	(186,024)
Total Stockholders' (Deficit) Equity	(26,700)	44,207
Total Liabilities and Stockholders' (Deficit) Equity	**$ 114,365**	**$ 111,561**

The accompanying notes are an integral part of these consolidated financial statements.

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

	Year ended December 31,		
	2019	**2018**	**2017**
Revenue:			
License revenue	$ —	$ —	$ 425
Total revenue	—	—	425
Operating expenses:			
Research and development	24,663	14,077	12,510
General and administrative	12,208	11,623	8,070
Change in fair value of contingent consideration	71,620	8,800	9,100
Total operating expenses	108,491	34,500	29,680
Loss from Operations	(108,491)	(34,500)	(29,255)
Other income (expense):			
Other income, net	991	807	226
Net Loss and Comprehensive Loss	**$ (107,500)**	**$ (33,693)**	**$ (29,029)**
Net loss per common share - basic and diluted	$ (1.18)	$ (0.55)	$ (1.11)
Weighted-average common shares outstanding - basic and diluted	90,929	61,774	26,105

The accompanying notes are an integral part of these consolidated financial statements.

SESEN BIO, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' (DEFICIT) EQUITY
(In thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' (Deficit) Equity
	Shares	Amount			
Balance at December 31, 2016	24,531,964	$ 25	$ 161,963	$ (123,311)	$ 38,677
Cumulative effect of adoption of ASU 2016-09	—	—	(9)	9	—
Net loss	—	—	—	(29,029)	(29,029)
Share-based compensation	—	—	1,381	—	1,381
Exercises of stock options and vesting of restricted stock awards	161,453	—	40	—	40
Sales of common stock under 2014 ESPP	9,148	—	12	—	12
Issuance of common stock and common stock warrants, net of issuance costs of $1,047	5,525,000	6	6,902	—	6,908
Exercises of pre-funded common stock warrants	4,475,000	4	41	—	45
Balance at December 31, 2017	34,702,565	35	170,330	(152,331)	18,034
Net loss	—	—	—	(33,693)	(33,693)
Share-based compensation	—	—	1,283	—	1,283
Exercises of stock options and vestings of restricted stock awards	443,443	—	277	—	277
Sales of common stock under 2014 ESPP	20,992	—	20	—	20
Issuance of common stock and common stock warrants, net of issuance costs of $5,029	33,523,684	33	50,938	—	50,971
Exercises of common stock warrants	8,765,496	9	7,306	—	7,315
Balance at December 31, 2018	77,456,180	77	230,154	(186,024)	44,207
Net loss	—	—	—	(107,500)	(107,500)
Share-based compensation	—	—	1,237	—	1,237
Exercises of stock options	89,812	—	98	—	98
Sales of common stock under 2014 ESPP	10,283	—	8	—	8
Issuance of common stock and common stock warrants, net of issuance costs of $2,171	20,410,000	21	27,812	—	27,833
Exercises of common stock warrants	6,772,928	7	5,474	—	5,481
Issuance of common stock under ATM Offering, net of issuance costs of $212	2,062,206	2	1,934	—	1,936
Balance at December 31, 2019	**106,801,409**	**$ 107**	**$ 266,717**	**$ (293,524)**	**$ (26,700)**

The accompanying notes are an integral part of these consolidated financial statements.

SESEN BIO, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year ended December 31,		
	2019	**2018**	**2017**
Cash Flows from Operating Activities:			
Net loss	$ (107,500)	$ (33,693)	$ (29,029)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	219	208	285
Share-based compensation	1,237	1,283	1,381
Change in fair value of contingent consideration	71,620	8,800	9,100
Gain on sale of equipment	—	(5)	(108)
Other	—	—	(5)
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(5,188)	(913)	164
Accounts payable	535	460	(760)
Accrued expenses and other liabilities	1,556	1,031	1,746
Deferred revenue	—	—	(425)
Due to related party	—	—	(114)
Net Cash Used in Operating Activities	**(37,521)**	**(22,829)**	**(17,765)**
Cash Flows from Investing Activities:			
(Purchases) sales of property and equipment	(136)	(2)	98
Net Cash (Used in) Provided by Investing Activities	**(136)**	**(2)**	**98**
Cash Flows from Financing Activities:			
Proceeds from issuance of common stock and common stock warrants, net of issuance costs	27,833	50,971	6,908
Proceeds from exercises of common stock warrants	5,481	7,315	45
Proceeds from issuance of common stock under ATM Offering, net of issuance costs	1,936	—	—
Proceeds from exercises of stock options	98	277	40
Proceeds from sales of common stock under 2014 ESPP	8	20	12
Net Cash Provided by Financing Activities	**35,356**	**58,583**	**7,005**
Net (Decrease) Increase in Cash, Cash Equivalents and Restricted Cash	(2,301)	35,752	(10,662)
Cash, Cash Equivalents and Restricted Cash - Beginning of Period	50,442	14,690	25,352
Cash, Cash Equivalents and Restricted Cash - End of Period	**$ 48,141**	**$ 50,442**	**$ 14,690**
Supplemental disclosure of non-cash operating activities:			
Right-of-use assets related to the adoption of ASC 842	$ 236	$ —	$ —
Cash paid for amounts included in the measurement of lease liabilities	$ 153	$ —	$ —
Supplemental disclosure of non-cash investing activities:			
Adjustment to fair value of assets acquired and liabilities assumed in acquisition during provisional period	$ —	$ —	$ 14,600
Supplemental disclosure of non-cash financing activities:			
Issuance of pre-funded warrants to purchase common stock	$ —	$ —	$ 2,679

The accompanying notes are an integral part of these consolidated financial statements.

1. DESCRIPTION OF BUSINESS

Sesen Bio, Inc. ("Sesen" or the "Company"), a Delaware corporation formed in February 2008, is a late-stage clinical company developing targeted fusion protein therapeutics ("TFPTs") for the treatment of patients with cancer. The Company's most advanced product candidate, Vicinium®, also known as VB4-845, is a locally-administered targeted fusion protein composed of an anti-epithelial cell adhesion molecule ("EpCAM") antibody fragment tethered to a truncated form of *Pseudomonas exotoxin A*. The Company has an ongoing single-arm, multi-center, open-label Phase 3 clinical trial of Vicinium as a monotherapy in patients with high-risk, bacillus Calmette-Guérin ("BCG")-unresponsive non-muscle invasive bladder cancer ("NMIBC") (the "VISTA Trial"). The VISTA Trial completed enrollment in April 2018 with a total of 133 patients, and in December 2019, the Company initiated submission of the Biologics License Application ("BLA") for Vicinium to the United States Food and Drug Administration ("FDA") under Rolling Review, which enables individual modules to be submitted and reviewed on an ongoing basis, rather than waiting for all sections to be completed before submission. The Company operates in one segment under the direction of its Chief Executive Officer (chief operating decision maker). The Company was formerly known as Eleven Biotherapeutics, Inc. until its name changed in May 2018.

Viventia Acquisition

In September 2016, the Company entered into a Share Purchase Agreement with Viventia Bio, Inc., a corporation incorporated under the laws of the Province of Ontario, Canada ("Viventia"), the shareholders of Viventia named therein (the "Selling Shareholders") and, solely in its capacity as seller representative, Clairmark Investments Ltd., a corporation incorporated under the laws of the Province of Ontario, Canada ("Clairmark") (the "Share Purchase Agreement"), pursuant to which the Company agreed to and simultaneously completed the acquisition of all of the outstanding capital stock of Viventia from the Selling Shareholders (the "Viventia Acquisition"). In connection with the closing of the Viventia Acquisition, the Company issued 4.0 million shares of its common stock to the Selling Shareholders, which at that time represented approximately 19.9% of the voting power of the Company as of immediately prior to the issuance of such shares. Clairmark is an affiliate of Leslie L. Dan, a director of the Company until his retirement in July 2019.

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

Liquidity and Going Concern

As of December 31, 2019, the Company had cash and cash equivalents of $48.1 million, net working capital of $45.9 million and an accumulated deficit of $293.5 million. The Company incurred negative cash flows from operating activities of $37.5 million, $22.8 million and $17.8 million for the years ended December 31, 2019, 2018 and 2017, respectively. Since its inception, the Company has received no revenue from sales of its products, and management anticipates that operating losses will continue for the foreseeable future as the Company continues its ongoing Phase 3 VISTA Trial of Vicinium for the treatment of high-risk NMIBC and seeks marketing approval from the FDA. The Company has financed its operations to date primarily through private placements of its common stock, preferred stock, common stock warrants and convertible bridge notes, venture debt borrowings, its initial public offering ("IPO"), follow-on public offerings, sales effected in an "at-the-market" ("ATM") offerings, a License Agreement with F. Hoffmann-La Roche Ltd and Hoffman-La Roche Inc. (collectively, "Roche") (the "License Agreement with Roche") and,

to a lesser extent, from a collaboration. See “Note 10. Stockholders’ Equity” below for information regarding the Company’s recently completed equity financings.

Under Accounting Standards Codification ("ASC") Topic 205-40, *Presentation of Financial Statements - Going Concern*, management is required at each reporting period to evaluate whether there are conditions and events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists, management evaluates whether the mitigating effect of its plans sufficiently alleviates the substantial doubt about the Company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (i) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued and (ii) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. Generally, to be considered probable of being effectively implemented, the plans must have been approved by the Company's board of directors before the date that the financial statements are issued.

The Company's future success is dependent on its ability to develop its product candidates, including Vicinium for the treatment of high-risk NMIBC, and ultimately upon its ability to attain profitable operations. In order to commercialize its product candidates, including Vicinium for the treatment of high-risk NMIBC, 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 late-stage clinical companies, including, but not limited to, successful discovery and development of its product candidates, raising additional capital, development and commercialization by its competitors of new technological innovations, protection of proprietary technology and market acceptance of its products. The successful discovery and development of product candidates, including Vicinium for the treatment of high-risk NMIBC, requires substantial working capital, and 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 at favorable terms, or at all. To the extent that the Company raises additional capital through the sale of equity or convertible debt securities, the ownership interests of existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include liens or other restrictive covenants limiting the Company's ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If the Company raises additional funds through government or other third-party funding, strategic collaborations and alliances or licensing arrangements, it may have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable. If the Company is unable to raise additional funds when needed, it may be required to implement cost reduction strategies and delay, limit, reduce or terminate its product development or future commercialization efforts or grant rights to develop and market products or product candidates that management would otherwise prefer to develop and market.

The Company's management does not believe that its cash and cash equivalents of $48.1 million as of December 31, 2019 is sufficient to fund the Company's current operating plan for at least twelve months after the issuance of these consolidated financial statements. Given the history of significant losses, negative cash flows from operations, limited cash resources currently on hand and dependence by the Company on its ability - about which there can be no certainty - to obtain additional financing to fund its operations after the current cash resources are exhausted, substantial doubt exists about the Company's ability to continue as a going concern. These consolidated financial statements were prepared under the assumption that the Company will continue as a going concern and do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

2. BASIS OF PRESENTATION

The accompanying financial statements have been prepared in accordance with United States generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the ASC and Accounting Standards Updates ("ASUs"), promulgated by the Financial Accounting Standards Board ("FASB").

Use of Estimates

The preparation of financial statements in accordance with GAAP and the rules and regulations of the United States Securities and Exchange Commission ("SEC") requires the use of estimates and assumptions, based on judgments considered reasonable, which affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The Company bases its

estimates and assumptions on historical experience, known trends and events and various other factors that management believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Although management believes its estimates and assumptions are reasonable when made, they are based upon information available at the time they are made. Management evaluates the estimates and assumptions on an ongoing basis and, if necessary, makes adjustments. Due to the risks and uncertainties involved in the Company's business and evolving market conditions, and given the subjective element of the estimates and assumptions made, actual results may differ from estimated results. The most significant estimates and judgments impact the fair value of intangible assets, goodwill and contingent consideration; income taxes (including the valuation allowance for deferred tax assets); research and development expenses; and going concern considerations.

Principles of Consolidation

The Company's consolidated financial statements include the accounts of the Company, its wholly owned subsidiary Viventia and its indirect subsidiaries, Viventia Bio USA Inc. and Viventia Biotech (EU) Limited. All intercompany transactions and balances have been eliminated in consolidation.

Foreign Currency Translation

The functional currency of the Company and each of its subsidiaries is the U.S. dollar.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Cash, Cash Equivalents and Concentration of Credit Risk

The Company's cash is held on deposit in demand accounts at a large financial institution in amounts in excess of the Federal Deposit Insurance Corporation ("FDIC") insurance coverage limit of $250,000 per depositor, per FDIC-insured bank, per ownership category. Restricted cash represents cash held by the Company's primary commercial bank to collateralize the credit limit on the Company's corporate credit card. The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. Financial instruments that potentially subject the Company to credit risk principally consists of cash equivalents. As of December 31, 2019 and 2018, the Company limited its credit risk associated with cash equivalents by placing investments in highly-rated money market funds.

Property and Equipment

Property and equipment are recorded at cost. Maintenance and repairs are charged to expense as incurred, and costs of improvements and renewals are capitalized. Depreciation is recognized using the straight-line method over the estimated useful lives of the relative assets. The Company uses an estimated useful life of five years for lab equipment, four years for furniture and fixtures, three years for computer equipment and software and the lesser of five years or the remaining lease term for leasehold improvements.

Impairment of Long-Lived Assets

Long-lived assets, such as property and equipment, are tested for impairment when events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. Impairment testing of long-lived assets requires management to estimate the future net undiscounted cash flows of an asset using assumptions believed to be reasonable. Actual cash flows may differ from the estimates used in the impairment testing. If such assets are considered to be impaired, the Company recognizes an impairment loss when and to the extent that the estimated fair value of an asset is less than its carrying value. The Company did not recognize any impairment charges during the years ended December 31, 2019 and 2018. The Company recognized a de minimis amount of impairment charges in the year ended December 31, 2017 related to the strategic restructuring of the Company in August 2017.

Indefinite-Lived Intangible Assets

The Company's intangible assets consist of indefinite-lived, acquired in-process research and development ("IPR&D") worldwide product rights to Vicinium as a result of the Viventia Acquisition in 2016. IPR&D assets acquired in a business combination are considered indefinite-lived until the completion or abandonment of the associated research and development efforts. Amortization over the estimated useful life will commence at the time of Vicinium's launch in the respective markets, if approved. If regulatory approval to market Vicinium for the treatment of high-risk NMIBC is not obtained, the Company will immediately expense the related capitalized cost.

Indefinite-lived intangible assets are quantitatively tested for impairment at least annually during the fourth quarter of the fiscal year, or more often if indicators of impairment are present. Impairment testing of indefinite-lived intangible assets requires management to estimate the future discounted cash flows of an asset using assumptions believed to be reasonable, but which are unpredictable and inherently uncertain. Actual future cash flows may differ from the estimates used in impairment testing. The Company recognizes an impairment loss when and to the extent that the estimated fair value of an intangible asset is less than its carrying value. In addition, on a quarterly basis, the Company performs a qualitative review of its business operations to determine

whether events or changes in circumstances have occurred which could indicate that the carrying value of its intangible assets was not recoverable. Based on the annual testing and quarterly reviews performed, the Company concluded that the carrying value of its intangible assets was not impaired as of December 31, 2019 and 2018.

Goodwill

Goodwill on the Company's consolidated balance sheet is the result of the Viventia Acquisition in September 2016 and represents the difference between the purchase price and the fair value of the identifiable tangible and intangible net assets acquired under the acquisition method of accounting. Goodwill is not amortized; rather than recording periodic amortization, goodwill is quantitatively tested for impairment at least annually during the fourth quarter of the fiscal year, or more often if indicators of impairment are present. Impairment testing of goodwill requires management to estimate the future discounted cash flows of a reporting unit using assumptions believed to be reasonable, but which are unpredictable and inherently uncertain. Actual future cash flows may differ from the estimates used in impairment testing. If the fair value of the equity of a reporting unit exceeds the reporting unit’s carrying value, including goodwill, then goodwill is considered not to be impaired. The Company recognizes a goodwill impairment when and to the extent that the fair value of the equity of a reporting unit is less than the reporting unit's carrying value, including goodwill. The Company has only one reporting unit. In addition, on a quarterly basis, the Company performs a qualitative review of its business operations to determine whether events or changes in circumstances have occurred which could have a material adverse effect on the estimated fair value of each reporting unit and thus indicate a potential impairment of the goodwill carrying value. Based on the annual testing and quarterly reviews performed, the Company concluded that there was no goodwill impairment during the years ended December 31, 2019, 2018 and 2017.

Contingent Consideration

Contingent consideration on the Company's consolidated balance sheet is the result of the Viventia Acquisition in September 2016 and represents the discounted present value of future launch milestones and net sales royalties due to the Selling Shareholders pursuant to the Share Purchase Agreement. See "Note 1. Description of Business" for additional information. Contingent consideration is measured at its estimated fair value on a recurring basis at each reporting period, with fluctuations in value resulting in a non-cash charge to earnings (or loss) during the period. The estimated fair value measurement is based on significant unobservable inputs (Level 3 within the fair value hierarchy), including internally developed financial forecasts, probabilities of success and timing of certain milestone events and achievements, which are unpredictable and inherently uncertain. Actual future cash flows may differ from the assumptions used to estimate the fair value of contingent consideration. The valuation of contingent consideration requires the use of significant assumptions and judgments, which management believes are consistent with those that would be made by a market participant. Management reviews its assumptions and judgments on an ongoing basis as additional market and other data is obtained, and any future changes in the assumptions and judgments utilized by management may cause the estimated fair value of contingent consideration to fluctuate materially, resulting in earnings volatility.

Leases

Effective January 1, 2019, the Company adopted ASC Topic 842, *Leases* (“ASC 842”) using the optional transition method outlined in ASU No. 2018-11, *Leases (Topic 842), Targeted Improvements*. The adoption of ASC 842 represents a change in accounting principle that aims to increase transparency and comparability among organizations by requiring the recognition of right-of-use assets and lease liabilities on the balance sheet for both operating and finance leases. In addition, the standard requires enhanced disclosures that meet the objective of enabling financial statement users to assess the amount, timing and uncertainty of cash flows arising from leases. The reported results for the year ended December 31, 2019 reflect the application of ASC 842 guidance, while the reported results for priors were prepared in accordance with the previous ASC Topic 840, *Leases* ("ASC 840") guidance. The adoption of ASC 842 resulted in the recognition of operating lease right-of-use assets and corresponding lease liabilities of $0.2 million on the Company’s consolidated balance sheet as of January 1, 2019. The adoption of this guidance did not have a material impact on the Company’s financial condition, results of operations or cash flows; however, the adoption did result in significant changes to the Company’s financial statement disclosures.

As part of the adoption of ASC 842, the Company utilized certain practical expedients outlined in the guidance. These practical expedients include:

- Accounting policy election to use the short-term lease exception by asset class;
- Election of the practical expedient package during transition, which includes:
  - An entity need not reassess whether any expired or existing contracts are or contain leases;
  - An entity need not reassess the classification for any expired or existing leases. As a result, all leases that were classified as operating leases in accordance with ASC 840 are classified as operating leases under ASC 842, and all leases that were classified as capital leases in accordance with ASC 840 are classified as finance leases under ASC 842; and

- An entity need not reassess initial direct costs for any existing leases.

The Company's lease portfolio as of the adoption date includes: a property lease for its manufacturing facility, a property lease for its headquarters in Cambridge, MA, and a property lease for office space in Philadelphia, PA. The Company determines if an arrangement is a lease at the inception of the contract and has made a policy election to not separate out non-lease components from lease components, for all classes of underlying assets. The asset components of the Company's operating leases are recorded as operating lease right-of-use assets and reported within other assets on the Company's consolidated balance sheet. The short-term and long-term liability components are recorded in other current liabilities and other liabilities, respectively, on the Company's consolidated balance sheet. As of December 31, 2019, the Company did not have any finance leases.

Right-of-use assets and operating lease liabilities are recognized based on the present value of lease payments over the lease term at the commencement date. Existing leases in the Company's lease portfolio as of the adoption date were valued as of January 1, 2019. The Company uses an incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments, if an implicit rate of return is not provided with the lease contract. Operating lease right-of-use assets are adjusted for incentives received.

Operating lease costs are recognized on a straight-line basis over the lease term, in accordance with ASC 842, and also include variable operating costs incurred during the period. Lease costs also include amounts related to short-term leases.

Research and Development Costs

Research and development activities are expensed in the period incurred. Research and development expenses consist of both internal and external costs associated with all basic research activities, clinical development activities and technical efforts required to develop a product candidate. Internal research and development consist primarily of personnel costs, including salaries, benefits and share-based compensation, facilities leases, research-related overhead, pre-approval regulatory and clinical trial costs, manufacturing and other contracted services, license fees and other external costs.

In certain circumstances, the Company is required to make advance payments to vendors for goods or services that will be received in the future for use in research and development activities. In such circumstances, the advance payments are recorded as prepaid assets and expensed when the activity has been performed or when the goods have been received.

Share-Based Compensation

The Company recognizes the grant-date fair value of share-based awards granted as compensation as expense on a straight-line basis over the requisite service period, which is generally the vesting period of the award. To date, the Company has not issued awards where vesting is subject to market conditions. From time to time, the Company has granted to its executives stock option awards which contain both performance-based and service-based vesting criteria. Performance milestone events were specific to the Company's corporate goals, including certain clinical development objectives related to the VISTA Trial, as well as a past financing objective. Share-based compensation expense associated with performance-based vesting criteria is recognized using the accelerated attribution method if the performance condition is considered probable of achievement in management's judgment. The fair value of stock options is estimated at the time of grant using the Black-Scholes option pricing model, which requires the use of inputs and assumptions such as the fair value of the underlying stock, exercise price of the option, expected term, risk-free interest rate, expected volatility and dividend yield.

The fair value of each grant of options during the years ended December 31, 2019, 2018 and 2017 was determined using the following methods and assumptions:

- *Expected Term.* Due to the lack of historical exercise data and given the plain vanilla nature of the options granted by the Company, the expected term is determined using the "simplified" method, as prescribed in SEC Staff Accounting Bulletin ("SAB") No. 107 ("SAB 107"), whereby the expected life equals the arithmetic average of the vesting term (generally four years) and the original contractual term (ten years) of the option, taking into consideration multiple vesting tranches.
- *Risk-Free Interest Rate.* The risk-free rate is based on the interest rate payable on United States Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected term.
- *Expected Volatility.* The expected volatility is based on historical volatilities of a representative group of publicly traded biopharmaceutical companies which were commensurate with the assumed expected term, as prescribed in SAB 107.
- *Dividend Yield.* The dividend yield is 0% because the Company has never declared or paid, and for the foreseeable future does not expect to declare or pay, a dividend on its common stock.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and net operating loss ("NOL") and research and development credit ("R&D credit") carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. A valuation allowance is recorded to the extent it is more likely than not that some portion or all of the deferred tax assets will not be realized.

Unrecognized income tax benefits represent income tax positions taken on income tax returns that have not been recognized in the financial statements. The Company recognizes the benefit of an income tax position only if it is more likely than not (greater than 50%) that the tax position will be sustained upon tax examination, based solely on the technical merits of the tax position. Otherwise, no benefit is recognized. The tax benefits recognized are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. The Company recognizes accrued interest and penalties related to uncertain tax positions as income tax expense in its consolidated statements of operations. As of December 31, 2019 and 2018, the Company did not have any uncertain tax positions.

Revenue Recognition

The Company has never received revenue from sales of its products. The Company has entered into the License Agreement with Roche, as discussed in "Note 15. License Agreements," pursuant to which the Company received upfront and development milestone payments in the third quarter of 2016 and may receive in the future additional development milestone payments and sales-based royalties. The Company recognizes revenue resulting from license agreements in accordance with ASC Topic 606, *Revenue* ("ASC 606"), which was effective for public companies on January 1, 2018. The Company adopted ASC 606 using the modified retrospective approach, and there was no resulting cumulative effect adjustment to opening accumulated deficit.

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, including 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 each performance obligation is satisfied. The Company only recognizes revenue under the five-step model when collectability of payment is reasonably assured.

The Company neither received nor earned any additional development milestones or sales-based royalty payments from Roche during the years ended December 31, 2019, 2018 and 2017. During the first quarter of 2017, the Company transferred its remaining pre-clinical inventory to Roche and, upon completion of its final performance obligation, recognized $0.4 million of deferred revenue remaining from the upfront milestone payment received in August 2016.

4. RECENT ACCOUNTING PRONOUNCEMENTS

Adopted in 2019

In January 2017, the FASB issued ASU No. 2017-04, *Simplifying the Test for Goodwill Impairmen*t ("ASU 2017-04"). ASU 2017-04 simplifies the accounting for goodwill impairment by removing Step 2 of the goodwill impairment test, which requires a hypothetical purchase price allocation. ASU 2017-04 is effective for annual or interim goodwill impairment tests in fiscal years beginning after December 15, 2019, and should be applied on a prospective basis. Early adoption is permitted, the Company adopted this guidance effective January 1, 2019, and it did not have a material impact on the Company’s financial position, results of operations or cash flows.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* (“ASU 2018-07”). ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees, and as a result, the accounting for share-based payments to non-employees will be substantially aligned. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. The Company adopted this guidance effective January 1, 2019, and it did not have a material impact on the Company’s financial position, results of operations or cash flows.

In July 2018, the FASB issued ASU No. 2018-09, *Codification Improvements* (“ASU 2018-09”). ASU 2018-09 provides amendments to a wide variety of topics in the FASB’s ASC, which applies to all reporting entities within the scope of the affected accounting guidance. The transition and effective date guidance are based on the facts and circumstances of each amendment.

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

Some of the amendments in ASU 2018-09 do not require transition guidance and were effective upon the issuance of ASU 2018-09. However, many of the amendments do have transition guidance with effective dates for annual periods beginning after December 15, 2018. The Company adopted this guidance effective January 1, 2019, and it did not have a material impact on the Company's financial position, results of operations or cash flows.

Pending Adoption

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). ASU 2016-13 requires measurement and recognition of expected credit losses for financial assets held. The amendments in ASU 2016-13 eliminate the probable threshold for initial recognition of a credit loss in current GAAP and reflect an entity's current estimate of all expected credit losses. ASU 2016-13 is effective for annual and interim periods beginning January 1, 2020 and is to be applied using a modified retrospective transition method. Earlier adoption is permitted. Because the Company holds only highly-rated money market funds, it does not expect the adoption of ASU 2016-13 to have a material impact on the Company's financial position, results of operations or cash flows.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurements* ("ASU 2018-13"). ASU 2018-13 modifies fair value measurement disclosure requirements. ASU 2018-13 is effective for annual and interim periods beginning after December 15, 2019. Early adoption is permitted. Because this ASU changes only the disclosure requirements and not the underlying accounting, the Company does not expect the adoption of ASU 2018-13 to have a material impact on the Company's financial position, results of operations or cash flows.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* ("ASU 2018-15"). ASU 2018-15 requires a customer in a cloud computing arrangement that is a service contract to follow the internal-use software guidance to determine which implementation costs to defer and recognize as an asset. The effective date for ASU 2018-15 is for annual and interim periods beginning after December 15, 2019. Early adoption is permitted. The amendments in this ASU should be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company will adopt the ASU prospectively to all implementation costs incurred after January 1, 2020 and does not expect the adoption of ASU 2016-13 to have a material impact on the Company's financial position, results of operations or cash flows.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"). ASU 2019-12 simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments in ASU 2019-12 also improve consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. ASU 2109-12 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. Early adoption is permitted. The method with which the amendments in this ASU are to be applied varies depending on the nature of the tax item impacted by amendment. Because the Company generates losses and pays no income taxes, it does not expect the adoption of ASU 2019-12 to have a material impact on the Company's financial position, results of operations or cash flows.

5. FAIR VALUE MEASUREMENT AND FINANCIAL INSTRUMENTS

The carrying values of cash and cash equivalents, restricted cash, prepaid expenses and other current assets, and accounts payable on the Company's consolidated balance sheets approximated their fair values as of December 31, 2019 and 2018 due to their short-term nature.

Certain of the Company's financial instruments are measured at fair value using a three-level hierarchy that prioritizes the inputs used to measure fair value. This fair value hierarchy prioritizes the use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

Level 1: Inputs are quoted prices for identical instruments in active markets,

Level 2: Inputs are quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; or model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3: Inputs are unobservable and reflect the Company's own assumptions, based on the best information available, including the Company's own data.

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

The following tables set forth the carrying amounts and fair values of the Company's financial instruments measured at fair value on a recurring basis as of December 31, 2019 and 2018 (in thousands):

	December 31, 2019				
			Fair Value Measurement Based on		
	Carrying Amount	Fair Value	Quoted Prices in Active Markets (Level 1)	Significant other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:					
Money market funds (cash equivalents)	$ 31,146	$ 31,146	$ 31,146	$ —	$ —
Liabilities:					
Contingent consideration	$ 120,020	$ 120,020	$ —	$ —	$ 120,020

	December 31, 2018				
			Fair Value Measurement Based on		
	Carrying Amount	Fair Value	Quoted Prices in Active Markets (Level 1)	Significant other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:					
Money market funds (cash equivalents)	$ 40,365	$ 40,365	$ 40,365	$ —	$ —
Liabilities:					
Contingent consideration	$ 48,400	$ 48,400	$ —	$ —	$ 48,400

The Company evaluates transfers between fair value levels at the end of each reporting period. There were no transfers of assets or liabilities between fair value levels during the year ended December 31, 2019.

Contingent Consideration

The estimated 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 2021 to 2033, the level of commercial sales of Vicinium forecasted for the United States, Europe, Japan and other potential markets and discount rates ranging from 5.6% to 11.8% as of December 31, 2019 and 6.6% to 13.7% as of December 31, 2018. There have been no changes to the valuation methods utilized during the year ended December 31, 2019.

The following table sets forth a summary by quarter of the change in the fair value of the Company's contingent consideration liability, measured on a recurring basis at each reporting period, for the year ended December 31, 2019 (in thousands):

Balance at December 31, 2018	**$ 48,400**
Change in fair value included in loss	(1,000)
Balance at March 31, 2019	47,400
Change in fair value included in loss[(1)]	44,000
Balance at June 30, 2019	91,400
Change in fair value included in loss[(2)]	3,600
Balance at September 30, 2019	95,000
Change in fair value included in loss[(3)]	25,020
Balance at December 31, 2019	**$ 120,020**

[(1)] During the quarter ended June 30, 2019, management reassessed the total addressable global market for high-risk NMIBC and determined that both the global market size and the estimated potential Vicinium commercial sales within the global

market were likely higher than the Company's previous estimates. Specific drivers of the increased revenue estimates include the expectation that Vicinium could achieve peak market penetration earlier than previously estimated and the expectation that Vicinium sales outside the United States could be two to three times the expected sales volumes in the United States. As contingent consideration incorporates a royalty rate of 2% on all commercial net sales of Vicinium through December 2033, an increase in expected future net sales correlated to a $44.0 million increase in the estimated fair value of the Company's contingent consideration as of June 30, 2019.

(2) The $3.6 million increase in the estimated fair value of contingent consideration was primarily attributable to a slightly lower discount rate, based on prevailing market conditions as of September 30, 2019, applicable to the earnout royalty payments potentially payable to Viventia's shareholders under the Share Purchase Agreement.

(3) The $25.0 million increase in the estimated fair value of contingent consideration was primarily attributable to increases in management's assumptions for both the estimated United States market share for Vicinium for the treatment of high-risk NMIBC, if approved, and the probability of success for achieving marketing approval by the FDA, based on expert commentary from a December 2019 public hearing of the FDA's Oncologic Drugs Advisory Committee during a review a competitor's product.

6. PROPERTY AND EQUIPMENT

The following table sets forth the composition of property and equipment, net as of December 31, 2019 and 2018 (in thousands):

	December 31,	
	2019	**2018**
Lab equipment	$ 572	$ 443
Furniture and fixtures	16	16
Computer equipment	87	80
Software	28	28
Leasehold improvements	293	293
Property and equipment, gross	996	860
Less: accumulated depreciation	(758)	(539)
Total Property and Equipment, Net	**$ 238**	**$ 321**

Depreciation expense was $0.2 million, $0.2 million and $0.3 million for the years ended December 31, 2019, 2018 and 2017, respectively. During the year ended December 31, 2017, the Company sold equipment with no remaining net book value for proceeds of $0.1 million.

7. INTANGIBLES AND GOODWILL

Intangibles

Intangible assets on the Company's consolidated balance sheet are the result of the Viventia Acquisition in September 2016. The following table sets forth the composition of intangible assets as of December 31, 2019 and 2018 (in thousands):

	December 31,	
	2019	**2018**
IPR&D intangible assets:		
Vicinium United States rights	$ 31,700	$ 31,700
Vicinium European Union rights	14,700	14,700
Total Intangibles	**$ 46,400**	**$ 46,400**

Goodwill

Goodwill on the Company's consolidated balance sheet is the result of the Viventia Acquisition in September 2016. Goodwill had a carrying value of $13.1 million as of December 31, 2019 and 2018.

8. ACCRUED EXPENSES

The following table sets forth the composition of accrued expenses as of December 31, 2019 and 2018 (in thousands):

	December 31,	
	2019	2018
Research and development	$ 3,688	$ 2,928
Payroll-related expenses	1,638	1,045
Severance to former Executives and other employees	378	278
Professional fees	378	464
Other	87	31
Total Accrued Expenses	**$ 6,169**	**$ 4,746**

Management Changes

On August 26, 2019, the Company announced that Richard Fitzgerald departed as its Chief Financial Officer, effective immediately. In connection with his separation from the Company, Mr. Fitzgerald and the Company entered into a Separation Agreement and General Release dated as of September 9, 2019 (the “Fitzgerald Separation Agreement”), pursuant to which the Company provided Mr. Fitzgerald with twelve months of separation payments and benefits. The Company recorded $0.3 million of expense, which will be paid through the normal payroll cycle through August 2020.

On August 2, 2019, Dennis Kim, M.D., MPH departed as the Company's Chief Medical Officer, effective immediately. In connection with his separation from the Company, Dr. Kim and the Company entered into a Separation Agreement and General Release dated as of August 2, 2019 (the “Kim Separation Agreement”), pursuant to which the Company provided Dr. Kim with six months of separation payments in the amount of $0.2 million. In addition, Dr. Kim and the Company entered into a Consulting Agreement dated as of August 3, 2019 (the "Kim Consulting Agreement"), pursuant to which the Company agreed to pay Dr. Kim $0.1 million in consulting fees and transition expenses over the following three months ending November 2, 2019. The Company recorded $0.3 million of expenses related to these agreements. The Kim Consulting Agreement payments were made in a lump sum when the agreement concluded in November 2019. The separation payments will be paid through the normal payroll cycle through January 2020.

On August 7, 2018, the Company announced that Stephen A. Hurly departed as its President and Chief Executive Officer, effective immediately. In connection with his separation from the Company, Mr. Hurly and the Company entered into a Separation Agreement and General Release dated as of September 28, 2018 (the “Hurly Separation Agreement”), pursuant to which the Company provided Mr. Hurly with twelve months of separation payments and benefits. The Company recorded $0.6 million of expense, consisting of Mr. Hurly’s base salary at the time of his departure of $0.4 million plus his target annual bonus for 2018 of $0.2 million, which was paid through the normal payroll cycle through August 2019, when the Company completed its obligations related to the Hurly Separation Agreement.

The remaining amounts of accrued severance as of December 31, 2019 relate to terminations of other employees during 2019.

Reduction-in-Force

In August 2017, the Company's board of directors approved a strategic restructuring to eliminate a portion of the Company’s workforce in order to preserve resources and refocus the Company's efforts. In September 2017, the Company completed the manufacturing of all Vicinium necessary for its ongoing Phase 3 VISTA Trial and for its Cooperative Research and Development Agreement with the National Cancer Institute. In conjunction with this achievement, the Company ended its manufacturing activities in Winnipeg and redirected its resources toward completing the technology transfer process necessary to outsource commercial scale drug supply manufacturing in the event it obtains approval from the FDA to market Vicinium for the treatment of high-risk NMIBC. The Company recorded total restructuring costs of $0.1 million, which included separation payments and benefits, in the third quarter of 2017.

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

9. COMMITMENTS AND CONTINGENCIES

Executive Employment Agreements

The Company has entered into employment agreements and offer letters with certain of its key executives, providing for separation payments and benefits in certain circumstances, as defined in the agreements.

Legal Contingencies

The Company is not currently subject to any material legal proceedings and has recorded no legal contingencies.

Leases

On January 1, 2019, the Company adopted ASC 842 using the optional transition method. The Company's lease portfolio includes:

1. An operating lease for its 31,100 square foot facility in Winnipeg, Manitoba which consists of manufacturing, laboratory, warehouse and office space, under a five-year renewable lease through September 2020 with a right to renew the lease for one subsequent five-year term. The minimum monthly rent under this lease is $12,600 per month. In addition to rent expense, the Company expects to incur $12,300 per month in related operating expenses. Operating lease cost under this lease, including the related operating costs, was $0.3 million for the year ended December 31, 2019. Rent expense (under ASC 840), including the related operating costs, was $0.3 million for each of the years ended December 31, 2018 and 2017, respectively;
2. A short-term property lease for modular office space for its current corporate headquarters in Cambridge, MA under a lease that renews every four months and currently extends through August 2020. The minimum monthly rent for this office space is currently $7,900 per month, which is subject to change if and as the Company adds or deducts space to or from the lease. The Company recorded $0.1 million and $0.1 million in rent expense for the years ended December 31, 2019 and 2018, respectively, for this lease; and
3. A short-term property lease for modular office space in Philadelphia, PA under a lease that renews every six months and currently extends through October 2020. The minimum monthly rent for this office space is currently $13,500 per month, which is subject to change if and as the Company adds or deducts space to or from the lease. The Company recorded $0.1 million and $0.2 million in rent expense for the years ended December 31, 2019 and 2018, respectively, for this lease.

The components of lease cost for the year ended December 31, 2019 is as follows (in thousands):

Lease Cost:	**Year ended December 31, 2019**
Operating lease (including related operating costs)	$ 298
Short-term property leases	263
Total Lease Costs	$ 561

Supplemental Information:	
Weighted-average remaining lease term - operating leases (in years)	0.75
Weighted-average discount rate - operating leases	12%

The following table sets forth the Company's future minimum lease payments under non-cancelable leases as of December 31, 2019 (in thousands):

Year ending December 31,	Minimum Lease Payments
2020	113
Total future minimum lease payments	113
Less: Amounts representing present value adjustment	(1)
Operating lease current liabilities as of December 31, 2019	$ 112

10. STOCKHOLDERS' (DEFICIT) EQUITY

Equity Financings

November 2019 ATM Offering

In November 2019, the Company entered into an Open Market Sale Agreement SM (the "Sales Agreement") with Jefferies LLC ("Jefferies"), under which the Company may issue and sell shares of its common stock from time to time for an aggregate sales price of up to $35.0 million through Jefferies (the "ATM Offering"). Sales of common stock under the Sales Agreement are made by any method that is deemed to be an ATM offering as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended, including but not limited to sales made directly on or through the Nasdaq Global Market or any other existing trading market for the common stock. The Company has no obligation to sell any of its common stock and may at any time suspend offers under the Sales Agreement or terminate the Sales Agreement. Subject to the terms and conditions of the Sales Agreement, Jefferies will use its commercially reasonable efforts to sell common stock from time to time, as the sales agent, based upon the Company's instructions, which include a prohibition on sales below a floor of $1.00 per share. The Company has provided Jefferies with customary indemnification rights, and Jefferies is entitled to a commission at a fixed rate equal to 3.0% of the gross proceeds for each sale of common stock. The Company incurred $0.2 million in legal, accounting and printing costs related to the Prospectus Supplement filed with the SEC in connection with the ATM Offering. Through December 31, 2019, the Company raised $1.9 million of net proceeds from the sale of 2.1 million shares of common stock under the ATM Offering.

June 2019 Financing

In June 2019, the Company raised $27.8 million of net proceeds from the sale of 20.4 million shares of common stock and accompanying warrants to purchase an additional 20.4 million shares of common stock in an underwritten public offering (the "June 2019 Financing"). The combined purchase price for each share of common stock and accompanying warrant was $1.47. Subject to certain ownership limitations, the warrants issued in the June 2019 Financing were exercisable immediately upon issuance at an exercise price of $1.47 per share, subject to adjustments as provided under the terms of such warrants, and have a one-year term expiring on June 21, 2020.

June 2018 Financing

In June 2018, the Company raised $41.9 million of net proceeds from the sale of 25.6 million shares of common stock at a price of $1.80 per share in an underwritten public offering.

March 2018 Financing

In March 2018, the Company raised $9.0 million of net proceeds from the sale of (i) 8.0 million shares of common stock at a price of $1.13 per share in a registered direct public offering and (ii) 8.0 million warrants to purchase shares of common stock (the "2018 Warrants") at a price of $0.125 per 2018 Warrant in a concurrent private placement (collectively, the "March 2018 Financing"). Subject to certain ownership limitations, the 2018 Warrants issued in the March 2018 Financing were exercisable immediately upon issuance at an original exercise price of $1.20 per share, subject to adjustments as provided under the terms of such warrants, and have a five-year term expiring on March 23, 2023. See "Warrant Modifications" below for additional information.

November 2017 Financing

In November 2017, the Company raised $7.0 million of net proceeds from the sale of (i) 5.5 million units (each unit consisting of one share of common stock and one warrant to purchase one share of common stock ("2017 Warrant")) at a price of $0.80 per unit and (ii) 4.5 million pre-funded units (each pre-funded unit consisting of one pre-funded warrant to purchase one share of common stock ("Pre-funded Warrant") and one 2017 Warrant) at a price of $0.79 per pre-funded unit (collectively, the "November 2017 Financing"). Each 2017 Warrant to purchase common stock contained in a unit or pre-funded unit had an original exercise price of $0.80 per share, was exercisable immediately and will expire five years from the date of issuance. See "Warrant Modifications" below for additional information. Each Pre-funded Warrant contained in a pre-funded unit was exercisable for one share of common

stock at an exercise price of $0.01 per share. As of December 31, 2017, all of the Pre-funded Warrants sold in the November 2017 Financing were exercised by the holders.

Preferred Stock

Pursuant to its Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation"), the Company is authorized to issue 5.0 million shares of "blank check" preferred stock, $0.001 par value per share, which enables its board of directors, from time to time, to create one or more series of preferred stock. Each series of preferred stock issued shall have the rights, preferences, privileges and restrictions as designated by the board of directors. The issuance of any series of preferred stock could affect, among other things, the dividend, voting and liquidation rights of the Company's common stock. The Company had no preferred stock issued and outstanding as of December 31, 2019 and 2018.

Common Stock

Pursuant to its Certificate of Incorporation, the Company is authorized to issue 200.0 million shares of common stock, $0.001 par value per share, of which 106.8 million and 77.5 million shares were issued and outstanding as of December 31, 2019 and 2018, respectively. In addition, the Company had reserved for issuance the following amounts of shares of its common stock for the purposes described below as of December 31, 2019 and 2018 (in thousands):

	December 31,	
	2019	**2018**
Shares of common stock issued	106,801	77,456
Shares of common stock reserved for issuance for:		
Warrants	22,895	9,258
Stock options	6,236	3,942
Shares available for grant under 2014 Stock Incentive Plan	8,753	2,001
Shares available for sale under 2014 Employee Stock Purchase Plan	28	38
Total shares of common stock issued and reserved for issuance	**144,713**	**92,695**

The voting, dividend and liquidation rights of holders of shares of common stock are subject to and qualified by the rights, powers and preferences of holders of shares of preferred stock. Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders; provided, however, that, except as otherwise required by law, holders of common stock shall not be entitled to vote on any amendment to the Company’s Certificate of Incorporation that relates solely to the terms of one or more outstanding series of preferred stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more such series, to vote thereon. There shall be no cumulative voting.

Dividends may be declared and paid on the common stock from funds lawfully available thereof as and when determined by the board of directors and subject to any preferential dividend or other rights of any then-outstanding preferred stock. The Company has never declared or paid, and for the foreseeable future does not expect to declare or pay, dividends on its common stock.

Upon the dissolution or liquidation of the Company, whether voluntary or involuntary, holders of common stock will be entitled to receive all assets of the Company available for distribution to its stockholders, subject to any preferential or other rights of any then-outstanding preferred stock.

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

Warrants

All of the Company's outstanding warrants are non-tradeable and equity-classified because they meet the derivative scope exception under ASC Topic 815-40, *Derivatives and Hedging - Contracts in Entity's Own Equity* ("ASC 815-40"). The following table sets forth the Company's warrant activity for the year ended December 31, 2019 (in thousands):

Issued	Exercise Price	Expiration	December 31, 2018	Issued	(Exercised)	December 31, 2019
Jun-2019	$1.47	Jun-2020	—	20,410	—	20,410
Mar-2018	$0.95*	Mar-2023	7,211	—	(5,268)	1,943
Nov-2017	$0.55*	Nov-2022	1,992	—	(1,505)	487
May-2015	$11.83	Nov-2024	28	—	—	28
Nov-2014	$11.04	Nov-2024	27	—	—	27
			9,258	**20,410**	**(6,773)**	**22,895**

** Exercise price shown (i) reflects modification described below and (ii) subject to further adjustment based on down round provision added by amendment described below.*

During the year ended December 31, 2019, the Company received proceeds of $5.5 million from the exercises of 5.3 million 2018 Warrants and 1.5 million 2017 Warrants.

Warrant Modifications

In October 2019, the Company entered into transactions with holders of its outstanding 2018 Warrants and 2017 Warrants to purchase the Company's common stock.

2018 Warrants

On October 28, 2019, the Company entered into transactions with the holders of its outstanding 2018 Warrants pursuant to which such holders either (i) exercised their warrants pursuant to a Warrant Exercise Agreement (the "2018 Warrant Exercise Agreements") or (ii) amended their warrants pursuant to a Warrant Amendment Agreement (the "2018 Warrant Amendment Agreements"). As consideration for those holders executing the 2018 Warrant Exercise Agreements, the Company reduced the exercise price of the warrants from $1.20 to $0.60 per share of the Company's common stock, resulting in proceeds of $2.0 million from the exercise of 3.4 million warrants. Pursuant to the 2018 Warrant Amendment Agreements, the prohibition on certain variable rate transactions included in the 2018 Warrants was amended to exclude ATM offerings and the exercise price of the warrants was reduced from $1.20 to the lesser of (a) $0.95 per share of common stock and (b) the exercise price as determined from time to time pursuant to the anti-dilution provisions in the 2018 Warrant Amendment Agreements.

In connection with the 2018 Warrant Exercise Agreements and 2018 Warrant Amendment Agreements, the Company entered into an amendment to the Securities Purchase Agreement dated March 21, 2018 related to the March 2018 Financing, by and among the Company and each purchaser identified on the signature pages thereto, with certain holders representing greater than 50.1% of the securities issued based on initial subscription amounts, pursuant to which the prohibition on variable rate transactions, including ATM offerings, contained in section 4.12(b) was deleted in its entirety.

2017 Warrants

On October 28, 2019, the Company entered into transactions with the holders of its outstanding 2017 Warrants pursuant to which such holders either (i) exercised their warrants pursuant to a Warrant Exercise Agreement (the "2017 Warrant Exercise Agreements") or (ii) amended their warrants pursuant to a Warrant Amendment Agreement (the "2017 Warrant Amendment Agreements"). As consideration for those holders executing the 2017 Warrant Exercise Agreements, the Company reduced the exercise price of the warrants from $0.80 to $0.55 per share of the Company's common stock. Pursuant to the 2017 Warrant Amendment Agreements, the prohibition on certain variable rate transactions included in the 2017 Warrants was amended to exclude ATM offerings and the exercise price of the warrants was reduced from $0.80 to the lesser of (a) $0.55 per share of common stock and (b) the exercise price as determined from time to time pursuant to the anti-dilution provisions in the 2017 Warrant Amendment Agreements.

Accounting Implications

The 2018 Warrants and 2017 Warrants utilize the same Form of Warrant, which contained in Section 5d) a prohibition on variable rate transactions (as defined therein). The warrant holders agreed to waive such prohibition in exchange for the concessions from the Company described above. Management evaluated the warrants after modifications and determined that they continued to be

equity-classified under the derivative scope exception of ASC 815-40. The warrants were revalued immediately before and immediately after the modifications to calculate the $1.1 million incremental value of the modified warrants. The Company considers this incremental value to be akin to an offering cost since the modifications were directly related to enabling the ATM Offering and would not have otherwise been incurred. Management initially capitalized the $1.1 million to deferred financing cost asset, with an offsetting credit to additional paid-in capital, and then reclassified the deferred financing cost asset to reduce the ATM Offering proceeds within equity as proceeds were received from sales of common stock under the ATM Offering.

11. LOSS PER SHARE

The Company's basic loss per common share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period. A net loss cannot be diluted, so when the Company is in a net loss position, basic and diluted loss per common share are the same. If in the future the Company achieves profitability, the denominator of a diluted earnings per common share calculation will include both the weighted-average number of shares outstanding and the number of common stock equivalents, if the inclusion of such common stock equivalents would be dilutive. Dilutive common stock equivalents potentially include warrants, stock options and non-vested restricted stock awards and units using the treasury stock method, along with the effect, if any, from outstanding convertible securities. The Company's outstanding warrants to purchase common stock have participation rights to any dividends that may be declared in the future 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 the holders have no contractual obligation to share in the losses of the Company.

The following potentially dilutive securities outstanding as of December 31, 2019, 2018 and 2017 have been excluded from the denominator of the diluted loss per share of common stock outstanding calculation (in thousands):

	December 31,		
	2019	**2018**	**2017**
Warrants	22,895	9,258	10,055
Stock options	6,236	3,942	2,696
Non-vested restricted stock awards	—	—	4
	29,131	**13,200**	**12,755**

12. SHARE-BASED COMPENSATION

The following table sets forth the amount of share-based compensation expense recognized by the Company by line item on its consolidated statements of operations for the years ended December 31, 2019, 2018 and 2017 (in thousands):

	Year ended December 31,		
	2019	**2018**	**2017**
Research and development	$ 188	$ 505	$ 404
General and administrative	1,049	778	977
Total Share-based Compensation	**$ 1,237**	**$ 1,283**	**$ 1,381**

2014 Stock Incentive Plan

The Company's 2014 Stock Incentive Plan, as amended ("2014 Plan"), was adopted by its board of directors in December 2013 and subsequently approved by its stockholders in January 2014. The 2014 Plan became effective immediately prior to the closing of the Company's IPO in February 2014 and provides for the grant of incentive and non-qualified stock options, restricted stock awards and units, stock appreciation rights and other stock-based awards, with amounts and terms of grants determined by the Company's board of directors at the time of grant, to the Company's employees, officers, directors, consultants and advisors. Currently there are only stock options outstanding under the 2014 Plan, which generally vest over a four-year period at the rate of 25% of the grant vesting on the first anniversary of the date of grant and 6.25% of the grant vesting at the end of each successive three-month period thereafter. Stock options granted under the 2014 Plan are exercisable for a period of ten years from the date of grant. There were 4.0 million stock options outstanding under the 2014 Plan as of December 31, 2019.

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

At the Annual Meeting of Stockholders in June 2019, the Company's stockholders approved an amendment to the 2014 Plan that (i) increased by 7.9 million the number of shares of common stock reserved for issuance under the 2014 Plan and (ii) eliminated the “evergreen” or automatic replenishment provision of the 2014 Plan, pursuant to which the number of shares of common stock authorized for issuance under the 2014 Plan was automatically increased on an annual basis. There were 8.8 million shares of common stock available for issuance under the 2014 Plan as of December 31, 2019.

2009 Stock Incentive Plan

The Company maintains a 2009 Stock Incentive Plan, as amended and restated ("2009 Plan"), which provided for the grant of incentive and non-qualified stock options and restricted stock awards and units, with amounts and terms of grants determined by the Company's board of directors at the time of grant, to its employees, officers, directors, consultants and advisors. Upon the closing of its IPO in February 2014, the Company ceased granting awards under the 2009 Plan and all shares (i) available for issuance under the 2009 Plan at such time and (ii) subject to outstanding awards under the 2009 Plan that expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased without having been fully exercised or resulting in any common stock being issued were carried over to the 2014 Plan. Stock options granted under the 2009 Plan are exercisable for a period of ten years from the date of grant. There were remaining 0.1 million fully vested stock options outstanding under the 2009 Plan as of December 31, 2019.

Out-of-Plan Inducement Grants

From time to time, the Company has granted equity awards to its newly hired employees in accordance with the Nasdaq Stock Market LLC ("Nasdaq") employment inducement grant exemption (Nasdaq Listing Rule 5635(c)(4)). Such grants are made outside of the 2014 Plan and act as an inducement material to the employee's acceptance of employment with the Company. As of December 31, 2019, there were 2.1 million stock options outstanding which were granted as employment inducement awards outside of the 2014 Plan.

Stock Options

The following table sets forth a summary of the Company’s total stock option activity, including awards granted under the 2014 Plan and 2009 Plan and inducement grants made outside of stockholder approved plans, for the years ended December 31, 2019, 2018 and 2017:

	Number of Shares under Option (in thousands)	Weighted-Average Exercise Price per Option	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2016	2,024	$4.41	8.73	$ 841
Granted	1,303	$1.64		
Exercised	(140)	$0.28		
Canceled or forfeited	(491)	$5.10		
Outstanding at December 31, 2017	2,696	$3.16	8.55	$ 146
Granted	3,546	$1.71		
Exercised	(439)	$0.62		
Canceled or forfeited	(1,861)	$3.21		
Outstanding at December 31, 2018	3,942	$2.12	9.14	$ 57
Granted	3,986	$1.02		
Exercised	(90)	$1.10		
Canceled or forfeited	(1,602)	$1.78		
Outstanding at December 31, 2019	6,236	$1.52	8.83	$ 358
Exercisable at December 31, 2019	1,866	$2.31	8.06	$ 62

The Company recognized share-based compensation expense related to stock options of $1.2 million, $1.1 million and $0.9 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, there was $3.2 million of total unrecognized compensation cost related to non-vested stock options which the Company expects to recognize over a weighted-average period of 2.90 years. The weighted-average grant-date fair value of stock options granted during the years ended

December 31, 2019, 2018 and 2017 were $0.69, $1.14 and $1.18, respectively. The total intrinsic value of options exercised for the years ended December 31, 2019, 2018 and 2017 was de minimis, $0.5 million and $0.3 million, respectively.

For the years ended December 31, 2019, 2018 and 2017, the grant-date fair value of stock options was determined using the following weighted-average inputs and assumptions in the Black-Scholes option pricing model:

	Year ended December 31,		
	2019	2018	2017
Fair value of common stock	$1.02	$1.71	$1.74
Exercise price of the option	$1.02	$1.71	$1.74
Expected term (years)	5.98	5.97	5.59
Risk-free interest rate	2.1%	2.8%	1.9%
Expected volatility	78.1%	74.2%	81.6%
Dividend yield	—%	—%	—%

Performance-Based Grants

In October 2017, the Company granted to certain executives a total of 0.9 million performance-based stock options with an exercise price of $1.59 and a grant-date fair value of $1.12 per option. The four performance milestone events were specific to the Company's corporate goals, including certain clinical development objectives related to the VISTA Trial, as well as a past financing objective. In the fourth quarter of 2017, management deemed it probable that two of the performance objectives were achieved. During 2018, management determined that one performance objective was achieved and deemed it probable that a second performance-based milestone would be achieved. The Company recognized share-based compensation expense related to performance-based stock options of de minimis, $0.2 million and $0.3 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, there was no unrecognized compensation cost related the performance-based stock options granted in October 2017.

Restricted Stock

From time to time, prior to December 31, 2016 and upon approval by the board of directors, certain employees and advisors were granted restricted stock awards ("RSAs") and restricted stock units ("RSUs"), all of which were vested prior to December 31, 2018. The Company did not grant RSAs or RSUs during the years ended December 31, 2019, 2018 and 2017.

The following table sets forth a summary of the Company's restricted stock activity for the years ended December 31, 2018 and 2017:

	Non-vested Restricted Stock Awards (in thousands)	Weighted-Average Grant Date Fair Value	Non-vested Restricted Stock Units (in thousands)	Weighted-Average Grant Date Fair Value
Non-vested at December 31, 2016	22	$11.43	3	$4.09
Vested	(18)	$11.43	(3)	$4.09
Non-vested at December 31, 2017	4	$11.43	—	
Vested	(4)	$11.43		
Non-vested at December 31, 2018	—			

The Company recognized share-based compensation expense related to restricted stock of de minimis and $0.2 million for the years ended December 31, 2018 and 2017, respectively.

13. EMPLOYEE BENEFIT PLANS

2014 Employee Stock Purchase Plan

The Company's 2014 Employee Stock Purchase Plan ("2014 ESPP") was adopted by its Board of Directors in December 2013 and subsequently approved by its stockholders in January 2014. The 2014 ESPP became effective immediately prior to the closing of the Company's IPO in February 2014 and established an initial reserve of 0.2 million shares of the Company's common stock for issuance to participating employees. The purpose of the 2014 ESPP is to enhance employee interest in the success and progress

of the Company by encouraging employee ownership of common stock of the Company. The 2014 ESPP provides employees with the opportunity to purchase shares of the Company's common stock at a 15% discount to the market price through payroll deductions or lump sum cash investments. The Company estimates the number of shares to be issued at the end of an offering period and recognizes expense over the requisite service period. Shares of the Company's common stock issued and sold pursuant to the 2014 ESPP are shown on the consolidated statements of changes in stockholders' (deficit) equity. As of December 31, 2019, there were approximately 28,000 shares of the Company's common stock available for sale under the 2014 ESPP.

Defined Contribution Plans

United States - 401(k) Plan

The Company maintains a 401(k) defined contribution retirement plan which covers all of its U.S. employees. Employees are eligible to participate on the first of the month following their date of hire. Under the 401(k) plan, participating employees may defer up to 100% of their pre-tax salary, subject to certain statutory limitations. Employee contributions vest immediately. The plan allows for a discretionary match per participating employee up to a maximum of $4,000 per year.

Canada - Defined Contribution Plan

The Company maintains a defined contribution plan for its Canadian employees. Participants may contribute a percentage of their annual compensation to this plan, subject to statutory limitations. The Company contributes up to the first 4% of eligible compensation for its Canadian-based employees to the retirement plan.

14. INCOME TAXES

The following table sets forth the components of the Company's loss before income taxes by country (in thousands):

	Year ended December 31,		
	2019	**2018**	**2017**
Country:			
United States	$ (27,468)	$ (15,977)	$ (9,246)
Canada	(80,032)	(17,716)	(19,783)
Total Loss before Income Taxes	**$ (107,500)**	**$ (33,693)**	**$ (29,029)**

The Company did not record current or deferred income tax or benefit for the years ended December 31, 2019, 2018 and 2017.

The following table sets forth a reconciliation of the statutory United States federal income tax rate to the Company's effective income tax rate:

	Year ended December 31,		
	2019	**2018**	**2017**
United States federal statutory income tax rate	21.0 %	21.0 %	34.0 %
Impact of foreign rate differential	4.4	1.6	(2.6)
State taxes, net of federal benefit	0.6	1.3	1.4
Stock option cancellations	—	(1.2)	(0.8)
Contingent consideration	(18.0)	(5.5)	(10.7)
General business credits and other credits	0.4	0.7	0.8
Permanent differences	—	(0.3)	0.3
Other	(0.5)	0.5	—
United States federal statutory tax rate change	—	—	(50.6)
Change in valuation allowance	(7.9)	(18.1)	28.2
Effective Income Tax Rate	**— %**	**— %**	**— %**

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

The following table sets forth the tax effects of temporary differences that gave rise to significant portions of the Company's deferred tax assets and liabilities (in thousands):

	December 31,	
	2019	2018
Deferred tax assets:		
NOL carryforwards	$ 50,727	$ 43,212
R&D credit carryforwards	4,385	3,876
Accruals and other	2,464	2,011
Capitalized start-up costs	91	122
Other	57	32
Gross deferred tax assets	57,724	49,253
Deferred tax liabilities:		
IPR&D	(12,528)	(12,528)
Property and equipment	—	(60)
Gross deferred tax liabilities	(12,528)	(12,588)
Valuation allowance	(57,724)	(49,193)
Net Deferred Tax Liability	**$ (12,528)**	**$ (12,528)**

In assessing the realizability of the Company's deferred tax assets, management considers all relevant positive and negative evidence in determining whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The realization of deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the NOL and R&D credit carryforwards. The Company has generated NOLs since its inception, and management believes that it is more likely than not that the Company's deferred tax assets will not be realized. As a result, valuation allowances of $57.7 million and $49.2 million have been established as of December 31, 2019 and 2018, respectively. The $8.5 million increase in the valuation allowance was attributable to the NOL for the year ended December 31, 2019.

The net deferred tax liability of $12.5 million primarily relates to the potential future impairments or amortization associated with IPR&D intangible assets, which is not deductible for tax purposes and cannot be considered as a source of income to realize deferred tax assets. As a result, the Company recorded the deferred tax liability with an offset to goodwill.

The following table summarizes the Company's NOL and R&D and other credit carryforwards in the United States and Canada as of December 31, 2019 (in millions):

	Amount	Expiration Beginning in	Through
United States:			
Federal NOL carryforwards - indefinite	$ 41.2	None	None
Federal NOL carryforwards	$ 118.9	2030	2039
State NOL carryforwards	$ 131.2	2030	2039
Federal R&D credit carryforwards	$ 2.2	2027	2039
State R&D credit carryforwards	$ 0.9	2027	2039
Canada:			
Federal non-capital loss carryforwards	$ 32.6	2035	2039
Federal scientific research and experimental development expense carryforwards	$ 6.2	2032	2039
Federal and provincial investment tax credit carryforwards	$ 1.5	2032	2039

Under the Tax Reform Act of 1986 (the "Act'), NOL and R&D credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service, and there are similar provisions in certain state and foreign tax laws. NOL and R&D credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interests

of significant shareholders over a three-year period in excess of 50 percent, as defined in Sections 382 and 383 of the Internal Revenue Code, respectively. This could limit the amount of tax attributes that can be utilized to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. Management completed a Section 382 study through March 31, 2016 and determined that it is more likely than not that the Company's NOL carryforwards are subject to a material limitation. Accordingly, the Company reduced its NOL carryforward by $0.8 million. The Company has continued to raise additional equity capital since March 2016 but has not done any additional analysis to determine whether or not ownership changes, as defined in the Act, have occurred, which would result in additional limitations. There could be additional ownership changes in the future that could further limit the amount of NOL carryforwards that the Company can utilize. The Company has not yet conducted a study of its R&D credit carryforwards. Such a study may result in an adjustment to the Company’s R&D credit carryforwards; however, until a study is completed and any adjustment is known, no amount is being presented as an uncertain tax position. A full valuation allowance has been provided against the Company’s R&D credit carryforwards, and, if an adjustment is required, it would be offset by an adjustment to the valuation allowance.

As of December 31, 2019, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's consolidated statements of operations. Due to NOL and R&D credit carryforwards that remain unutilized, income tax returns filed in the United States, certain states within the United States and Canadian tax jurisdictions from the Company's inception through 2018 remain subject to examination by the taxing jurisdictions. There are currently no audits in process in any of the Company's tax filing jurisdictions.

15. LICENSE AGREEMENTS

Vicinium License Agreements

License Agreement with Zurich

The Company has a License Agreement with the University of Zurich ("Zurich") which grants the Company exclusive license rights, with the right to sublicense, to make, have made, use and sell under certain patents primarily directed to the Company's targeting agent, including an EpCAM chimera and related immunoconjugates and methods of use and manufacture of the same. These patents cover some key aspects of Vicinium. The Company may be obligated to pay $0.75 million in milestone payments for the first product candidate that achieves applicable clinical development milestones. Based on current status, the Company anticipates that these milestones may be triggered by Vicinium's clinical development pathway. As part of the consideration, the Company is also obligated to pay up to a 4% royalty on the net product sales for products covered by or manufactured using a method covered by a valid claim in the Zurich patent rights. Royalties owed to Zurich will be reduced if the total royalty rate owed by the Company to Zurich and any other third party is 10% or greater, provided that the royalty rate to Zurich may not be less than 2% of net sales. The obligation to pay royalties in a particular country expires upon the expiration or termination of the last of the Zurich patent rights that covers the manufacture, use or sale of a product. There is no obligation to pay royalties in a country if there is no valid claim that covers the product or a method of manufacturing the product.

License Agreement with Micromet

The Company has a License Agreement with Micromet AG ("Micromet"), now part of Amgen, Inc., which grants it nonexclusive rights, with certain sublicense rights, for know-how and patents allowing exploitation of certain single chain antibody products. These patents cover some key aspects of Vicinium. Under the terms of the License Agreement with Micromet, the Company may be obligated to pay up to €3.6 million in milestone payments for the first product candidate that achieves applicable clinical development milestones. Based on current clinical status, the Company anticipates that certain of these milestones may be triggered by Vicinium’s clinical development pathway. The Company is also required to pay up to a 3.5% royalty on the net sales for products covered by the agreement, which includes Vicinium. The royalty rate owed to Micromet in a particular country will be reduced to 1.5% if there are no valid claims covering the product in that country. The obligation to pay royalties in a particular country expires upon the later of the expiration date of the last valid claim covering the product and the tenth anniversary of the first commercial sale of the product in such country. Finally, the Company is required to pay to Micromet an annual license maintenance fee of €50,000, which can be credited towards any royalty payment the Company owes to Micromet.

License Agreement with XOMA

The Company has a License Agreement with XOMA Ireland Limited ("XOMA") which grants it non-exclusive rights to certain XOMA patent rights and know-how related to certain expression technology, including plasmids, expression strains, plasmid maps and production systems. These patents and related know-how cover some key aspects of Vicinium. Under the terms of the License Agreement with XOMA, the Company is required to pay up to $0.25 million in milestone payments for a product candidate that

incorporates know-how under the license and achieves applicable clinical development milestones. Based on current clinical status, the Company anticipates that these milestones may be triggered by Vicinium's clinical development pathway. The Company is also required to pay a 2.5% royalty on the net sales for products incorporating XOMA's technology, which includes Vicinium. The Company has the right to reduce the amount of royalties owed to XOMA on a country-by-country basis by the amount of royalties paid to other third parties, provided that the royalty rate to XOMA may not be less than 1.75% of net sales. In addition, the foregoing royalty rates are reduced by 50% with respect to products that are not covered by a valid patent claim in the country of sale. The obligation to pay royalties in a particular country expires upon the later of the expiration date of the last valid claim covering the product and the tenth anniversary of the first commercial sale of the product in such country.

Other License Agreements

License Agreement with Roche

In June 2016, the Company entered into the License Agreement with Roche, pursuant to which 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 and all other IL-6 anti-IL-6 antagonist monoclonal antibody technology owned by the Company (collectively, the "Licensed Intellectual Property"). Under the License Agreement, Roche is required to continue developing, at its cost, EBI-031 and any other product made from the Licensed Intellectual Property that contains an IL-6 antagonist anti-IL monoclonal antibody ("Licensed Product") and pursue ongoing patent prosecution, at its cost.

Financial Terms

The Company received from Roche an upfront license fee of $7.5 million in August 2016 upon the effectiveness of the License Agreement with Roche following approval by the Company's stockholders, and Roche agreed to pay up to an additional $262.5 million upon the achievement of specified regulatory, development and commercial milestones with respect to up to two unrelated indications. Specifically, an aggregate amount of up to $197.5 million is payable to the Company for the achievement of specified milestones with respect to the first indication, consisting of $72.5 million in development milestones, $50.0 million in regulatory milestones and $75.0 million in commercialization milestones. In September 2016, Roche paid the Company the first development milestone of $22.5 million as a result of the Investigational New Drug application for EBI-031 becoming effective on or before September 15, 2016. Additional amounts of up to $65.0 million are payable upon the achievement of specified development and regulatory milestones in a second indication.

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

Buy-Out Options

The License Agreement with Roche provides for two "option periods" during which Roche may elect to make a one-time payment to the Company and, in turn, terminate its diligence, milestone and royalty payment obligations under the License Agreement. Specifically, (i) Roche may exercise a buy-out option following the first dosing ("Initiation") in the first Phase 2 study for a Licensed Product until the day before Initiation of the first Phase 3 study for a Licensed Product, in which case Roche is required to pay the Company $135.0 million within 30 days after Roche's exercise of such buy-out option and receipt of an invoice from the Company, or (ii) Roche may exercise a buy-out option following the day after Initiation of the first Phase 3 study for a Licensed Product until the day before the acceptance for review by the FDA or other regulatory authority of a BLA or similar application for marketing approval for a Licensed Product in either the United States or in the E.U., in which case Roche is required to pay the Company, within 30 days after Roche's exercise of such buy-out option and receipt of an invoice from the Company, $265.0 million, which amount would be reduced to $220.0 million if none of the Company's patent rights containing a composition of matter claim covering any compound or Licensed Product has issued in the E.U.

Termination

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

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

16. RELATED-PARTY TRANSACTIONS

The Company leases its facility in Winnipeg, Manitoba from an affiliate of Leslie L. Dan, a director of the Company until his retirement in July 2019. For each of the years ended December 31, 2019, 2018 and 2017, the Company paid $0.3 million of rent, which includes the related operating expenses.

The Company pays fees under an intellectual property license agreement to Protoden Technologies Inc. ("Protoden"), a company owned by 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, to certain patents and technology to make, use and sell products that utilize such patents and technology. The annual fee is $0.1 million. Upon expiration of the term on December 31, 2024, the licenses granted to the Company will require no further payments to Protoden. For each of the years ended December 31, 2019, 2018 and 2017, the Company paid $0.1 million to this related party.

The Company previously leased office space in Toronto, Ontario from Mr. Dan. The lease was terminated by the Company in December 2018. For each of the years ended December 31, 2018 and 2017, the Company paid $18,000 of rent.

17. SUPPLEMENTARY FINANCIAL INFORMATION (Unaudited)

The following tables set forth selected financial information for the quarterly periods noted (in thousands, except per share data):

	2019			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Total revenue	$ —	$ —	$ —	$ —
Total operating expenses	$ 6,741	$ 54,561	$ 13,451	$ 33,738
Loss from operations	$ (6,741)	$ (54,561)	$ (13,451)	$ (33,738)
Net loss and comprehensive loss	$ (6,480)	$ (54,335)	$ (13,132)	$ (33,553)
Net loss per common share - basic and diluted	$ (0.08)	$ (0.67)	$ (0.13)	$ (0.32)

	2018			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Total revenue	$ —	$ —	$ —	$ —
Total operating expenses	$ 4,007	$ 9,030	$ 14,397	$ 7,066
Loss from operations	$ (4,007)	$ (9,030)	$ (14,397)	$ (7,066)
Net loss and comprehensive loss	$ (3,963)	$ (8,958)	$ (14,015)	$ (6,757)
Net loss per common share - basic and diluted	$ (0.11)	$ (0.16)	$ (0.18)	$ (0.09)

Quarterly computations of net loss per common share amounts are made independently for each quarterly reporting period, and the sum of the per share amounts for the quarterly reporting periods may not equal the per share amounts for the year-to-date reporting period.

18. SUBSEQUENT EVENTS

Listing Non-Compliance Notice

On March 2, 2020, the Company received written notice (the “Notice”) from Nasdaq Stock Market LLC ("Nasdaq") indicating that the Company is not in compliance with the $1.00 minimum bid price requirement for continued listing on the Nasdaq Global Market, as set forth in Nasdaq Listing Rule 5450(a)(1). The Notice has no effect at this time on the listing of the Company’s common stock, which will continue to trade on the Nasdaq Global Market under the symbol “SESN.”

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has a period of 180 calendar days, or until August 31, 2020, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of the Company’s common stock must meet or exceed $1.00 per share for a minimum of ten consecutive business days during this 180-day period. If the Company is not in compliance by August 31, 2020, the Company may be afforded a second 180 calendar day period to regain compliance. To qualify, the Company would be required to apply to have its common stock listed on the Nasdaq Capital Market and meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, except for the minimum bid price requirement, and will need to provide written notice to Nasdaq of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary.

The Company intends to monitor the closing bid price of its common stock and may, if appropriate, consider implementing available options to regain compliance with the minimum bid price requirement, including, but not limited to, a proposal for a reverse stock split of the Company's common stock to be submitted for stockholder approval at the Company's 2020 Annual Meeting of Stockholders.

Stock Options Granted

In January 2020, the Company granted 0.1 million stock options with an exercise price of $0.84 to new employees as inducement equity awards outside of the Company's 2014 Plan in accordance with Nasdaq Listing Rule 5635(c)(4). These stock options had a grant-date fair value of $0.59 and vest at the rate of 25% of the grant on the first anniversary of the date of grant and thereafter 6.25% of the grant at the end of each successive three-month period following the first anniversary of the date of grant, subject to the recipient's continued service with the Company through the applicable vesting dates.

In February 2020, the Company's board of directors granted 3.1 million stock options with an exercise price of $0.89 to employees and officers under the Company's 2014 Plan. These stock options had a grant-date fair value of $0.62 and vest at the rate of 6.25%

of the grant every three months over a period of four years, subject to the recipient's continued service with the Company through the applicable vesting dates.

Exhibit 4.0

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of the date of the Annual Report on Form 10-K of which this exhibit forms a part, the only class of securities of Sesen Bio, Inc. ("we," "us" and "our") registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is our common stock, $0.001 par value per share.

COMMON STOCK

The following description of our common stock summarizes provisions of our certificate of incorporation, as amended, our by-laws, as amended, and the Delaware General Corporation Law. For a complete description, refer to our certificate of incorporation, our by-laws and the amendments thereto, which are incorporated by reference as exhibits to the Annual Report on Form 10-K of which this exhibit is a part, and to the applicable provisions of the Delaware General Corporation Law.

Our certificate of incorporation authorizes us to issue up to 200,000,000 shares of common stock with a par value of $0.001 per share. As of February 29, 2020, there were 109,988,768 shares of common stock outstanding. The shares of common stock currently outstanding are fully paid and nonassessable.

Rights

Voting Rights. Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders. When a quorum is present at any meeting, a plurality of the votes properly cast for election to any office shall elect to such office and a majority of the votes properly cast upon any question other than an election to an office shall decide the question, except when a larger vote is required by law, by our certificate of incorporation or by our by-laws.

Our certificate of incorporation and by-laws do not provide for cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividends. Subject to the preferences that may be applicable to any then outstanding preferred stock, the holders of our outstanding shares of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation Rights. In the event of our liquidation or dissolution, the holders of our common stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any of our then outstanding preferred stock.

Other Rights. The terms of our common stock do not include any preemptive, conversion or subscription rights, nor any redemption or sinking fund provisions. The common stock is not subject to future calls or assessments by us.

Preferred Stock. Our board of directors is authorized to issue up to 5,000,000 shares of preferred stock in one or more series, with such rights, preferences and privileges as shall be determined by our board of directors. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of shares of any series of our preferred stock that we may classify and issue in the future.

Registration Rights. In connection with our acquisition of Viventia Bio, Inc., or Viventia, we entered into a registration rights agreement dated September 20, 2016, or the Registration Rights Agreement, with Clairmark Investments Ltd., or Clairmark, a former stockholder of Viventia and an affiliate of Leslie Dan, one of our former directors, which acquired shares of our common stock in the acquisition. Under the Registration Rights Agreement, if Clairmark requests that we register at least 1,791,164 shares of our common stock which represent an anticipated net aggregate offering price of at least $5 million, then we shall file a registration statement under the Securities Act covering such shares. In addition, if we propose to register for our own account any of our securities under the Securities Act, Clairmark has the right to require us to use our best efforts to register all or a portion of the shares acquired in the acquisition and still held by it in such registration statement. If not otherwise exercised, the rights under the Registration Rights Agreement described below will expire on September 20, 2021.

Anti-Takeover Effects of Our Certificate of Incorporation and By-laws and Delaware Law

Staggered Board; Removal of Directors. Our certificate of incorporation and our bylaws divide our board of directors into three classes with staggered three-year terms. In addition, our certificate of incorporation and our bylaws provide that directors may be removed only for cause and only by the affirmative vote of the holders of 75% of our shares of common stock present in person or by proxy and entitled to vote. Under our certificate of incorporation and bylaws, any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our

directors then in office. Furthermore, our certificate of incorporation provides that the authorized number of directors may be changed only by the resolution of our board of directors. The classification of our board of directors and the limitations on the ability of our stockholders to remove directors, change the authorized number of directors and fill vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our company.

Stockholder Action; Special Meeting of Stockholders; Advance Notice Requirements for Stockholder Proposals and Director Nominations. Our certificate of incorporation and our bylaws provide that any action required or permitted to be taken by our stockholders at an annual meeting or special meeting of stockholders may only be taken if it is properly brought before such meeting and may not be taken by written action in lieu of a meeting. Our certificate of incorporation and our bylaws also provide that, except as otherwise required by law, special meetings of the stockholders can only be called by the chairman of our board of directors, our chief executive officer or our board of directors. In addition, our bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of candidates for election to our board of directors. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors, or by a stockholder of record on the record date for the meeting who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities. These provisions also could discourage a third party from making a tender offer for our common stock because even if the third party acquired a majority of our outstanding voting stock, it would be able to take action as a stockholder, such as electing new directors or approving a merger, only at a duly called stockholders meeting and not by written consent.

Super-Majority Voting. The Delaware General Corporation Law provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws unless a corporation's certificate of incorporation or bylaws, as the case may be, requires a greater percentage. Our bylaws may be amended or repealed by a majority vote of our board of directors or the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in any annual election of directors. In addition, the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in any election of directors is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of our certificate of incorporation described above.

Delaware Law. We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding upon consummation of the transaction, excluding for purposes of determining the number of shares outstanding (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the consummation of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, Inc.

Stock Market Listing

Our common stock is listed for trading on the Nasdaq Global Market under the symbol “SESN.”

Exhibit 10.9

INDEMNIFICATION AGREEMENT

This Indemnification Agreement ("Agreement") is made as of [ ], 20[ ] by and between Sesen Bio, Inc., a Delaware corporation (the "Company"), and [ ] (the "Indemnitee"). This Agreement supersedes and replaces any and all previous Agreements between the Company and Indemnitee covering the subject matter of this Agreement.

RECITALS

WHEREAS, highly competent persons have become more reluctant to serve publicly-held corporations as directors, officers or in other capacities unless they are provided with adequate protection through insurance or adequate indemnification against inordinate risks of claims and actions against them arising out of their service to and activities on behalf of the corporation;

WHEREAS, the Board of Directors of the Company (the "Board") has determined that, in order to attract and retain qualified individuals, the Company will attempt to maintain on an ongoing basis, at its sole expense, liability insurance to protect persons serving the Company and its subsidiaries from certain liabilities. Although the furnishing of such insurance has been a customary and widespread practice among United States-based corporations and other business enterprises, the Company believes that, given current market conditions and trends, such insurance may be available to it in the future only at higher premiums and with more exclusions. At the same time, directors, officers, and other persons in service to corporations or business enterprises are being increasingly subjected to expensive and time-consuming litigation relating to, among other things, matters that traditionally would have been brought only against the Company or business enterprise itself. The Certificate of Incorporation of the Company (as the same may be amended from time to time, the "Certificate of Incorporation") requires indemnification of the officers and directors of the Company. Indemnitee may also be entitled to indemnification pursuant to the General Corporation Law of the State of Delaware (the "DGCL"). The Certificate of Incorporation and the DGCL expressly provide that the indemnification provisions set forth therein are not exclusive, and thereby contemplate that contracts may be entered into between the Company and members of the board of directors, officers and other persons with respect to indemnification;

WHEREAS, the uncertainties relating to such insurance and to indemnification have increased the difficulty of attracting and retaining such persons;

WHEREAS, the Board has determined that the increased difficulty in attracting and retaining such persons is detrimental to the best interests of the Company and its stockholders and that the Company should act to assure such persons that there will be increased certainty of such protection in the future;

WHEREAS, it is reasonable, prudent and necessary for the Company contractually to obligate itself to indemnify, and to advance expenses on behalf of, such persons to the fullest extent permitted by applicable law so that they will serve or continue to serve the Company free from undue concern that they will not be so indemnified;

WHEREAS, this Agreement is a supplement to and in furtherance of the Certificate of Incorporation and any resolutions adopted pursuant thereto, and shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder;

WHEREAS, Indemnitee does not regard the protection available under the Certificate of Incorporation and insurance as adequate in the present circumstances, and may not be willing to serve as an officer or director without adequate protection, and the Company desires Indemnitee to serve in such capacity. Indemnitee is willing to serve, continue to serve and to take on additional service for or on behalf of the Company on the condition that he be so indemnified; and

[WHEREAS, Indemnitee is a representative of [ ] [and its affiliated investment funds] (the "Fund"), and has certain rights to indemnification and/or insurance provided by the Fund which Indemnitee and the Fund intend to be secondary to the primary obligation of the Company to indemnify Indemnitee as provided herein, with the Company's acknowledgement and agreement to the foregoing being a material condition to Indemnitee's willingness to serve on the Board;]

NOW, THEREFORE, in consideration of the premises and the covenants contained herein, the Company and Indemnitee do hereby covenant and agree as follows:

Section 1. Services to the Company. Indemnitee agrees to serve a[n] [director] [officer] of the Company. Indemnitee may at any time and for any reason resign from such position (subject to any other contractual obligation or any obligation imposed by operation of law), in which event the Company shall have no obligation under this Agreement to continue Indemnitee in such position. This Agreement shall not be deemed an employment contract between the Company (or of its subsidiaries or any Enterprise) and Indemnitee. Indemnitee specifically acknowledges that Indemnitee's employment with the Company (or of its subsidiaries or any Enterprise), if any, is at will, and the Indemnitee may be discharged at any time for any reason, with or without cause, except as may be otherwise provided in any written employment contract between

Indemnitee and the Company (or of its subsidiaries or any Enterprise), other applicable formal severance policies duly adopted by the Board, or, with respect to service as a director or officer of the Company, by the Certificate of Incorporation, the Company's Bylaws, and the DGCL. The foregoing notwithstanding, this Agreement shall continue in force after Indemnitee has ceased to serve as a[n] [director] [officer] of the Company, as provided in Section 16 hereof.

Section 2. Definitions. As used in this Agreement:

(a) References to "agent" shall mean any person who is or was a director, officer, or employee of the Company or a subsidiary of the Company or other person authorized by the Company to act for the Company, to include such person serving in such capacity as a director, officer, employee, fiduciary or other official of another corporation, partnership, limited liability company, joint venture, trust or other enterprise at the request of, for the convenience of, or to represent the interests of the Company or a subsidiary of the Company.

(b) A "Change in Control" shall be deemed to occur upon the earliest to occur after the date of this Agreement of any of the following events:

i. Acquisition of Stock by Third Party. Any Person (as defined below) is or becomes the Beneficial Owner (as defined below), directly or indirectly, of securities of the Company representing forty percent (40%) or more of the combined voting power of the Company's then outstanding securities unless the change in relative Beneficial Ownership of the Company's securities by any Person results solely from a reduction in the aggregate number of outstanding shares of securities entitled to vote generally in the election of directors;

ii. Change in Board of Directors. During any period of two (2) consecutive years (not including any period prior to the execution of this Agreement), individuals who at the beginning of such period constitute the Board, and any new director (other than a director designated by a person who has entered into an agreement with the Company to effect a transaction described in Sections 2(b)(i), 2(b)(iii) or 2(b)(iv)) whose election by the Board or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the period or whose election or nomination for election was previously so approved, cease for any reason to constitute at least a majority of the members of the Board;

iii. Corporate Transactions. The effective date of a merger or consolidation of the Company with any other entity, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or its ultimate parent, as applicable) more than 51% of the combined voting power of the voting securities of the surviving entity or its ultimate parent, as applicable, outstanding immediately after such merger or consolidation and with the power to elect at least a majority of the board of directors or other governing body of such surviving entity or its ultimate parent, as applicable;

iv. Liquidation or Sale of Assets. The approval by the stockholders of the Company of a complete liquidation of the Company or an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets; and

v. Other Events. There occurs any other event of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A (or a response to any similar item on any similar schedule or form) promulgated under the Exchange Act (as defined below), whether or not the Company is then subject to such reporting requirement.

For purposes of this Section 2(b), the following terms shall have the following meanings:

(A) "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended from time to time.

(B) "Person" shall have the meaning as set forth in Sections 13(d) and 14(d) of the Exchange Act; provided, however, that Person shall exclude (i) the Company, (ii) any trustee or other fiduciary holding securities under an employee benefit plan of the Company, and (iii) any corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company.

(C) "Beneficial Owner" shall have the meaning given to such term in Rule 13d-3 under the Exchange Act; provided, however, that Beneficial Owner shall exclude any Person otherwise becoming a Beneficial Owner by reason of the stockholders of the Company approving a merger of the Company with another entity.

(D) “Corporate Status” describes the status of a person as a current or former director or officer of the Company or as a current or former director, manager, partner, officer, employee, agent, or trustee of any other entity or enterprise that such person is or was serving at the request of the Company.

(E) “Disinterested Director” shall mean a director of the Company who is not and was not a party to the Proceeding in respect of which indemnification is sought by Indemnitee.

(F) “Enterprise” shall mean the Company and any other corporation, limited liability company, partnership, joint venture, trust or other enterprise of which Indemnitee is or was serving at the request of the Company as a director, officer, trustee, partner, managing member, employee, agent or fiduciary.

(G) “Expenses” shall include all reasonable attorneys’ fees, retainers, court costs, transcript costs, fees of experts and other professionals, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees, any federal, state, local or foreign taxes imposed on Indemnitee as a result of the actual or deemed receipt of any payments under this Agreement, ERISA excise taxes and penalties, and all other disbursements or expenses of the types customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, being or preparing to be a witness in, or otherwise participating in, a Proceeding. Expenses also shall include (i) Expenses incurred in connection with any appeal resulting from any Proceeding, including without limitation the premium, security for, and other costs relating to any cost bond, supersedeas bond, or other appeal bond or its equivalent, and (ii) for purposes of Section 14(d) only, Expenses incurred by Indemnitee in connection with the interpretation, enforcement or defense of Indemnitee’s rights under this Agreement, by litigation or otherwise. The parties agree that for the purposes of any advancement of Expenses for which Indemnitee has made written demand to the Company in accordance with this Agreement, all Expenses included in such demand that are certified by affidavit of Indemnitee’s counsel as being reasonable shall be presumed conclusively to be reasonable. Expenses, however, shall not include amounts paid in settlement by Indemnitee or the amount of judgments or fines against Indemnitee.

(H) “Independent Counsel” shall mean a law firm, or a member of a law firm, that is experienced in matters of corporation law and neither presently is, nor in the past five years has been, retained to represent: (i) the Company or Indemnitee in any matter material to either such party (other than with respect to matters concerning the Indemnitee under this Agreement, or of other indemnitees under similar indemnification agreements), or (ii) any other party to the Proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term “Independent Counsel” shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company or Indemnitee in an action to determine Indemnitee’s rights under this Agreement. The Company agrees to pay the reasonable fees and expenses of the Independent Counsel referred to above and to fully indemnify such counsel against any and all Expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.

(I) The term “Proceeding” shall include any threatened, pending or completed action, suit, claim, counterclaim, cross claim, arbitration, mediation, alternate dispute resolution mechanism, investigation, inquiry, administrative hearing or any other actual, threatened or completed proceeding, whether brought in the right of the Company or otherwise and whether of a civil, criminal, administrative, legislative, or investigative (formal or informal) nature, including any appeal therefrom, in which Indemnitee was, is or will be involved as a party, potential party, non-party witness or otherwise by reason of the fact that Indemnitee is or was a director or officer of the Company, by reason of any action taken by him (or a failure to take action by him) or of any action (or failure to act) on his part while acting pursuant to his Corporate Status, in each case whether or not serving in such capacity at the time any liability or Expense is incurred for which indemnification, reimbursement, or advancement of Expenses can be provided under this Agreement. If the Indemnitee believes in good faith that a given situation may lead to or culminate in the institution of a Proceeding, this shall be considered a Proceeding under this paragraph.

(J) Reference to “other enterprise” shall include employee benefit plans; references to “fines” shall include any excise tax assessed with respect to any employee benefit plan; references to “serving at the request of the Company” shall include any service as a director, officer, employee or agent of the Company which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner he reasonably believed to be in the best interests of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in manner “not opposed to the best interests of the Company” as referred to in this Agreement.

Section 3. Indemnity in Third-Party Proceedings. The Company shall indemnify Indemnitee in accordance with the provisions of this Section 3 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding, other than a Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 3, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses, judgments, fines and amounts paid in settlement (including all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses, judgments, fines and amounts paid in settlement) actually and reasonably incurred by Indemnitee or on his behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the Company and, in the case of a criminal Proceeding had no reasonable cause to believe that his conduct was unlawful. The parties hereto intend that this Agreement shall provide to the fullest extent permitted by law for indemnification in excess of that expressly permitted by statute, including, without limitation, any indemnification provided by the Certificate of Incorporation, the Bylaws, vote of its stockholders or disinterested directors or applicable law.

Section 4. Indemnity in Proceedings by or in the Right of the Company. The Company shall indemnify Indemnitee in accordance with the provisions of this Section 4 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 4, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses actually and reasonably incurred by him or on his behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the Company. No indemnification for Expenses shall be made under this Section 4 in respect of any claim, issue or matter as to which Indemnitee shall have been finally adjudged by a court to be liable to the Company, unless and only to the extent that the Delaware Court of Chancery (the "Delaware Court") or any court in which the Proceeding was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnification for such expenses as the Delaware Court shall deem proper.

Section 5. Indemnification for Expenses of a Party Who is Wholly or Partly Successful. Notwithstanding any other provisions of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is a party to (or a participant in) and is successful, on the merits or otherwise, in any Proceeding or in defense of any claim, issue or matter therein, in whole or in part, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by him in connection therewith. If Indemnitee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, as to one or more but less than all claims, issues or matters in such Proceeding, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by him or on his behalf in connection with or related to each successfully resolved claim, issue or matter to the fullest extent permitted by law. For purposes of this Section and without limitation, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, shall be deemed to be a successful result as to such claim, issue or matter.

Section 6. Indemnification For Expenses of a Witness. Notwithstanding any other provision of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is, by reason of his Corporate Status, a witness or otherwise asked to participate in any Proceeding to which Indemnitee is not a party, he shall be indemnified against all Expenses actually and reasonably incurred by him or on his behalf in connection therewith.

Section 7. Partial Indemnification. If Indemnitee is entitled under any provision of this Agreement to indemnification by the Company for some or a portion of Expenses, but not, however, for the total amount thereof, the Company shall nevertheless indemnify Indemnitee for the portion thereof to which Indemnitee is entitled.

Section 8. Additional Indemnification.

(a) Notwithstanding any limitation in Sections 3, 4, or 5, the Company shall indemnify Indemnitee to the fullest extent permitted by applicable law if Indemnitee is a party to or threatened to be made a party to any Proceeding (including a Proceeding by or in the right of the Company to procure a judgment in its favor) against all Expenses, judgments, fines and amounts paid in settlement (including all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses, judgments, fines and amounts paid in settlement) actually and reasonably incurred by Indemnitee in connection with the Proceeding.

(b) For purposes of Section 8(a), the meaning of the phrase "to the fullest extent permitted by applicable law" shall include, but not be limited to:

i. to the fullest extent permitted by the provision of the DGCL that authorizes or contemplates additional indemnification by agreement, or the corresponding provision of any amendment to or replacement of the DGCL, and

ii. to the fullest extent authorized or permitted by any amendments to or replacements of the DGCL adopted after the date of this Agreement that increase the extent to which a corporation may indemnify its officers and directors.

Section 9. Exclusions. Notwithstanding any provision in this Agreement [but subject to Section 15(e), however], the Company shall not be obligated under this Agreement to make any indemnification payment in connection with any claim made against Indemnitee:

(a) for which payment has actually been made to or on behalf of Indemnitee under any insurance policy or other indemnity provision, except with respect to any excess beyond the amount paid under any insurance policy or other indemnity provision; or

(b) for (i) an accounting of profits made from the purchase and sale (or sale and purchase) by Indemnitee of securities of the Company within the meaning of Section 16(b) of the Exchange Act (as defined in Section 2(b) hereof) or similar provisions of state statutory law or common law, or (ii) any reimbursement of the Company by the Indemnitee of any bonus or other incentive-based or equity-based compensation or of any profits realized by the Indemnitee from the sale of securities of the Company, as required in each case under the Exchange Act (including any such reimbursements that arise from an accounting restatement of the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), or the payment to the Company of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 306 of the Sarbanes-Oxley Act); or

(c) except as provided in Section 14(d) of this Agreement, in connection with any Proceeding (or any part of any Proceeding) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against the Company or its directors, officers, employees or other indemnitees, unless (i) the Board authorized the Proceeding (or any part of any Proceeding) prior to its initiation or (ii) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law.

Section 10. Advances of Expenses. Notwithstanding any provision of this Agreement to the contrary (other than Section 14(d)), the Company shall advance, to the extent not prohibited by law, the Expenses incurred by Indemnitee in connection with any Proceeding (or any part of any Proceeding) not initiated by Indemnitee, and such advancement shall be made within thirty (30) days after the receipt by the Company of a statement or statements requesting such advances from time to time, whether prior to or after final disposition of any Proceeding. Advances shall be unsecured and interest free. Advances shall be made without regard to Indemnitee's ability to repay the Expenses and without regard to Indemnitee's ultimate entitlement to indemnification under the other provisions of this Agreement. In accordance with Section 14(d), advances shall include any and all reasonable Expenses incurred pursuing an action to enforce this right of advancement, including Expenses incurred preparing and forwarding statements to the Company to support the advances claimed. The Indemnitee shall qualify for advances upon the execution and delivery to the Company of this Agreement, which shall constitute an undertaking providing that the Indemnitee undertakes to repay the amounts advanced (without interest) to the extent that it is ultimately determined that Indemnitee is not entitled to be indemnified by the Company. No other form of undertaking shall be required other than the execution of this Agreement. This Section 10 shall not apply to any claim made by Indemnitee for which indemnity is excluded pursuant to Section 9.

Section 11. Procedure for Notification and Defense of Claim.

(a) Indemnitee shall notify the Company in writing of any matter with respect to which Indemnitee intends to seek indemnification or advancement of Expenses hereunder as soon as reasonably practicable following the receipt by Indemnitee of written notice thereof. The written notification to the Company shall include a description of the nature of the Proceeding and the facts underlying the Proceeding. To obtain indemnification under this Agreement, Indemnitee shall submit to the Company a written request, including therein or therewith such documentation and information as is reasonably available to Indemnitee and is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification following the final disposition of such Proceeding. The omission by Indemnitee to notify the Company hereunder will not relieve the Company from any liability which it may have to Indemnitee hereunder or otherwise than under this Agreement, and any delay in so notifying the Company shall not constitute a waiver by Indemnitee of any rights under this Agreement. The Secretary of the Company shall, promptly upon receipt of such a request for indemnification, advise the Board in writing that Indemnitee has requested indemnification.

(b) The Company will be entitled to participate in the Proceeding at its own expense.

Section 12. Procedure Upon Application for Indemnification.

(a) Upon written request by Indemnitee for indemnification pursuant to Section 11(a), a determination, if required by applicable law, with respect to Indemnitee's entitlement thereto shall be made in the specific case: (i) if a Change

in Control shall have occurred, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to Indemnitee; or (ii) if a Change in Control shall not have occurred, (A) by a majority vote of the Disinterested Directors, even though less than a quorum of the Board, (B) by a committee of Disinterested Directors designated by a majority vote of the Disinterested Directors, even though less than a quorum of the Board, (C) if there are no such Disinterested Directors or, if such Disinterested Directors so direct, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to Indemnitee or (D) if so directed by the Board, by the stockholders of the Company; and, if it is so determined that Indemnitee is entitled to indemnification, payment to Indemnitee shall be made within ten (10) days after such determination. Indemnitee shall cooperate with the person, persons or entity making such determination with respect to Indemnitee's entitlement to indemnification, including providing to such person, persons or entity upon reasonable advance request any documentation or information which is not privileged or otherwise protected from disclosure and which is reasonably available to Indemnitee and reasonably necessary to such determination. Any costs or Expenses (including attorneys' fees and disbursements) incurred by Indemnitee in so cooperating with the person, persons or entity making such determination shall be borne by the Company (irrespective of the determination as to Indemnitee's entitlement to indemnification) and the Company hereby indemnifies and agrees to hold Indemnitee harmless therefrom. The Company promptly will advise Indemnitee in writing with respect to any determination that Indemnitee is or is not entitled to indemnification, including a description of any reason or basis for which indemnification has been denied.

(b) In the event the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 12(a) hereof, the Independent Counsel shall be selected as provided in this Section 12(b). If a Change in Control shall not have occurred, the Independent Counsel shall be selected by the Board, and the Company shall give written notice to Indemnitee advising him of the identity of the Independent Counsel so selected. If a Change in Control shall have occurred, the Independent Counsel shall be selected by Indemnitee (unless Indemnitee shall request that such selection be made by the Board, in which event the preceding sentence shall apply), and Indemnitee shall give written notice to the Company advising it of the identity of the Independent Counsel so selected. In either event, Indemnitee or the Company, as the case may be, may, within ten (10) days after such written notice of selection shall have been given, deliver to the Company or to Indemnitee, as the case may be, a written objection to such selection; provided, however, that such objection may be asserted only on the ground that the Independent Counsel so selected does not meet the requirements of "Independent Counsel" as defined in Section 2 of this Agreement, and the objection shall set forth with particularity the factual basis of such assertion. Absent a proper and timely objection, the person so selected shall act as Independent Counsel. If such written objection is so made and substantiated, the Independent Counsel so selected may not serve as Independent Counsel unless and until such objection is withdrawn or the Delaware Court has determined that such objection is without merit. If, within twenty (20) days after the later of submission by Indemnitee of a written request for indemnification pursuant to Section 11(a) hereof and the final disposition of the Proceeding, no Independent Counsel shall have been selected and not objected to, either the Company or Indemnitee may petition the Delaware Court for resolution of any objection which shall have been made by the Company or Indemnitee to the other's selection of Independent Counsel and/or for the appointment as Independent Counsel of a person selected by such court or by such other person as such court shall designate, and the person with respect to whom all objections are so resolved or the person so appointed shall act as Independent Counsel under Section 12(a) hereof. Upon the due commencement of any judicial proceeding or arbitration pursuant to Section 14(a) of this Agreement, Independent Counsel shall be discharged and relieved of any further responsibility in such capacity (subject to the applicable standards of professional conduct then prevailing).

Section 13. Presumptions and Effect of Certain Proceedings.

(a) In making a determination with respect to entitlement to indemnification hereunder, the person or persons or entity making such determination shall, to the fullest extent not prohibited by law, presume that Indemnitee is entitled to indemnification under this Agreement if Indemnitee has submitted a request for indemnification in accordance with Section 11(a) of this Agreement, and the Company shall, to the fullest extent not prohibited by law, have the burden of proof to overcome that presumption in connection with the making by any person, persons or entity of any determination contrary to that presumption. Neither the failure of the Company (including by its directors or Independent Counsel) to have made a determination prior to the commencement of any action pursuant to this Agreement that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Company (including by its directors or Independent Counsel) that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct.

(b) Subject to Section 14(e), if the person, persons or entity empowered or selected under Section 12 of this Agreement to determine whether Indemnitee is entitled to indemnification shall not have made a determination within sixty (60) days after receipt by the Company of the request therefor, the requisite determination of entitlement to indemnification shall, to the fullest extent not prohibited by law, be deemed to have been made and Indemnitee shall be entitled to such indemnification, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law; provided, however, that such 60-day period may be extended for a reasonable time, not to exceed an additional thirty (30) days, if the person, persons or entity making the determination with respect to entitlement to indemnification in good faith requires such additional time for the obtaining or evaluating of documentation and/or information relating thereto; and provided, further, that the foregoing provisions of this Section 13(b) shall not apply (i) if the determination of entitlement to indemnification is to be made by the stockholders pursuant to Section 12(a) of this Agreement and if (A) within fifteen (15) days after receipt by the Company of the request for such determination the Board has resolved to submit such determination to the stockholders for their consideration at an annual meeting thereof to be held within seventy-five (75) days after such receipt and such determination is made thereat, or (B) a special meeting of stockholders is called within fifteen (15) days after such receipt for the purpose of making such determination, such meeting is held for such purpose within sixty (60) days after having been so called and such determination is made thereat, or (ii) if the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 12(a) of this Agreement.

(c) The termination of any Proceeding or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or upon a plea of nolo contendere or its equivalent, shall not (except as otherwise expressly provided in this Agreement) of itself adversely affect the right of Indemnitee to indemnification or create a presumption that Indemnitee did not act in good faith and in a manner which he reasonably believed to be in or not opposed to the best interests of the Company or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that his conduct was unlawful.

(d) For purposes of any determination of good faith, Indemnitee shall be deemed to have acted in good faith if Indemnitee's action is based on the records or books of account of the Enterprise, including financial statements, or on information supplied to Indemnitee by the directors or officers of the Enterprise in the course of their duties, or on the advice of legal counsel for the Enterprise or on information or records given or reports made to the Enterprise by an independent certified public accountant or by an appraiser or other expert selected with the reasonable care by the Enterprise. The provisions of this Section 13(d) shall not be deemed to be exclusive or to limit in any way the other circumstances in which the Indemnitee may be deemed to have met the applicable standard of conduct set forth in this Agreement.

(e) The knowledge and/or actions, or failure to act, of any director, officer, trustee, partner, managing member, fiduciary, agent or employee of the Enterprise shall not be imputed to Indemnitee for purposes of determining the right to indemnification under this Agreement.

Section 14. Remedies of Indemnitee.

(a) Subject to Section 14(e), in the event that (i) a determination is made pursuant to Section 12 of this Agreement that Indemnitee is not entitled to indemnification under this Agreement, (ii) advancement of Expenses is not timely made pursuant to Section 10 of this Agreement, (iii) no determination of entitlement to indemnification shall have been made pursuant to Section 12(a) of this Agreement within ninety (90) days after receipt by the Company of the request for indemnification, (iv) payment of indemnification is not made pursuant to Section 5, 6 or 7 or the last sentence of Section 12(a) of this Agreement within ten (10) days after receipt by the Company of a written request therefor, (v) payment of indemnification pursuant to Section 3, 4 or 8 of this Agreement is not made within ten (10) days after a determination has been made that Indemnitee is entitled to indemnification, or (vi) in the event that the Company or any other person takes or threatens to take any action to declare this Agreement void or unenforceable, or institutes any litigation or other action or Proceeding designed to deny, or to recover from, the Indemnitee the benefits provided or intended to be provided to the Indemnitee hereunder, Indemnitee shall be entitled to an adjudication by a court of his entitlement to such indemnification or advancement of Expenses. Alternatively, Indemnitee, at his option, may seek an award in arbitration to be conducted by a single arbitrator pursuant to the Commercial Arbitration Rules of the American Arbitration Association. Indemnitee shall commence such proceeding seeking an adjudication or an award in arbitration within 180 days following the date on which Indemnitee first has the right to commence such proceeding pursuant to this Section 14(a); provided, however, that the foregoing clause shall not apply in respect of a proceeding brought by Indemnitee to enforce his rights under Section 5 of this Agreement. The Company shall not oppose Indemnitee's right to seek any such adjudication or award in arbitration.

(b) In the event that a determination shall have been made pursuant to Section 12(a) of this Agreement that Indemnitee is not entitled to indemnification, any judicial proceeding or arbitration commenced pursuant to this Section 14 shall be conducted in all respects as a de novo trial, or arbitration, on the merits and Indemnitee shall not be prejudiced by reason of that adverse determination. In any judicial proceeding or arbitration commenced pursuant to this Section 14, the Company shall have the burden of proving Indemnitee is not entitled to indemnification or advancement of Expenses, as the case may be.

(c) If a determination shall have been made pursuant to Section 12(a) of this Agreement that Indemnitee is entitled to indemnification, the Company shall be bound by such determination in any judicial proceeding or arbitration commenced pursuant to this Section 14, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law.

(d) The Company shall, to the fullest extent not prohibited by law, be precluded from asserting in any judicial proceeding or arbitration commenced pursuant to this Section 14 that the procedures and presumptions of this Agreement are not valid, binding and enforceable and shall stipulate in any such court or before any such arbitrator that the Company is bound by all the provisions of this Agreement. It is the intent of the Company that, to the fullest extent permitted by law, the Indemnitee not be required to incur legal fees or other Expenses associated with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement by litigation or otherwise because the cost and expense thereof would substantially detract from the benefits intended to be extended to the Indemnitee hereunder. The Company shall, to the fullest extent permitted by law, indemnify Indemnitee against any and all Expenses and, if requested by Indemnitee, shall (within ten (10) days after receipt by the Company of a written request therefor) advance, to the extent not prohibited by law, such Expenses to Indemnitee, which are incurred by Indemnitee in connection with any action brought by Indemnitee for indemnification or advance of Expenses from the Company under this Agreement or under any directors' and officers' liability insurance policies maintained by the Company if, in the case of indemnification, Indemnitee is wholly successful on the underlying claims; if Indemnitee is not wholly successful on the underlying claims, then such indemnification shall be only to the extent Indemnitee is successful on such underlying claims or otherwise as permitted by law, whichever is greater.

(e) Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement of Indemnitee to indemnification under this Agreement shall be required to be made prior to the final disposition of the Proceeding.

Section 15. Non-exclusivity; Survival of Rights; Insurance; Subrogation.

(a) The rights of indemnification and to receive advancement of Expenses as provided by this Agreement shall not be deemed exclusive of any other rights to which Indemnitee may at any time be entitled under applicable law, the Certificate of Incorporation, the Bylaws, any agreement, a vote of stockholders or a resolution of directors, or otherwise. No amendment, alteration or repeal of this Agreement or of any provision hereof shall limit or restrict any right of Indemnitee under this Agreement in respect of any action taken or omitted by such Indemnitee in his Corporate Status prior to such amendment, alteration or repeal. To the extent that a change in Delaware law, whether by statute or judicial decision, permits greater indemnification or advancement of Expenses than would be afforded currently under the Certificate of Incorporation and this Agreement, it is the intent of the parties hereto that Indemnitee shall enjoy by this Agreement the greater benefits so afforded by such change. No right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. The assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other right or remedy.

(b) To the extent that the Company maintains an insurance policy or policies providing liability insurance for directors, officers, employees, or agents of the Enterprise, Indemnitee shall be covered by such policy or policies in accordance with its or their terms to the maximum extent of the coverage available for any such director, officer, employee or agent under such policy or policies. If, at the time of the receipt of a notice of a claim pursuant to the terms hereof, the Company has director and officer liability insurance in effect, the Company shall give prompt notice of such claim or of the commencement of a Proceeding, as the case may be, to the insurers in accordance with the procedures set forth in the respective policies. The Company shall thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of the Indemnitee, all amounts payable as a result of such Proceeding in accordance with the terms of such policies.

(c) In the event of any payment under this Agreement, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee [(other than any rights of recovery of Indemnitee from a Fund Indemnitor or under any insurance provided by the Fund or its affiliates)], who shall execute all papers required and take all

action necessary to secure such rights, including execution of such documents as are necessary to enable the Company to bring suit to enforce such rights.

(d) [Except as provided for under Section 15(e) of this Agreement, the] The Company shall not be liable under this Agreement to make any payment of amounts otherwise indemnifiable (or for which advancement is provided hereunder) hereunder if and to the extent that Indemnitee has otherwise actually received such payment under any insurance policy, contract, agreement or otherwise.

(e) [The Company hereby acknowledges that Indemnitee has certain rights to indemnification, advancement of expenses and/or insurance provided by the Fund and certain of its affiliates (collectively, the "Fund Indemnitors"). The Company hereby agrees (i) that it is the indemnitor of first resort (i.e., its obligations to Indemnitee are primary and any obligation of the Fund Indemnitors to advance expenses or to provide indemnification for the same expenses or liabilities incurred by Indemnitee are secondary), (ii) that it shall be required to advance the full amount of Expenses incurred by Indemnitee and shall be liable for the full amount of all Expenses, judgments, penalties, fines and amounts paid in settlement to the extent legally permitted and as required by the Certificate of Incorporation or Bylaws (or any agreement between the Company and Indemnitee), without regard to any rights Indemnitee may have against the Fund Indemnitors, and, (iii) that it irrevocably waives, relinquishes and releases the Fund Indemnitors from any and all claims against the Fund Indemnitors for contribution, subrogation or any other recovery of any kind in respect thereof. The Company further agrees that no advancement or payment by the Fund Indemnitors on behalf of Indemnitee with respect to any claim for which Indemnitee has sought indemnification from the Company shall affect the foregoing and the Fund Indemnitors shall have a right of contribution and/or be subrogated to the extent of such advancement or payment to all of the rights of recovery of Indemnitee against the Company. The Company and Indemnitee agree that the Fund Indemnitors are express third party beneficiaries of the terms hereof.]

Section 16. Duration of Agreement. This Agreement shall continue until and terminate upon the later of: (a) ten (10) years after the date that Indemnitee shall have ceased to serve as a [director] [officer] of the Company or (b) one (1) year after the final termination of any Proceeding then pending in respect of which Indemnitee is granted rights of indemnification or advancement of Expenses hereunder and of any proceeding commenced by Indemnitee pursuant to Section 14 of this Agreement [or by a Fund Indemnitor pursuant to Section 15(e) of this Agreement, in either case,] relating thereto. The indemnification and advancement of expenses rights provided by or granted pursuant to this Agreement shall be binding upon and be enforceable by the parties hereto and their respective successors and assigns (including any direct or indirect successor by purchase, merger, consolidation or otherwise to all or substantially all of the business or assets of the Company), shall continue as to an Indemnitee who has ceased to be a director, officer, employee or agent of the Company or of any other Enterprise, and shall inure to the benefit of Indemnitee and his or her spouse, assigns, heirs, devisees, executors and administrators and other legal representatives.

Section 17. Severability. If any provision or provisions of this Agreement shall be held to be invalid, illegal or unenforceable for any reason whatsoever: (a) the validity, legality and enforceability of the remaining provisions of this Agreement (including without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and shall remain enforceable to the fullest extent permitted by law; (b) such provision or provisions shall be deemed reformed to the extent necessary to conform to applicable law and to give the maximum effect to the intent of the parties hereto; and (c) to the fullest extent possible, the provisions of this Agreement (including, without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested thereby.

Section 18. Enforcement.

(a) The Company expressly confirms and agrees that it has entered into this Agreement and assumed the obligations imposed on it hereby in order to induce Indemnitee to serve as a director or officer of the Company, and the Company acknowledges that Indemnitee is relying upon this Agreement in serving as a director or officer of the Company.

(b) This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral, written and implied, between the parties hereto with respect to the subject matter hereof; provided, however, that this Agreement is a supplement to and in furtherance of the Certificate of Incorporation, the Bylaws and applicable law, and shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder.

Section 19. Modification and Waiver. No supplement, modification or amendment of this Agreement shall be binding unless executed in writing by the parties hereto. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions of this Agreement nor shall any waiver constitute a continuing waiver.

Section 20. Notice by Indemnitee. Indemnitee agrees promptly to notify the Company in writing upon being served with any summons, citation, subpoena, complaint, indictment, information or other document relating to any Proceeding or matter which may be subject to indemnification or advancement of Expenses covered hereunder. The failure of Indemnitee to so notify the Company shall not relieve the Company of any obligation which it may have to the Indemnitee under this Agreement or otherwise.

Section 21. Notices. All notices, requests, demands and other communications under this Agreement shall be in writing and shall be deemed to have been duly given if (a) delivered by hand and receipted for by the party to whom said notice or other communication shall have been directed, (b) mailed by certified or registered mail with postage prepaid, on the third business day after the date on which it is so mailed, (c) mailed by reputable overnight courier and receipted for by the party to whom said notice or other communication shall have been directed or (d) sent by facsimile transmission, with receipt of oral confirmation that such transmission has been received:

(a) If to Indemnitee, at the address indicated on the signature page of this Agreement, or such other address as Indemnitee shall provide to the Company.

(b) If to the Company to:

Sesen Bio, Inc.
245 First Street, Suite 1800
Cambridge, MA 02142
Attention: Chief Financial Officer
or to any other address as may have been furnished to Indemnitee by the Company.

Section 22. Contribution. To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to Indemnitee for any reason whatsoever, the Company, in lieu of indemnifying Indemnitee, shall contribute to the amount incurred by Indemnitee, whether for judgments, fines, penalties, excise taxes, amounts paid or to be paid in settlement and/or for Expenses, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in light of all of the circumstances of such Proceeding in order to reflect (i) the relative benefits received by the Company, on the one hand, and Indemnitee, on the other hand, as a result of the event(s) and/or transaction(s) giving cause to such Proceeding; and/or (ii) the relative fault of the Company (and its other directors, officers, employees and agents), on the one hand, and Indemnitee, on the other hand, in connection with such event(s) and/or transaction(s).

Section 23. Applicable Law and Consent to Jurisdiction. This Agreement and the legal relations among the parties shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, without regard to its conflict of laws rules. Except with respect to any arbitration commenced by Indemnitee pursuant to Section 14(a) of this Agreement, the Company and Indemnitee hereby irrevocably and unconditionally (i) agree that any action or proceeding arising out of or in connection with this Agreement shall be brought only in the Delaware Court, and not in any other state or federal court in the United States of America or any court in any other country, (ii) consent to submit to the exclusive jurisdiction of the Delaware Court for purposes of any action or proceeding arising out of or in connection with this Agreement, (iii) appoint, to the extent such party is not otherwise subject to service of process in the State of Delaware, irrevocably the Corporation Trust Center as its agent in the State of Delaware as such party's agent for acceptance of legal process in connection with any such action or proceeding against such party with the same legal force and validity as if served upon such party personally within the State of Delaware, (iv) waive any objection to the laying of venue of any such action or proceeding in the Delaware Court, and (v) waive, and agree not to plead or to make, any claim that any such action or proceeding brought in the Delaware Court has been brought in an improper or inconvenient forum.

Section 24. Identical Counterparts. This Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement. Only one such counterpart signed by the party against whom enforceability is sought needs to be produced to evidence the existence of this Agreement.

Section 25. Miscellaneous. Use of the masculine pronoun shall be deemed to include usage of the feminine pronoun where appropriate. The headings of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.

[*The remainder of this page is intentionally left blank.*]

The parties executed this Agreement as of the day and year first set forth above.

SESEN BIO, INC.

By: _____
Name: _____
Office: _____

INDEMNITEE

Name: _____
Address: _____
_____
_____

Schedule of Material Differences to Exhibit 10.9

The following directors and executive officers are parties to an Indemnification Agreement with the Company, each of which are substantially identical in all material respects to the representative Indemnification Agreement filed herewith as Exhibit 10.9 except as to the name of the signatory and the effective date of each signatory's Indemnification Agreement and the fund affiliation of each signatory, which are listed below. The actual Indemnification Agreements are omitted pursuant to Instruction 2 to Item 601 of Regulation S-K.

Indemnitee	Effective Date	Fund Affiliation
Wendy L. Dixon, Ph.D.	October 22, 2014	
Daniel S. Lynch	February 11, 2014	
Jane V. Henderson	February 11, 2014	
Jay S. Duker	January 20, 2015	
Leslie L. Dan	September 20, 2016	
Stephen A. Hurly	September 20, 2016	
Richard F. Fitzgerald	January 23, 2018	
Thomas R. Cannell, D.V.M.	August 7, 2018	
Dennis Kim, M.D., MPH	December 3, 2018	
Glen MacDonald, Ph.D.	August 26, 2019	
Mark R. Sullivan	August 26, 2019	
Monica Forbes	August 26, 2019	
Carrie L. Bourdow	February 24, 2020	
Jason A. Keyes	February 24, 2020	

Exhibit 21.1

Subsidiaries of Sesen Bio, Inc.

Subsidiary	Jurisdiction of Incorporation
Viventia Bio Inc.	Province of Ontario, Canada
Viventia Bio USA Inc.	Province of Ontario, Canada
Viventia Biotech (EU) Limited	United Kingdom

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-195170) pertaining to the Eleven Biotherapeutics, Inc. Amended and Restated 2009 Stock Incentive Plan, 2014 Stock Incentive Plan and 2014 Employee Stock Purchase Plan;
(2) Registration Statement (Post-Effective Amendment No. 1 to Form S-1 on Form S-3 No. 333-201176) of Eleven Biotherapeutics, Inc.;
(3) Registration Statement (Form S-8 No. 333-202677) pertaining to the Eleven Biotherapeutics, Inc. 2014 Stock Incentive Plan;
(4) Registration Statement (Form S-8 No. 333-210523) pertaining to the Eleven Biotherapeutics, Inc. 2014 Stock Incentive Plan;
(5) Registration Statement (Form S-8 No. 333-217686) pertaining to the Eleven Biotherapeutics, Inc. 2014 Stock Incentive Plan;
(6) Registration Statement (Form S-8 No. 333-217687) pertaining to the Eleven Biotherapeutics, Inc. Inducement Stock Option Awards;
(7) Registration Statement (Amendment No. 3 to Form S-1 No. 333-220809) of Eleven Biotherapeutics, Inc.;
(8) Registration Statement (Form S-3 No. 333-224682) of Eleven Biotherapeutics, Inc.;
(9) Registration Statement (Pre-Effective Amendment No. 1 to Form S-3 No. 333-223750) of Eleven Biotherapeutics, Inc.;
(10) Registration Statement (Post-Effective Amendment No. 1 to Form S-8 No. 333-224959) pertaining to the Sesen Bio, Inc. 2014 Stock Incentive Plan (formerly known as the Eleven Biotherapeutics, Inc. 2014 Stock Incentive Plan);
(11) Registration Statement (Form S-8 No. 333-231644) pertaining to the Sesen Bio, Inc. 2014 Stock Incentive Plan (formerly known as the Eleven Biotherapeutics, Inc. 2014 Stock Incentive Plan) and Sesen Bio, Inc. Inducement Stock Option Awards; and
(12) Registration Statement (Form S-8 No. 333-234697) pertaining to the Sesen Bio, Inc. 2014 Stock Incentive Plan (formerly known as the Eleven Biotherapeutics, Inc. 2014 Stock Incentive Plan) and Sesen Bio, Inc. Inducement Stock Option Awards

of our reports dated March 16, 2020, with respect to the consolidated financial statements of Sesen Bio, Inc. and the effectiveness of internal control over financial reporting of Sesen Bio, Inc. included in this Annual Report (Form 10-K) of Sesen Bio, Inc. for the year ended December 31, 2019.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 16, 2020

Exhibit 31.1

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

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

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2019 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.

Date: March 16, 2020

By: /s/ Thomas R. Cannell, D.V.M.
Name: Thomas R. Cannell, D.V.M.
Title: President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Monica Forbes, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2019 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.

Date: March 16, 2020

By: /s/ Monica Forbes
Name: Monica Forbes
Title: Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Sesen Bio, Inc. (the "Company") for the fiscal year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 16, 2020

By: /s/ Thomas R. Cannell, D.V.M.
Name: Thomas R. Cannell, D.V.M.
Title: President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Sesen Bio, Inc. (the "Company") for the fiscal year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 16, 2020

By: /s/ Monica Forbes
Name: Monica Forbes
Title: Chief Financial Officer
(Principal Financial Officer)