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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

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 ☒

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 ☒

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	☒
Accelerated filer	☐	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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

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 30, 2020, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $84.0 million.

There were 167,578,637 shares of the registrant's common stock outstanding as of March 8, 2021.

Documents Incorporated by Reference

Portions of the registrant's Definitive Proxy Statement relating to the 2021 Annual Meeting of Stockholders ("2021 Proxy Statement"), 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, 2020, 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, 2020

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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 Vicineum™ for the treatment of bacillus Calmette-Guérin ("BCG")-unresponsive non-muscle invasive bladder cancer ("NMIBC"), if approved;
- the expectation that the United States Food and Drug Administration (the "FDA"), will make a decision regarding the Company's Biologics License Application (the "BLA"), for Vicineum for the treatment of BCG-unresponsive NMIBC on or before the anticipated target Prescription Drug User Fee Act ("PDUFA") date of August 18, 2021;
- the expectation that the FDA will not hold an advisory committee meeting to discuss the BLA for Vicineum;
- our expectation for the potential commercial launch of Vicineum for the treatment of BCG-unresponsive NMIBC in the U.S., if approved;
- the potential impact of the COVID-19 pandemic on our business;
- our expected future loss and accumulated deficit levels;
- the difficulties and expenses associated with obtaining and maintaining regulatory approval of Vicineum for the treatment of BCG-unresponsive NMIBC in the United States and other foreign 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, and other foreign jurisdictions;
- the potential that results of pre-clinical studies and clinical trials indicate our product candidates are unsafe or ineffective;
- our dependence on third parties, including contract research organizations ("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 "Roche License Agreement");
- the timing and costs associated with our manufacturing process and technology transfer to FUJIFILM Diosynth Biotechnologies U.S.A., Inc. ("Fujifilm") for the production of Vicineum drug substance, and our reliance on Fujifilm to perform under our agreement with Fujifilm;
- the timing and costs associated with our manufacturing process and technology transfer to Baxter Oncology GmbH ("Baxter") for the production of Vicineum drug product, and our reliance on Baxter to perform under our agreement with Baxter;
- market acceptance of our product candidates, including Vicineum for the treatment of BCG-unresponsive NMIBC, the size and growth of the potential markets for our product candidates, and our ability to serve those markets;
- obtaining and maintaining intellectual property protection for our product candidates and our proprietary technology;
- the successful development of our commercialization capabilities, including sales and marketing capabilities;
- our expectation for the potential commercial launch of Vicineum in the U.S., if approved, in mid-2021;
- our expectation that the European Medicines Agency (the "EMA") will potentially approve our marketing authorization application ("MAA") for Vicineum for the treatment of BCG-unresponsive NMIBC in early 2022;
- our expectations regarding the amount and timing of milestone and royalty payments pursuant to our out-license agreements and commercialization partnership agreements, including our exclusive license agreement with Qilu Pharmaceutical Co., Ltd. ("Qilu") for the development, manufacture and commercialization of Vicineum in Greater China; 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 FDA or other comparable foreign regulatory authorities. On December 18, 2020, we submitted our completed BLA for Vicineum to the FDA. On February 12, 2021, the FDA notified us that it has accepted for filing our BLA. The FDA also granted Priority Review for the BLA and the anticipated target PDUFA date for a decision on the BLA is August 18, 2021. In addition to the file acceptance and granting of Priority Review, the FDA also indicated that it is not currently planning to hold an advisory committee meeting to discuss the BLA for Vicineum. 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 “Item 1A. Risk Factors”, 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.

Risk Factors Summary

The following summarizes the principal factors that make an investment in us speculative or risky, all of which are more fully described in "Item 1A. Risk Factors" below. This summary should be read in conjunction with "Item 1A. Risk Factors" and should not be relied upon as an exhaustive summary of the material risks facing our business.

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.
- With the exception of specified regulatory, development and commercial milestones under our out-licensing and commercialization partnership agreements, we currently have no source of product revenue and may never become profitable.
- 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.

Risks Related to Clinical Development and Regulatory Approval of Vicineum

- We are dependent on our lead product candidate, Vicineum for the treatment of BCG-unresponsive NMIBC. If we are unable to obtain marketing approval for or successfully commercialize our lead product candidate, either alone or through an out-license or a commercialization partnership, or experience significant delays in doing so, our business could be materially harmed.
- If clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC fail to demonstrate safety and efficacy to the satisfaction of the FDA or other foreign 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 Vicineum for the treatment of BCG-unresponsive NMIBC.
- Vicineum for the treatment of BCG-unresponsive 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.
- We are seeking in the U.S. and intend to seek outside the U.S., approval for Vicineum for the treatment of BCG-unresponsive NMIBC through the use of accelerated approval pathways. If we are 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 trial(s) do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.
- Because we plan to produce commercial supply of our product candidate Vicineum for the treatment of BCG-unresponsive NMIBC, if approved, through third-party manufacturers, the FDA will require us to demonstrate that the product manufactured by our third-party manufacturers 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 marketing approval and/or commercialization of Vicineum could be delayed, adversely affected or terminated, or may result in significantly higher costs.
- 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.

Risks Related to the Commercialization of Vicineum

- Our commercial success depends upon attaining significant market acceptance of Vicineum for the treatment of BCG-unresponsive NMIBC, if approved, among physicians, patients, third-party payors and the medical community.
- The market opportunity for Vicineum may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small.
- If we are unable to establish sales, marketing and distribution capabilities, we may not be successful in commercializing Vicineum for the treatment of BCG-unresponsive NMIBC, if and when it is approved.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- Our product candidates for which we intend to seek approval as biological products may face competition from biosimilar products.
- Even if we are able to commercialize Vicineum for the treatment of BCG-unresponsive NMIBC, it may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business.
- Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of Vicineum for the treatment of BCG-unresponsive NMIBC, if approved.

Risks Related to Our Dependence on Third Parties

- We will depend on Qilu for the development and commercialization of Vicineum in the greater China region.

- We may enter into additional partnerships or license agreements with third parties for the development or commercialization of our product candidates. If our commercialization partnerships or licenses are not successful, we may not be able to capitalize on the market potential of these product candidates.
- Our experience manufacturing Vicineum is limited to our pre-clinical studies and clinical trials. We have no experience manufacturing Vicineum 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 Vicineum could be delayed.

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

Risks Related to Regulatory Compliance

- Any product candidate, including Vicineum for the treatment of BCG-unresponsive NMIBC, 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.
- 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.

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, Vicineum, 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 BCG-unresponsive NMIBC.

On December 18, 2020, we submitted our completed BLA for Vicineum for the treatment of BCG-unresponsive NMIBC to the FDA. On February 12, 2021, the FDA notified us that it has accepted for filing our BLA. The FDA also granted Priority Review for the BLA and the anticipated target PDUFA date for a decision on the BLA is August 18, 2021. In addition to the file acceptance and granting of Priority Review, the FDA also indicated that it is not currently planning to hold an advisory committee meeting to discuss the BLA for Vicineum.

In August 2019, we reported updated preliminary efficacy data from our ongoing single-arm, multi-center, open-label Phase 3 clinical trial of Vicineum as a monotherapy in patients with 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 Vicineum for the treatment of BCG-unresponsive 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 was determined to be refractory or recurred within six months of their last course of adequate BCG;
- Cohort 2 (n=7): Patients with CIS with or without papillary disease that 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 recurred within six months of their last course of adequate BCG.

The primary endpoints of the VISTA Trial were 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") patient 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 patient who completed the induction phase.*

Pooled Cohorts 1 and 2 (n=93) 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 patient 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 patient 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 Vicineum in the VISTA Trial, greater than 75% of all patients are estimated to remain cystectomy-free at 3 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 high 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 Vicineum 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 Vicineum 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 Vicineum 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 Vicineum for the treatment of BCG-unresponsive 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 Vicineum Activity

In August 2018, we received Fast Track designation from the FDA for Vicineum for the treatment of BCG-unresponsive NMIBC.

In May 2019, we met with the FDA for a Type C meeting regarding chemistry, manufacturing and controls (“CMC”) for Vicineum for the treatment of BCG-unresponsive NMIBC 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 Vicineum for the treatment of patients with BCG-unresponsive NMIBC. At the meeting, we reached alignment with the FDA on an accelerated approval pathway for Vicineum along with 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 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 expected that a meeting with the FDA's Oncologic Drugs Advisory Committee ("ODAC") will be required as part of the accelerated approval pathway. If Vicineum receives marketing approval for treatment of BCG-unresponsive 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 Vicineum for the treatment of BCG-unresponsive NMIBC. At that meeting, we reached agreement with the FDA that the post-marketing confirmatory trial for Vicineum 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 Vicineum 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 Vicineum to the FDA under Rolling Review. This submission consisted of Modules 1, 2, 4 and 5 only.

On May 7, 2020, we received clinical Scientific Advice from the Committee for Medicinal Products for Human Use ("CHMP") of the EMA stating that the Committee agreed that our nonclinical, clinical pharmacology and safety database are all sufficient to support a MAA. Furthermore, additional clinical trials were not requested by the CHMP in support of the MAA submission for Vicineum for the treatment of BCG-unresponsive NMIBC.

On May 29, 2020, we received CMC Scientific Advice from the CHMP of the EMA, stating that the committee agreed that our comparability plan provides a strong analytical package, and no additional clinical trials to establish comparability are deemed necessary at this time. Furthermore, the CHMP agreed to accept the current Good Manufacturing Practice ("cGMP") inspections conducted by the FDA and will therefore not conduct an independent inspection of the manufacturing facilities.

On June 17, 2020, we were informed that the FDA has conditionally accepted the proprietary brand name VICINEUM™ for our product candidate, oportuzumab monatox. The name VICINEUM was developed in compliance with the FDA's final Guidance for Industry, Contents of a Complete Submission for the Evaluation of Proprietary Names and the FDA's draft Guidance for Industry, Best Practices in Developing Proprietary Name for Drugs. We believe VICINEUM is a proprietary name with strong marketing potential that is also consistent with FDA's goal of preventing medication errors and potential harm to the public by ensuring that only appropriate proprietary names are approved for use. Final approval of the VICINEUM brand name is conditional on FDA approval of our product candidate, oportuzumab monatox. Based upon FDA feedback, we withdrew our previously submitted proposed brand name, VICINIUM®, from consideration due to potential for confusion with ammonium derivative products with the "-ium" suffix as established by the United States Adopted Names Council.

On July 28, 2020, we received notice from the EMA that it has approved our request to review Vicineum under the EMA's centralized authorization procedure drug review process and on September 29, 2020, we received notice from the EMA that it has appointed the Rapporteur and Co-Rapporteur for our planned MAA. The Rapporteur and Co-Rapporteur are members of EMA's CHMP and will jointly coordinate CHMP's evaluation of our MAA for Vicineum.

On October 23, 2020, we completed a successful pre-submission meeting with the EMA which addressed product specific, legal, regulatory and scientific topics related to Vicineum. The information and insights gained from the meeting will help to facilitate the validation of the MAA and support a smooth evaluation. The agency also provided guidance on various administrative topics which helps to clarify the regulatory path forward.

We held two successful meetings with the assigned Rapporteurs on November 2, 2020 and December 14, 2020 in which we received guidance on the contents of the MAA. The success of these meetings, in addition to the receipt of centralized procedure eligibility confirmation from the EMA, are significant milestones toward our regulatory path forward in Europe and supported our MAA submission on March 5, 2021, with potential approval anticipated in early 2022.

On December 18, 2020, we submitted the completed BLA, including Module 3 (CMC), to the FDA. After we submitted the BLA to the FDA, we were invited to participate in an Application Orientation Meeting, which is available in certain Center for Drug Evaluation and Research ("CDER") review divisions, at the review team's discretion, for priority applications where early action is expected and/or desired. The objectives of an Application Orientation Meeting include familiarizing the FDA with application datasets, discussing scientific aspects including clinical risk-benefit, and establishing early communication between applicants and the FDA.

On February 12, 2021, the FDA notified us that it has accepted for filing our BLA. The FDA also granted Priority Review for the BLA and the anticipated target PDUFA date for a decision on the BLA is August 18, 2021. In addition to the file acceptance and granting of Priority Review, the FDA also indicated that it is not currently planning to hold an advisory committee meeting to discuss the BLA for Vicineum.

On March 5, 2021, we submitted the MAA to the EMA for Vicineum for the treatment of BCG-unresponsive NMIBC under the EMA's centralized procedure.

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 Vicineum drug substance production.

In November 2019, we entered into a Commercial Manufacturing and Supply Agreement with Baxter (the "Baxter CSA") for the manufacturing process and technology transfer of Vicineum drug product production.

In April 2019, the first full, commercial-scale cGMP run was completed at Fujifilm. Full quality release testing was completed and all Phase 3 release specifications were met, supporting Fujifilm's ability to produce the bulk drug substance form of Vicineum for commercial purposes if we receive regulatory approval to market Vicineum for the treatment of BCG-unresponsive NMIBC.

In February 2020, manufacturing of the pre-process performance qualification ("pre-PPQ") cGMP batch was completed at Fujifilm. Full quality release testing of the drug substance was completed and all quality acceptance criteria were met.

On August 4, 2020, we completed manufacturing of the drug substance PPQ batches at Fujifilm and in September 2020, we successfully completed the final of three drug product PPQ batches at Baxter. All of the completed drug substance PPQ batches and drug product PPQ batches met all quality acceptance criteria.

In December 2020, we received and analyzed all of the analytical comparability test results from the drug substance and drug product PPQ batches. For analytical comparability, we conducted testing across four categories: release testing, biophysical characterization, forced degradation studies, and stability studies. This approach is in alignment with requirements of the FDA, the EMA and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. The test results for product intended for commercial use were found to be highly comparable to the Company's clinical supply of Vicineum. Based on these results, we are optimistic that the FDA will determine that the commercial supply of Vicineum is comparable to the clinical supply of Vicineum, and that no additional clinical trials are warranted. The comparability data from the PPQ campaigns for both drug substance and drug product were the final material components of our completed BLA, which was submitted to the FDA on December 18, 2020.

In December 2020, we entered into a commercial manufacturing and supply framework agreement with Qilu (the "Qilu CMO Framework Agreement") for Qilu to be a contract manufacturer for the global commercial supply of Vicineum. We believe that the technology transfer to Qilu for the manufacturing of Vicineum is on track to be completed in mid-2021.

Commercial Partnering

On July 30, 2020, we and our wholly-owned subsidiary, Viventia Bio, Inc., entered into an exclusive license agreement with Qilu ("Qilu License Agreement") pursuant to which we granted Qilu an exclusive, sublicensable, royalty-bearing license, under certain intellectual property owned or exclusively licensed by us, to develop, manufacture and commercialize Vicineum for the treatment of NMIBC and other types of cancer in China, Hong Kong, Macau and Taiwan ("Greater China"). We also granted Qilu a non-exclusive, sublicensable, royalty-bearing sublicense, under certain other intellectual property licensed by us to develop, manufacture and commercialize Vicineum in Greater China. We retain (i) development and commercialization rights in the rest of the world excluding Greater China and MENA and (ii) manufacturing rights with respect to Vicineum in the rest of the world excluding Greater China.

We have received a total of $10 million in net proceeds associated with the $12 million upfront payment due pursuant to the Qilu License Agreement. We are also entitled to receive up to an additional $23 million upon the achievement of certain technology transfer, development and regulatory milestones, as well as a 12% royalty based upon annual net sales of Vicineum in Greater China. The royalties are payable upon the first commercial sale of Vicineum in a region and continuing until the latest of (i) twelve years after the first commercial sale of Vicineum in such region, (ii) the expiration of the last valid patent claim covering or claiming the composition of matter, method of treatment, or method of manufacture of such Vicineum in such region, and (iii) the expiration of regulatory or data exclusivity for such Vicineum in such region. The royalty rate is subject to reduction under certain circumstances, including when there is no valid claim of a licensed patent that covers Vicineum in a particular region or no data or regulatory exclusivity of Vicineum in a particular region.

The Investigational New Drug application for Vicineum submitted by Qilu to the Center for Drug Evaluation of the China National Medical Products Administration was accepted for review in January 2021.

On November 30, 2020, we entered into an exclusive licensing agreement with Hikma Pharmaceuticals LLC ("Hikma") (the "Hikma License Agreement"), pursuant to which we granted Hikma an exclusive, sublicensable, royalty-bearing license, under certain intellectual property owned or exclusively licensed by us, to commercialize Vicineum in the Middle East

and North Africa ("MENA") region. We retain development and commercialization rights in the rest of the world excluding Greater China and MENA. In consideration for the rights granted by us, Hikma agreed to pay to us an upfront payment, sales related milestones payments, and royalties on net sales in the MENA region for the term of the Hikma License Agreement.

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 Vicineum for the treatment of BCG-unresponsive NMIBC, we intend to build a North American specialty urology sales force to market the product in the United States. Outside the United States, we will continue to seek additional 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 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 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 Vicineum, which is our lead product candidate in development for the treatment of BCG-unresponsive 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 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 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, that require a pre-existing immune response for maximum efficacy.

Our most advanced locally-administered TFTP product candidate is Vicineum, in development for the treatment of BCG-unresponsive NMIBC and recurrent, locally advanced or metastatic EpCAM-expressing squamous cell carcinoma of the head and neck ("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 those estimated for 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 the 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

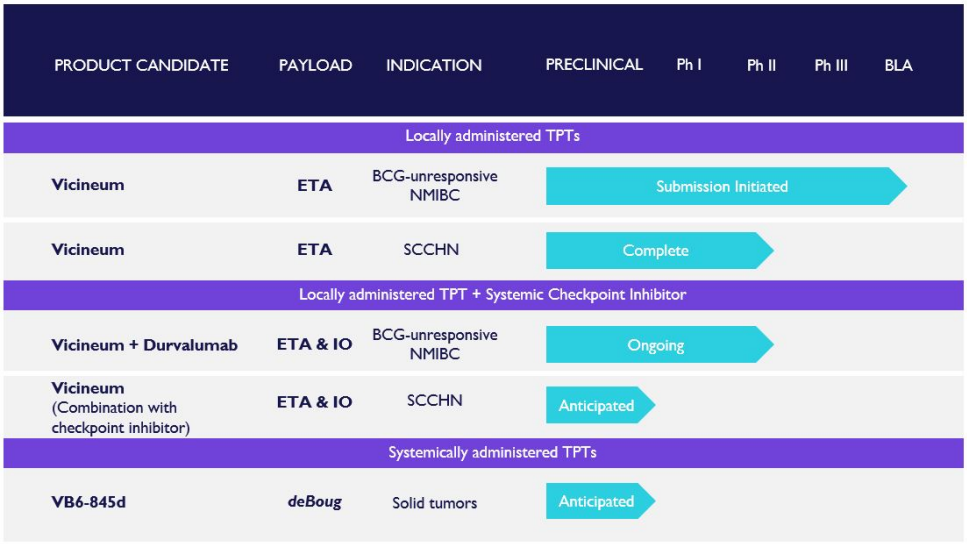
We are committed to designing, engineering, developing and commercializing TFPTs to identify and address oncology indications that suffer from a high unmet medical need. The key elements of our strategy are as follows:

- ***Obtain regulatory approval of Vicineum for the treatment of BCG-unresponsive NMIBC.*** On December 18, 2020, we submitted the completed BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. On February 12, 2021, the FDA notified us that it has accepted for filing the BLA, and granted the application Priority Review. With Priority Review, the anticipated target PDUFA date for a decision on the BLA is August 18, 2021. In addition, the FDA stated that it is not currently planning to hold an advisory committee meeting to discuss the BLA for Vicineum. We initiated discussions with the EMA in 2020 regarding a regulatory pathway for European Union ("E.U.") approval and completed all pre-submission activities by the end of 2020, and submitted the MAA to the EMA on March 5, 2021.
- ***Maximize the commercial potential Vicineum for the treatment of BCG-unresponsive NMIBC***. We own exclusive, worldwide rights to Vicineum and we have out licensed the rights to Vicineum in Greater China and the MENA region. If Vicineum receives marketing approval from the FDA for the treatment of BCG-unresponsive NMIBC, we plan to pursue commercialization strategies that maximize the value of Vicineum in the United States by partnering with a contract sales organization. Based on our market research, we believe Vicineum has an innovative profile with a high possibility that patients, healthcare professionals and payors will be advocates for its use for the treatment of BCG-unresponsive NMIBC, which we believe represents a significant commercial opportunity. We believe that we will be able to effectively communicate differentiating characteristics and key attributes of Vicineum to patients, physicians and payors, with the goal of establishing favorable reimbursement as well as a favorable formulary status in targeted Urology practices. Additionally, we believe that our plans to partner with a contract sales organization should allow us to address the Urologists-initiated treatment market for BCG-unresponsive NMIBC in the United States in an efficient and effective way.
- ***Expand on the value of Vicineum through strategic partnerships.*** If we obtain regulatory approval for Vicineum for the treatment of BCG-unresponsive NMIBC, we intend to build a North American specialty urology sales force to market the product in the United States. Outside the United States, we will continue to seek additional commercialization partners with urology expertise by selectively partnering with pharmaceutical and biopharmaceutical companies when we believe that a partner could bring additional resources and expertise to maximize the value of Vicineum for the treatment of BCG-unresponsive NMIBC. In 2020, we entered into license agreements to support such commercialization efforts outside the United States.
- ***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 Cooperative Research and Development Agreement ("CRADA") with the NCI for the development of Vicineum 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 BCG-unresponsive NMIBC to evaluate the safety, efficacy and biological correlates of Vicineum in combination with durvalumab. This Phase 1 clinical trial is open and actively recruiting patients.

We have deferred further development of Vicineum for the treatment of SCCHN and of VB6-845d in order to focus our efforts and our resources on our ongoing development and, if approved, the commercialization of Vicineum for the treatment of BCG-unresponsive NMIBC. We are also exploring collaborations for Vicineum for the treatment of SCCHN and for VB6-845d.

Our Product Pipeline

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



Vicineum for the Treatment of BCG-unresponsive NMIBC

Overview

Vicineum is being developed for the treatment of BCG-unresponsive NMIBC in patients who have previously received adequate BCG and whose disease is now BCG-unresponsive. Vicineum is administered by intravesical administration directly into the bladder. Vicineum utilizes an immunogenic cytotoxic protein payload that is a truncated form of ETA produced by the bacterial species *Pseudomonas*. Vicineum 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 BCG-unresponsive NMIBC who have received adequate BCG and whose disease is now BCG-unresponsive, and for whom the then-current standard of care was 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 endpoints 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 trials. 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 trials. We believe that our VISTA Trial design was 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 Vicineum for the treatment of BCG-unresponsive NMIBC. On December 6, 2019, we initiated our BLA submission for Vicineum to the FDA under Rolling Review. This submission consisted of Modules 1, 2, 4 and 5 only. On December 18, 2020, we submitted the completed BLA, including Module 3 (CMC), to the FDA. On February 12, 2021, the FDA notified us that it has accepted for filing our BLA. The FDA also granted Priority Review for the BLA and the anticipated target PDUFA date for a decision on the BLA is August 18, 2021. In addition to the file acceptance and granting of Priority Review, the FDA also indicated that it is not currently planning to hold an advisory committee meeting to discuss the BLA for Vicineum. We initiated discussions with the EMA in 2020 regarding a regulatory pathway for E.U. approval and submitted the MAA on March 5, 2021.

Overall, we believe that our efficacy and safety data support the continued clinical development and, if approved, the commercialization of Vicineum to fulfill a significant unmet medical need in patients with BCG-unresponsive NMIBC. Because Vicineum contains ETA, an immunogenic cytotoxic payload that elicits an anti-ETA immune response, we believe the local administration of Vicineum 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 Vicineum intellectual property portfolio that provides an unextended patent term until 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 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 Vicineum for the treatment of BCG-unresponsive NMIBC is approved by the FDA, patients would receive treatment until the earlier of 2 years and disease recurrence.

Current Approaches to Treatment

Within BCG-unresponsive 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 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 (Anktiva/N-803 in combination with BCG), Theralase Technologies Inc. (TLD-1433), Janssen (Erdafitinib and TAR-200) and CG Oncology (CG0070). In addition, systemically-administered checkpoint inhibitors are being evaluated for the treatment of NMIBC including products developed by Bristol-Myers Squibb (Opdivo alone or in combination with BCG +/- BMS986205), F. Hoffmann-La Roche AG (Tecentriq) and AstraZeneca (Imfinzi).

Phase 1 and 2 Clinical Trials

Phase 1 Clinical Trial. We initiated an open-label, dose-escalating Phase 1 clinical trial of Vicineum for the treatment of BCG-unresponsive 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 Vicineum.

Eight dose levels were initially evaluated, ranging from 0.1 to 10.56 mg, and 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. Vicineum was generally well-tolerated at each of these escalated doses.

A CR was defined in this Phase 1 clinical trial as non-positive urine 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-<1 mg/dose range were CRs. In contrast, seven of the 14 patients (50%) treated in 1.0-<10 mg/dose range and 14 of the 30 patients (46.7%) treated in the ≥10 mg/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.

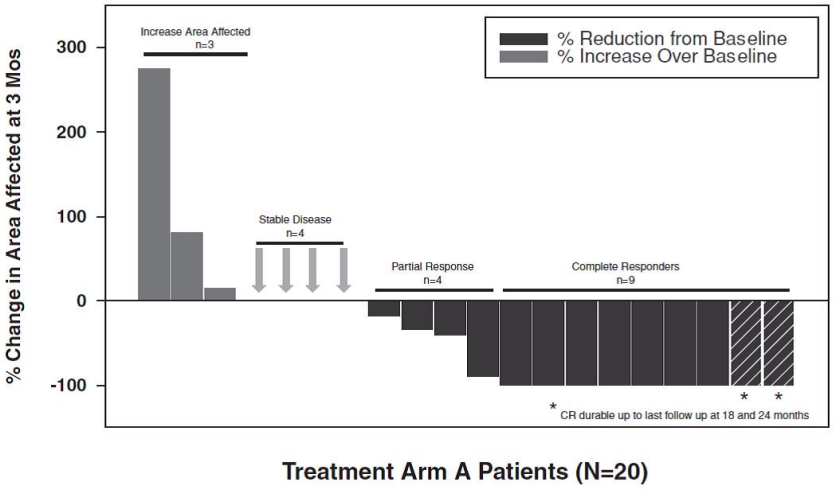
Phase 2 Clinical Trial. Based on our Phase 1 clinical trial conducted in Canada, we submitted the IND for Vicineum for the treatment of BCG-unresponsive NMIBC to the FDA in August 2005, and we initiated an open-label Phase 2 clinical trial of Vicineum in March 2007 at 20 sites in Canada and the United 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 Vicineum. 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. 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 Vicineum. At the three-month assessment, patients with residual disease but no disease progression-where disease progression was 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 who did not 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 using the same dose. In Treatment Arm B, 23 patients in the induction phase received 12 consecutive once-weekly instillations of 30 mg Vicineum. At the three-month assessment, the combined CR rate for both treatment arms was 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.

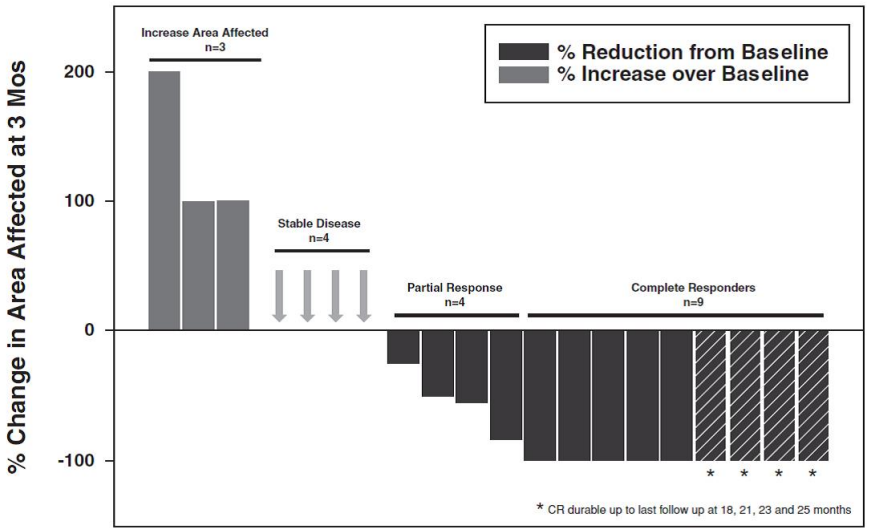
The data below shows the percentage change in surface area of cancer within the bladder, based on bladder mapping data utilizing cystoscopy in 40 patients. The following charts demonstrate the responses in this Phase 2 clinical trial in Treatment Arm A and Treatment Arm B:

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 Vicineum 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 Vicineum in BCG-unresponsive 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 Vicineum for the treatment of NMIBC BCG failures. There were no Grade 4 or Grade 5 serious adverse events that were considered by the clinical investigators to be related to Vicineum during the Phase 1 and Phase 2 clinical trials of Vicineum for the treatment of NMIBC BCG failures. There was one Grade 5 serious adverse event, or death, which was determined by the clinical investigator to be unrelated to Vicineum. 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 Vicineum-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 BCG-unresponsive NMIBC who have received adequate BCG and whose disease is now BCG-unresponsive, and for whom the then-current standard of care was 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 endpoints 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 trials. 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 trials. We believe that our VISTA Trial design was 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 Vicineum (in 50 mL of saline)
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 Vicineum 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 was determined to be refractory or recurred within six months of their last course of adequate BCG;
- Cohort 2 (n=7): Patients with CIS with or without papillary disease that 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 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 patient 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 patient who completed the induction phase.*

Pooled Cohorts 1 and 2 (n=93) 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 patient 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 patient 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 Vicineum in the VISTA Trial, greater than 75% of all patients are estimated to remain cystectomy-free at 3 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 high 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 Vicineum 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 Vicineum 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 Vicineum 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 Vicineum for the treatment of BCG-unresponsive 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 Development

In June 2017, we entered into a CRADA with the National Cancer Institute ("NCI") for the development of Vicineum 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 BCG-unresponsive NMIBC to evaluate the safety, efficacy and biological correlates of Vicineum in combination with durvalumab. This Phase 1 clinical trial is open and actively recruiting patients.

Commercial Partnering

Greater China

On July 30, 2020, we entered into the Qilu License Agreement pursuant to which we granted Qilu an exclusive, sublicensable, royalty-bearing license, under certain intellectual property owned or exclusively licensed by us, to develop, manufacture and commercialize Vicineum for the treatment of NMIBC and other types of cancer in China, Hong Kong, Macau and Taiwan ("Greater China"). We also granted Qilu a non-exclusive, sublicensable, royalty-bearing sublicense, under certain other intellectual property licensed by us to develop, manufacture and commercialize Vicineum™ in Greater China. We retain (i) development and commercialization rights in the rest of the world excluding Greater China and MENA and (ii) manufacturing rights with respect to Vicineum in the rest of the world excluding Greater China.

We have received a total of $10 million in net proceeds associated with the $12 million upfront payment due pursuant to the Qilu License Agreement. We are also entitled to receive up to an additional $23 million upon the achievement of certain technology transfer, development and regulatory milestones, as well as a 12% royalty based upon annual net sales of Vicineum in Greater China. The royalties are payable upon the first commercial sale of Vicineum in a region and continuing until the latest of (i) twelve years after the first commercial sale of Vicineum in such region, (ii) the expiration of the last valid patent claim covering or claiming the composition of matter, method of treatment, or method of manufacture of such Vicineum in such region, and (iii) the expiration of regulatory or data exclusivity for such Vicineum in such region. The royalty rate is subject to reduction under certain circumstances, including when there is no valid claim of a licensed patent that covers Vicineum in a particular region or no data or regulatory exclusivity of Vicineum in a particular region.

MENA

On November 30, 2020, we entered into the Hikma License Agreement pursuant to which we granted Hikma an exclusive, sublicensable, royalty-bearing license, under certain intellectual property owned or exclusively licensed by the Company, to commercialize Vicineum in the MENA region. We retain development and commercialization rights in the rest of the world excluding Greater China and MENA. In consideration for the rights granted by us, Hikma agreed to pay to us an upfront payment, which would be subject to certain tax withholdings, and subject to delivery by us of certain documentation. In addition, Hikma agreed to pay milestone payments upon the achievement of certain regulatory and sales milestones, as well as a royalty based upon annual net sales in the MENA region.

Vicineum for the Treatment of SCCHN

Vicineum (formerly referred to as Proxinium in publications, focused on this clinical setting), is also being developed as a treatment for patients with recurrent, locally advanced or metastatic EpCAM-expressing SCCHN who have received at least one prior platinum-based chemotherapy regimen. To treat SCCHN, Vicineum is administered via injection directly into the targeted tumor, or intratumoral injection. Vicineum 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 encompassing 44 patients treated with Vicineum, a complete resolution or reduction in size of injected tumors was observed in 16 of the 30 evaluable patients (53%) with EpCAM-expressing tumors as assessed by the investigators' clinical measurements, the investigators' overall assessment including qualitative changes and assessment of available radiologic data. An additional 27% of evaluable patients had stable disease and, therefore, the results indicate an overall tumor control rate of approximately 80%.. 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%). Vicineum 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 Vicineum 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 Vicineum 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 Vicineum, 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 Vicineum approval for the treatment of SCCHN. During the clinical evaluation of Vicineum 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 Vicineum.

Overall, we believe that our efficacy and safety data support the continued clinical development of Vicineum 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 Vicineum tumor cell killing mediates ICD of cancer cells leading to the release of tumor-specific neoantigens and recruitment/activation of cells of the host immune system. Further, Vicineum 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 Vicineum due to its potential immunogenic effect.

We have deferred further development of Vicineum for the treatment of SCCHN in order to focus our efforts and our resources on our ongoing development and, if approved, the commercialization of Vicineum for the treatment of BCG-unresponsive NMIBC. We are also exploring collaborations for the development of Vicineum for the treatment of SCCHN.

We own or exclusively license worldwide rights to our Vicineum for the treatment of SCCHN intellectual property portfolio that provide an unextended patent term until 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 and, if approved, commercialization of Vicineum for the treatment of BCG-unresponsive 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, method of treatment patents and applications for VB6-845d are granted, until at least 2036. See ''Our Intellectual Property'' below for additional details.

LUMC

On December 8, 2020, the Company and Leiden University Medical Center ("LUMC") agreed to the co-development of an imaging agent (the "Imaging Agent") that is comprised of an antibody fragment of Vicineum™, and an imaging molecule supplied by LUMC. The Imaging Agent is designed to delineate tumor from normal tissue during surgery so that the tumor margin is clearly visible, thereby helping to ensure clear margins after surgical excision of cancerous tissue. A Phase 1/2 clinical trial of the Imaging Agent was successfully completed by LUMC with favorable tolerability and demonstrated tumor detection, which we believe further supports the targeting specificity of Vicineum. We signed an agreement with LUMC whereby we have an option to obtain an exclusive, worldwide license to any intellectual property related to the Imaging Agent. Additionally, the Company and LUMC have agreed to negotiate terms for the next clinical trial, which would begin after the anticipated U.S. approval of Vicineum for the treatment of BCG-unresponsive NMIBC.

EBI-031 - Out-License Agreement with Roche

In June 2016, we entered into the Roche License Agreement, pursuant to which we granted Roche an exclusive, worldwide license, including the right to sublicense, to the Licensed Intellectual Property. Under the Roche 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 Roche 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 Roche License Agreement 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 (i) $72.5 million in development milestones, the first of which is $20.0 million for initiation of the first Phase II study, (ii) $50.0 million in regulatory milestones and (iii) $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 Roche License Agreement provides for two “option periods” during which Roche may elect to make a one-time payment to us and, in turn, terminate its diligence, milestone and royalty payment obligations under the Roche 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 Roche License Agreement if the other party breaches any of its material obligations under the Roche License Agreement and does not cure such breach within a specified cure period. Roche may terminate the Roche 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 Roche 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 13 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 where possible.

Product Candidate - Vicineum

We exclusively license two families under a license agreement with the University of Zurich ("Zurich") (the "Zurich License Agreement") 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 Vicineum, as well as methods of treating bladder and head and neck cancer consist of issued patents in the United States, Europe, Canada, China, Israel and Japan and also include a pending application 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. See "Our Vicineum License Agreements" below for additional information.

In addition to the Zurich portfolio, we own an issued U.S. patent with composition of matter claims directed to modified nucleic acid sequences that encode Vicineum and are potentially useful for high expression yield of Vicineum. 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 patent families relating to treatment regimens using Vicineum that include issued patents in the United States and Australia and patent applications in Canada, China, Europe, Hong Kong and Japan. These patents will expire in 2036.

Additionally, we have a license agreement with Micromet AG ("Micromet") (the "Micromet License Agreement"), 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 Vicineum. See "Our Vicineum License Agreements" below for additional information.

We also have a license agreement with XOMA Ireland Limited ("XOMA") (the "XOMA License Agreement") which grants us non-exclusive rights, with certain sublicense 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 Vicineum. See "Our Vicineum 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 March 3, 2021, 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 3, 2021, the following families are owned by us, and licensed to Roche pursuant to the Roche 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, Korea, tNew 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, 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, Chile, 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, 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 Vicineum License Agreements

In-License Agreement with Zurich

Overview and Exclusivity

The Zurich License Agreement 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 Vicineum.

Under the terms of the Zurich License Agreement, we may be obligated to pay $0.5 million in milestone payments for the first product candidate that achieves applicable regulatory development milestones. Based on current clinical status, we anticipate that these milestones may be triggered by the regulatory development pathway of Vicineum. 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, 2020, aggregate license fees of $0.6 million have been accrued or paid to Zurich since the inception of the license agreement, which includes $0.3 million accrued as of December 31, 2020 related to achievement of a development milestone due to the submission of the Company's BLA application with the FDA in December 2020.

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 Zurich License Agreement 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 Zurich 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 Zurich License Agreement at any time and for any reason by giving 90 days written notice to Zurich.

In-License Agreement with Micromet

Overview

Micromet is now part of Amgen, Inc. The Micromet License Agreement 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 Vicineum. Under the terms of the Micromet License Agreement, 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 €2.9 million in milestone payments for the first product candidate that achieves applicable development milestones. Based on current clinical status, we anticipate that certain of these milestones may be triggered by the Vicineum regulatory and commercial 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 Vicineum. 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, 2020, aggregate license fees of €1.8 million have been paid to Micromet since the inception of the license agreement, and we owe an additional €0.7 million of license fees as of December 31, 2020 related to the submission of our BLA to the FDA in December 2020. We paid €50,000 in annual license maintenance fees during each of the years ended December 31, 2020, 2019 and 2018.

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

In-License Agreement with XOMA

Overview

The XOMA License Agreement grants us non-exclusive rights, with certain sublicense 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 Vicineum. Under the terms of the XOMA License Agreement, 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 the Vicineum 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 Vicineum. 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, 2020, 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, 2020.

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

Commercialization Strategy

According to 2020 American Cancer Society figures, bladder cancer is the sixth most common type of cancer in the United States, with an estimated 81,400 new cases of bladder cancer and an estimated 17,980 deaths from bladder cancer. There is a significant unmet need for patients with bladder cancer, with very few treatment options. Since BCG was approved for first line treatment of NMIBC in the 1980s, only two products have been approved for second line use: VALSTAR in 1998, and Keytruda in 2020. Approximately 1,500 Urologists are responsible for treating 75% of bladder cancer patients treated with first line BCG treatment.

If approved on the August 18, 2021 PDUFA review date, we plan on launching Vicineum upon approval, with promotion to physicians and patients beginning immediately after approval and commercial product supply anticipated to be available in Urology clinics by the fourth quarter of 2021. We intend to pursue commercialization strategies that maximize the value of Vicineum in the United States by partnering with a contract sales organization, 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 significant financial and management resources, some of which would have to be deployed prior to the approval of Vicineum. Based on our market research, we believe Vicineum has an innovative profile with a high possibility that patients, healthcare professionals and payors will be advocates for its use for the treatment of BCG-unresponsive NMIBC, which we believe represents a significant commercial opportunity. We believe that we will be able to effectively communicate the differentiating characteristics and key attributes of Vicineum to patients, physicians and payors, with the goal of establishing favorable reimbursement as well as a favorable formulary status in targeted Urology practices. Additionally, we believe that our plans to partner with a contract sales organization should allow us to address the Urologists-initiated treatment market for BCG-unresponsive NMIBC in the United States in an efficient and effective way.

Other than in Greater China and the MENA region, where we have out-licensed development and commercialization rights to Vicineum, we own exclusive, worldwide rights to Vicineum. We plan to continue our pre-commercialization activities to prepare for a potential commercial launch of Vicineum, subject to receiving marketing approval in the United States. Outside of the United States, we will continue to engage key commercialization partners with local expertise in targeted regions, who will be the marketing authorization holders, to commercialize Vicineum.

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 Vicineum. In September 2017, we completed the manufacturing of all Vicineum 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 at our facility in Winnipeg and have redirected our resources toward completing the technology transfer process necessary to outsource commercial scale drug supply manufacturing to third-party manufacturers in the event we obtain approval from the FDA to market Vicineum for the treatment of BCG-unresponsive NMIBC.

Fujifilm and Baxter

In October 2018, we entered into the Fujifilm MSA for the manufacturing process and technology transfer of Vicineum drug substance production.

In April 2019, the first full, commercial-scale cGMP run was completed at Fujifilm. Full quality release testing was completed and all Phase 3 release specifications were met, supporting Fujifilm's ability to produce the bulk drug substance form of Vicineum for commercial purposes if we receive regulatory approval to market Vicineum for the treatment of BCG-unresponsive NMIBC.

In November 2019, we entered into the Baxter CSA for the manufacturing process and technology transfer of Vicineum drug product production.

In February 2020, manufacturing of the pre-process performance qualification ("pre-PPQ") cGMP batch was completed at Fujifilm. Full quality release testing of the drug substance was completed and all quality acceptance criteria were met.

In August 2020, we completed manufacturing of the drug substance PPQ batches at Fujifilm and in September 2020, we successfully completed the final of three drug product PPQ batches at Baxter. All of the completed drug substance PPQ batches and drug product PPQ batches met all quality acceptance criteria.

In December 2020, we received and analyzed all of the analytical comparability test results from the drug substance and drug product PPQ batches. For analytical comparability, we conducted testing across four categories: release testing, biophysical characterization, forced degradation studies, and stability studies. This approach is in alignment with requirements of the FDA, the EMA and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. The test results for product intended for commercial use were found to be highly comparable to the Company's clinical supply of Vicineum. Based on these results, we are optimistic that the FDA will determine that the commercial supply of Vicineum is comparable to the clinical supply of Vicineum, and that no additional clinical trials are warranted. The comparability data from the PPQ campaigns for both drug substance and drug product were the final material components of our completed BLA, which was submitted to the FDA on December 18, 2020.

Qilu

In December 2020, we entered into the Qilu CMO Framework Agreement for Qilu to be a contract manufacturer for the global commercial supply of Vicineum. We believe that the technology transfer to Qilu for the manufacturing of Vicineum is on track to be completed in mid-2021.

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 (Anktiva/N-803 in combination with BCG), CG Oncology. (CG0070), Theralase Technologies Inc. (TLD-1433 photodynamic compound), Bristol-Myers Squibb (Opdivo/nivolumab with or without BCG or BMS-986205), F. Hoffmann-La Roche AG (Tecentriq/Atezolizumab), 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, 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 ("GLP") 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 ("GCP") 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 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, GLP 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) GCP 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 Vicineum for the treatment of BCG-unresponsive NMIBC may have to meet the expectations set forth in this guidance document to obtain approval.

Under Prescription Drug User Fee Act, 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. On February 12, 2021, the FDA notified us that it has accepted for filing our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. The FDA also granted Priority Review for the BLA and the anticipated target PDUFA date for a decision on the BLA is August 18, 2021.

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. The FDA has indicated that it is not currently planning to hold an advisory committee meeting to discuss the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC.

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 GCP. 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 an already-licensed FDA biological product, or 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 biosimilar ‘‘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 in one or more appropriate conditions of use for which the reference product is licensed and for which licensure is sought for the biological product. 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. 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 Vicineum 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 at our facility in Winnipeg and have redirected our resources toward completing the technology transfer process necessary to outsource commercial scale drug supply manufacturing to third-party manufacturers in the event we obtain approval from the FDA to market Vicineum for the treatment of BCG-unresponsive NMIBC. In October 2018, we entered into the Fujifilm MSA for the manufacturing process and technology transfer of Vicineum drug substance production. In November 2019, we entered into the Baxter CSA for the manufacturing process and technology transfer of Vicineum drug product production. In April 2019, the first full, commercial-scale cGMP run was completed at Fujifilm. Full quality release testing was completed and all Phase 3 release specifications were met, supporting Fujifilm's ability to produce the bulk drug substance form of Vicineum for commercial purposes if we receive regulatory approval to market Vicineum for the treatment of BCG-unresponsive NMIBC. 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 term extension 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 patent term extension 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.

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 centralized 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 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 GCPs, 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 marketing authorization, 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.

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.

Vicineum 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. On February 12, 2021, the FDA notified us that it has granted Priority Review for our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC and the anticipated target PDUFA date for a decision on the BLA is August 18, 2021.

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.

Vicineum has received Fast Track and Priority Review designations from the FDA for the treatment of BCG-unresponsive and Fast Track designation from the FDA for the treatment of SCCHN.

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 partners, 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 partners, may receive for any approved products.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (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 and Medicaid programs, also may revise reimbursement and implement coverage restrictions. Any reduction in reimbursement from Medicare, Medicaid 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.

In addition, in March 2010, President Obama signed one of the most significant healthcare reform measures in decades. The Patient Protection and 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.

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 (subsequent legislation increased this amount to 70% effective as of January 1, 2019);
- 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 Act'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

Certain provisions of the ACA have been subject to judicial challenges, as well as efforts to repeal, replace, or otherwise modify 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 payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, as amended, 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 prescription 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, replace, or otherwise modify, or invalidate, the ACA, or portions thereof, will affect our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012, 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 2030 (with the exception of a temporary suspension from May 1, 2020 through March 31, 2021) unless Congress takes additional action. 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, regulatory changes, or guidance could be adopted, which may impact the marketing approvals and reimbursement for our product candidates. For example, there has been increasing legislative, regulatory, and enforcement interest in the United States with respect to drug pricing practices. There have been several Congressional inquiries and proposed and enacted federal and state legislation and regulatory initiatives designed to, among other things, bring more transparency to product pricing, evaluate the relationship between pricing and manufacturer patient programs, and reform government healthcare program reimbursement methodologies for drug products. For example, on November 20, 2020, CMS issued an interim final rule to implement a "Most Favored Nation" demonstration project to test Medicare Part B reimbursement of certain separately payable drugs and biologicals based on international reference prices. The rule has become subject to judicial challenges, and federal courts have enjoined the rule at this time. If the rule survives judicial scrutiny, the Most Favored Nation model will subject certain drugs or biologicals identified by CMS as having the highest annual Medicare Part B spending to an alternative payment methodology based on international reference prices, with the list of products to be updated annually to add more products and products not to be removed absent limited circumstances. There has also been legislation that would establish an international reference price-based Medicare Part B drug and biological payment methodology.

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, 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, 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, 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. 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 Vicineum for the treatment of BCG-unresponsive NMIBC were to receive low ratings, this could adversely affect the price and reimbursement of Vicineum, 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 will 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. 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. In November 2020, HHS finalized a previously abandoned proposal to amend the discount safe harbor regulation of the Anti-Kickback Statute in a purported effort to create incentives to manufacturers to lower their list prices, and to lower federal program beneficiary out-of-pocket costs. The rule, which is currently slated to take full effect January 1, 2023, revises the Anti-Kickback Statute discount safe harbor to exclude manufacturer rebates to Medicare Part D plans, either directly or through pharmacy benefit managers (“PBMs”), creates a new safe harbor for point-of-sale price reductions that are set in advance and are available to the beneficiary at the point-of-sale, and creates a new safe harbor for service fees paid by manufacturers to PBMs for services rendered to the manufacturer. It is too early to know whether the Biden Administration will further delay, rewrite, or allow the rule to go into effect, and what effect the rule might may have on negotiations for coverage for products with Medicare Part D plans or commercial insurers. 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 and its implementing regulations (collectively, "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 healthcare 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 healthcare 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 ("CCPA"), govern the collection, use, disclosure, and protection of health-related and other personal information. 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. 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 imposes requirements relating to the privacy, security and transmission of individually identifiable health information. 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, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Other jurisdictions 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 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 available 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. On December 21, 2020, CMS issued a final rule that modified MDRP regulations to permit reporting multiple best price figures with regard to value based purchasing arrangements (beginning in 2022); provide definitions of “line extension,” “new formulation,” and related terms with the practical effect of expanding the scope of drugs considered to be line extensions (beginning in 2022); and revise best price and AMP exclusions of manufacturer-sponsored patient benefit programs, specifically regarding inapplicability of such exclusions in the context of pharmacy benefit manager “accumulator” programs (beginning in 2023).

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.

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 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 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. HRSA then publishes those prices to 340B covered entities. Moreover, under a final regulation effective January 13, 2021, HRSA newly established an administrative dispute resolution (“ADR”) process for claims by covered entities that a manufacturer has engaged in overcharging, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that could be appealed only in federal court. An ADR proceeding could subject a manufacturer to onerous procedural requirements and could result in additional liability.

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 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 Vicineum (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.

Human Capital

The Company's key human capital management objectives are to recruit, retain, manage and motivate our employees. There are a 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 given the numerous pharmaceutical and biotechnology companies looking for similar personnel as well as universities and research institutions. We rely on our executive officers and other key employees to achieve our research, development and commercialization objectives and to successfully implement our business strategy. We also rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy.

We are committed to maintaining a diverse and inclusive workplace in which our employees from all backgrounds can fully contribute to the growth and success of our business. We communicate shared values and leadership behaviors, which are expected of all employees. Additionally, every employee has an annual performance review and has opportunities to contribute to corporate goals. We rely on a variety of sources to fill open positions, including job boards and postings on the our company website.

We have a demonstrated history of investing in our workforce through comprehensive and competitive compensation and benefits, and a focus on health and employee wellbeing. We have adopted the Company's 2014 Stock Incentive Plan ("2014 Plan") and Employee Stock Purchase Plan ("ESPP") 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, 2020, we had twenty-seven full-time employees and no part-time employees, eight hold Ph.D. degrees and one is a veterinary doctor. This number consists of eleven employees engaged in administration, five employees engaged in clinical and regulatory activities, five employees engaged in research and development, four employees engaged in operations (two in manufacturing and two in facility/engineering) and two employees engaged in quality and support. Three of our employees are located in our corporate headquarters in Boston, thirteen 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.

Since the beginning of the COVID-19 pandemic, approximately 30% of our employees have continued to work at our Winnipeg facility, where we have adopted health screening, implemented socially distancing and personal protective equipment requirements, enhanced cleaning and sanitation protocols, and modified workspaces to reduce the potential for transmission of the virus. All other employees who do not require access to our facility to perform their work have been working from home during the pandemic.

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.

Our business is subject to substantial risks and uncertainties. The occurrence of any of the following risks and uncertainties, either alone or taken together, could materially and adversely affect our business, financial condition, results of operations or prospects. In these circumstances, the market price of our common shares could decline and you may lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Risks and uncertainties of general applicability and additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially and adversely affect our business, financial condition, results of operations or prospects.

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, Vicineum for the treatment of BCG-unresponsive 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 the follow-up stage of our ongoing Phase 3 VISTA Trial of Vicineum for the treatment of BCG-unresponsive NMIBC and seek marketing approval from the FDA. We had net losses of $22.4 million, $107.5 million and $33.7 million for the years ended December 31, 2020, 2019 and 2018, respectively. We incurred negative cash flows from operating activities of $30.8 million, $37.5 million and $22.8 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, we had cash and cash equivalents of $52.4 million, net working capital (current assets less current liabilities) of $44.8 million and an accumulated deficit of $315.9 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 ATM offerings and, our out-licensing and commercialization partnership agreements. The majority of our revenue to date has been from milestone payments received under our out-licensing and commercialization partnership agreements. 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 Vicineum for the treatment of BCG-unresponsive NMIBC in the United States and Europe;
- establish a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize Vicineum for the treatment of BCG-unresponsive NMIBC, if approved;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed drugs;
- continue our clinical development activities for Vicineum for the treatment of BCG-unresponsive 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;
- 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 out-licensing and commercialization partnership agreements, 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 payments under our out-licensing and commercialization partnership agreements, neither we nor any of our commercialization partners have 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 or one of our commercialization partners obtain marketing approval

for, and commercialize, Vicineum for the treatment of BCG-unresponsive NMIBC. Our ability to generate revenue from Vicineum for the treatment of BCG-unresponsive NMIBC, if approved, will depend on a number of factors, including:

- our ability to obtain regulatory approval for, and successfully commercialize, Vicineum for the treatment of BCG-unresponsive NMIBC;
- our ability to complete and submit applications to, and obtaining regulatory approval from, foreign regulatory authorities;
- the size of the markets in the territories for which we or our commercialization partners gain regulatory approval;
- our ability to find a suitable contract sales organization ("CSO") to help us market and promote Vicineum, if approved;
- our ability to develop and maintain effective medical affairs, sales, marketing and distribution to market and sell Vicineum, 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 Vicineum, if approved;
- our success in defending against potential competition and other developments in our market generally;
- our ability to manufacture commercial quantities of Vicineum at acceptable cost levels;
- our ability to obtain coverage and adequate reimbursement from third-party payors, including government payors; and
- our and our commercialization partners' ability to successfully complete development activities, including the necessary clinical trials, for Vicineum for the treatment of BCG-unresponsive NMIBC.

Even if Vicineum for the treatment of BCG-unresponsive NMIBC is approved for commercial sale, Vicineum 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 Vicineum. In addition, we would anticipate incurring significant costs associated with commercializing Vicineum, if approved. We may not achieve profitability soon after generating product sales from Vicineum, if ever. If we are unable to generate product revenues from Vicineum, 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 Vicineum for the treatment of BCG-unresponsive 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 Vicineum for the treatment of BCG-unresponsive NMIBC, if approved;
- the outcome, timing and cost of the regulatory approval process for Vicineum for the treatment of BCG-unresponsive 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 and maintain commercial arrangements on favorable terms, if at all, particularly manufacturing, marketing and distribution arrangements for Vicineum for the treatment of BCG-unresponsive NMIBC;
- 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 in-licensing agreements;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies; and
- the effect of competing technological and market developments.

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 out-licensing or commercialization partners to assist in the commercialization of Vicineum for the treatment of BCG-unresponsive NMIBC in the United States and other markets;
- relinquish or license on unfavorable terms our rights to Vicineum for the treatment of BCG-unresponsive 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 commercialization partnerships 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 $52.4 million as of December 31, 2020 will be sufficient to fund our operations into the fourth quarter of 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, 2020 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 $52.4 million at December 31, 2020 will be sufficient to fund our operations into the fourth quarter of 2021, given our planned expenditures for the next several years, we and our independent registered public accounting firm have concluded that there is 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, licensing and commercialization partnership agreements, strategic alliances and marketing and distribution arrangements and other commercial arrangements. We do not have any committed external source of funds other than the amounts payable under our out-licensing and commercialization partnership agreements. 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, 2020, and subject to adjustment upon certain corporate events, including stock dividends, stock splits and distributions of cash, up to 2,246,594 shares of our common stock could be issuable by us, with a weighted-average exercise price of $0.82 per share, in connection with the exercise of our outstanding warrants to purchase our common stock.

We have also adopted the 2014 Plan to enable us and our subsidiaries to recruit and retain highly qualified employees, directors and consultants, provide those individuals with an incentive for productivity, and provide those individuals with an opportunity to share in our growth and value. As of December 31, 2020, we had an aggregate of 10,146,844 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, 2020, we had 4,863,562 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, licensing or commercialization partnership agreements, strategic alliances 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.

Risks Related to Clinical Development and Regulatory Approval of Vicineum

We are dependent on our lead product candidate, Vicineum for the treatment of BCG-unresponsive NMIBC. If we are unable to obtain marketing approval for or successfully commercialize our lead product candidate, either alone or through an out-license or a commercialization partnership, 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 Vicineum for the treatment of BCG-unresponsive NMIBC. Our prospects are substantially dependent on our out-licensing and commercialization partners' ability to obtain marketing approval for and successfully commercialize Vicineum for the treatment of BCG-unresponsive NMIBC. The success of Vicineum will depend on several factors, including the following:

- receipt of marketing approvals from the FDA or comparable foreign regulatory authorities;
- developing and maintaining the commercial manufacturing supply and distribution chain for Vicineum;
- performance of our future out-licensing or commercialization partners, 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 or our commercialization partners are unable to develop, receive marketing approval for, or successfully commercialize Vicineum for the treatment of BCG-unresponsive NMIBC or experience delays as a result of any of these factors or otherwise, our business could be materially harmed.

If clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC fail to demonstrate safety and efficacy to the satisfaction of the FDA or other foreign 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 Vicineum for the treatment of BCG-unresponsive NMIBC.

Before obtaining marketing approval from regulatory authorities for the sale of Vicineum for the treatment of BCG-unresponsive NMIBC, we must complete pre-clinical development and conduct extensive clinical trials to demonstrate the safety and efficacy of Vicineum 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.

Clinical trial results may fail to support approval of our product candidates.

Even if our clinical trials are successfully completed as planned, the results may not support approval of Vicineum for the treatment of BCG-unresponsive NMIBC under the laws and regulations of the FDA or comparable foreign regulatory authorities. The clinical trial process may fail to demonstrate Vicineum is both safe and effective for its intended uses. Pre-clinical and clinical data and analyses are often able to be interpreted in different ways. Even if we view our results favorably, if a regulatory authority has a different view, we may still fail to obtain regulatory approval of Vicineum. This, in turn, would significantly adversely affect our business prospects.

Vicineum for the treatment of BCG-unresponsive 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 Vicineum for the treatment of BCG-unresponsive 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.

There were no Grade 4 or Grade 5 serious adverse events that were considered by the clinical investigators to be related to Vicineum during the Phase 1 and Phase 2 clinical trials of Vicineum for the treatment of NMIBC BCG failures. There was one Grade 5 serious adverse event, or death, which was determined by the clinical investigator to be unrelated to Vicineum. 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 Vicineum-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 Vicineum for the treatment of BCG-unresponsive 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 or other comparable foreign regulatory authority'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 could order us to cease further development or deny approval of Vicineum for the treatment of BCG-unresponsive 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 Vicineum for the treatment of BCG-unresponsive NMIBC receives marketing approval, and we or others later identify undesirable side effects or serious adverse events caused by Vicineum, a number of potentially significant negative consequences could result, including:

- we may suspend or be forced to suspend marketing of Vicineum for the treatment of BCG-unresponsive NMIBC;
- we may be obliged to conduct a product recall or product withdrawal;
- regulatory authorities may suspend, vary, or withdraw their approvals of Vicineum for the treatment of BCG-unresponsive NMIBC;
- regulatory authorities may order the seizure or recall of Vicineum;
- regulatory authorities may require additional warnings on the label or a REMS or other post-marketing obligations that could diminish the usage or otherwise limit the commercial success of Vicineum for the treatment of BCG-unresponsive 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 Vicineum for the treatment of BCG-unresponsive NMIBC, if approved.

We are seeking in the U.S. and intend to seek outside the U.S., approval for Vicineum for the treatment of BCG-unresponsive NMIBC through the use of accelerated approval pathways. If we are 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 trial(s) 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 in the U.S., and intend to seek outside the U.S., approval for Vicineum for the treatment of BCG-unresponsive NMIBC under accelerated approval pathways. On February 16, 2021, the Company announced that the FDA has accepted for

filing the Company's BLA for Vicineum, for the treatment of BCG-unresponsive NMIBC, and granted the application Priority Review. With Priority Review, the anticipated target PDUFA date for a decision on the BLA is August 18, 2021.

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 our BLA will be approved by the FDA on a timely basis, or at all. The FDA or foreign regulatory authorities also could require us to conduct further studies or trials prior to granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for Vicineum for the treatment of BCG-unresponsive NMIBC would result in a longer time period to commercialize Vicineum for the treatment of BCG-unresponsive NMIBC, could increase the cost of development of Vicineum for the treatment of BCG-unresponsive 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 Vicineum for the treatment of BCG-unresponsive 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, our confirmatory post-market clinical trial(s) do not confirm the predicted clinical benefit, other evidence shows that the product is not safe or effective under the conditions of use, and/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 Vicineum for the treatment of BCG-unresponsive NMIBC, if approved, through third-party manufacturers, the FDA will require us to demonstrate that the product manufactured by our third-party manufacturers 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 marketing approval and/or commercialization of Vicineum could be delayed, adversely affected or terminated, or may result in significantly higher costs.

Our product candidate, Vicineum for the treatment of BCG-unresponsive NMIBC, has been produced in our own manufacturing facility for all clinical trials for Vicineum to date, including our ongoing Phase 3 VISTA Trial. In September 2017, we completed the manufacturing of all Vicineum 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 at our facility in Winnipeg and have redirected our resources toward completing the technology transfer process necessary to outsource commercial scale drug supply manufacturing to third-party manufacturers in the event we obtain approval from the FDA to market Vicineum for the treatment of BCG-unresponsive NMIBC. We have had discussions with the FDA regarding the criteria for demonstrating comparability of Vicineum produced by our third-party manufacturers to Vicineum produced in our own manufacturing facility.

As of December 2, 2020, we had received and analyzed from our third-party manufacturers all of the analytical comparability test results from the commercial-scale drug substance and drug product process performance qualification batches of Vicineum. For analytical comparability, we conducted testing across four categories: release testing, biophysical characterization, forced degradation studies, and stability studies. This approach is in alignment with requirements of the FDA, the EMA and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. The test results for Vicineum intended for commercial use were found to be highly comparable to our clinical supply of Vicineum. Based on these results, we are optimistic that the FDA will determine that the commercial supply of Vicineum is comparable to the clinical supply of Vicineum, and that no additional clinical trials are warranted.

Because this manufacturing change was introduced at an advanced stage of development of Vicineum, the FDA may require a comprehensive comparability assessment, potentially including additional nonclinical studies or clinical trials utilizing Vicineum produced by our third-party manufacturers, and/or a modification of our ongoing Phase 3 VISTA Trial to include Vicineum produced by our third-party manufacturers. Such requirements could result in lengthy delays and significantly higher costs for the clinical development, approval of our BLA, and potential commercialization of Vicineum for the treatment of BCG-unresponsive NMIBC. If we are unable to demonstrate to the FDA comparability of Vicineum produced in our own manufacturing to Vicineum produced by our third-party manufacturers, we may not be able to obtain marketing approval of Vicineum for the treatment of BCG-unresponsive NMIBC.

The marketing approval process is expensive, time-consuming and uncertain. As a result, we cannot predict when or if we, or any licensees or partners, will obtain marketing approval to commercialize Vicineum for the treatment of BCG-unresponsive NMIBC or any other product candidate.

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 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 different requirements and expectations of the comparable regulatory authorities 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.

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

Risks Related to the Commercialization of Vicineum

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

Even if we obtain regulatory approval for Vicineum for the treatment of BCG-unresponsive NMIBC, Vicineum may not gain market acceptance among physicians, patients, third-party payors or the medical community. Vicineum 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, Vicineum for the treatment of BCG-unresponsive NMIBC. Market acceptance of Vicineum for the treatment of BCG-unresponsive NMIBC, if approved, depends on a number of factors, including:

- the perceived quality, efficacy and safety of Vicineum;
- clinical indications for which Vicineum is approved;
- availability of alternative effective treatments for BCG-unresponsive NMIBC and the relative risks, benefits and costs of those treatments;
- acceptance by physicians, major operators of cancer clinics and patients of Vicineum as a safe and effective treatment for BCG-unresponsive NMIBC;
- the success of our physician education programs;
- potential and perceived advantages of Vicineum over alternative treatments;

- safety of Vicineum 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 Vicineum 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 Vicineum;
- 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 Vicineum for the treatment of BCG-unresponsive 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 Vicineum 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 Vicineum for the treatment of BCG-unresponsive NMIBC after prior therapies have failed.

Our projections of both the number of people who have BCG-unresponsive 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 Vicineum, 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 Vicineum for the treatment of BCG-unresponsive 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 Vicineum as a first-line therapy.

If we are unable to establish sales, marketing and distribution capabilities, we may not be successful in commercializing Vicineum for the treatment of BCG-unresponsive 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 Vicineum for the treatment of BCG-unresponsive NMIBC, if approved, we will need to establish sales, marketing and distribution capabilities, either ourselves or through commercialization partnerships 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 Vicineum for the treatment of BCG-unresponsive 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 Vicineum for the treatment of BCG-unresponsive 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 Vicineum for the treatment of BCG-unresponsive NMIBC ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute Vicineum for the treatment of BCG-unresponsive 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 Vicineum for the treatment of BCG-unresponsive 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 Vicineum for the treatment of BCG-unresponsive 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 Vicineum for the treatment of BCG-unresponsive 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 BCG-unresponsive 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 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 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. On May 17, 2020, the FDA issued a complete response letter that indicated outstanding questions regarding CMC and manufacturing issues of Adstiladrin. A new PDUFA date has not been disclosed yet. In addition, in February 2021, FerGene issued a letter to Key Opinion Leaders, also referred to as KOLs stating additional delays leading to the restructuring of their organization and the elimination of commercial positions. In September 2020, CG Oncology (CG0070, a recombinant adenovirus type 5, same type as Adstiladrin) initiated a Phase 3 study for the treatment of BCG-unresponsive patients with expected primary and study completion dates of December 2022 and December 2024, respectively. In December 2020, ImmunityBio (Anktiva/N-803 in combination with BCG) released preliminary Phase 2 data for the CIS cohort and is expected to file its BLA following a meeting with the FDA in the second half of 2021. However, the Phase 2 trial did not include a BCG only control arm. In May 2020, the preliminary results of the Phase 2 study of Tecentriq for the treatment of BCG-unresponsive CIS patients were presented at ASCO by the NCI (National Cancer Institute) which sponsored the trial. The data showed that the trial did not meet its primary endpoint and further development of Tecentriq remains uncertain. 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.
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.

Our product candidates for which we intend to seek approval as biological products may face competition 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 Vicineum for the treatment of BCG-unresponsive 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.

Even if we are able to commercialize Vicineum for the treatment of BCG-unresponsive 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 Vicineum for the treatment of BCG-unresponsive NMIBC, if approved, will depend, in part, on the extent to which coverage and adequate reimbursement for Vicineum 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 Vicineum for the treatment of BCG-unresponsive NMIBC, if approved, and, even if they are available, the level of reimbursement may not be satisfactory. For example, if CMS were to implement the “Most Favored Nation” demonstration model to pay for drugs and biologicals under Medicare Part B, and Vicineum, if approved, were to be included in the demonstration, the Medicare reimbursement level for the product may be materially reduced, which would have a material adverse effect on our results of operations and financial condition.
Inadequate reimbursement may adversely affect the demand for, or the price of, Vicineum for the treatment of BCG-unresponsive NMIBC, if approved. Obtaining and maintaining adequate reimbursement for Vicineum for the treatment of BCG-unresponsive 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 Vicineum for the treatment of BCG-unresponsive 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. 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 Vicineum for the treatment of BCG-unresponsive 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 Vicineum for the treatment of BCG-unresponsive NMIBC in a particular country, but then be subject to price regulations that delay our commercial launch of Vicineum for the treatment of BCG-unresponsive NMIBC, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of Vicineum for the treatment of BCG-unresponsive 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 Vicineum for the treatment of BCG-unresponsive NMIBC to other available therapies. Adverse pricing limitations may hinder our ability to recoup our investment in Vicineum for the treatment of BCG-unresponsive NMIBC, even if Vicineum for the treatment of BCG-unresponsive NMIBC obtains marketing approval.

There can be no assurance that Vicineum for the treatment of BCG-unresponsive 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 healthcare industry or third-party coverage and reimbursement may be enacted in the future and how such legislation or regulation could impact our business.

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

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

- decreased demand for Vicineum for the treatment of BCG-unresponsive 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 Vicineum for the treatment of BCG-unresponsive 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 Vicineum for the treatment of BCG-unresponsive 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.

Risks Related to Our Dependence on Third Parties

We will depend on Qilu for the development and commercialization of Vicineum in the greater China region.

On July 30, 2020 we entered into the Qilu License Agreement. Under the terms of the Qilu License Agreement, Qilu has an exclusive license to manufacture, develop and commercialize Vicineum in the greater China region, including mainland China, Hong Kong, Macau and Taiwan. The timing and amount of any milestone and royalty payments we may receive under the Qilu License Agreement will depend in part on Qilu's efforts. We will also depend on Qilu to comply with all applicable laws relative to the manufacturing, development and commercialization of Vicineum in the greater China region. We do not control the individual efforts of Qilu, and any failure by Qilu to devote sufficient time and effort to the manufacture, development and commercialization of Vicineum could have a material adverse impact on our financial results and operations, such as by a failure of Qilu to meet its obligations to us, including future milestone and royalty payments. In addition, if Qilu were to violate, or was alleged to have violated, any laws or regulations during the performance of its obligations for us, it is possible that we could suffer financial and reputational harm or other negative outcomes, including possible legal consequences.

Any termination, breach or expiration of the Qilu License Agreement could have a material adverse effect on our financial position by reducing or eliminating the potential for us to receive milestones and royalties. In such an event, we may be required to devote additional efforts and to incur additional costs associated with pursuing the manufacture, development and commercialization of Vicineum in greater China. If we breach our obligations under the Qilu License Agreement and are unable

to cure such breach, Qilu may terminate the Qilu License Agreement and retain all rights to manufacture, develop and commercialize Vicineum in the greater China region with no obligation to make any additional milestone or royalty payments. Qilu has the right to receive a refund of all amounts paid us in the event the Qilu License Agreement is terminated under certain circumstances. In addition, the royalty rate is subject to reduction under certain circumstances, including when there is no valid claim of a licensed patent for Vicineum in a particular region or no data or regulatory exclusivity for Vicineum in a particular region.

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

In June 2016, we entered into the Roche License Agreement, pursuant to which we granted Roche an exclusive, worldwide license, including the right to sublicense, to the Licensed Intellectual Property. Under the Roche 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 Roche 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 Roche License Agreement 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 (i) $72.5 million in development milestones, the first of which is $20.0 million for initiation of the first Phase II study, (ii) $50.0 million in regulatory milestones and (iii) $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 Roche License Agreement provides for two “option periods” during which Roche may elect to make a one-time payment to us and, in turn, terminate its diligence, milestone and royalty payment obligations under the Roche 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 Roche License Agreement represents a significant portion of the value of the Roche 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 Roche 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 partner for the development and commercialization of the licensed products on similar terms, or at all.

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

We may seek additional third-party partners or licensees for development and commercialization of our product candidates, including Vicineum for the treatment of BCG-unresponsive NMIBC. Our likely commercialization partners or licensees for any sales, marketing, distribution, development, licensing or broader partnership arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. Our ability to generate revenues from these arrangements will depend on our partners' or licensees' abilities and efforts to successfully perform the functions assigned to them in these arrangements.

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

- commercialization partners or licensees have significant discretion in determining the amount and timing of efforts and resources that they will apply to these partnerships or licenses;
- commercialization partners or licensees may not perform their obligations as expected;
- commercialization partners or licensees may not pursue commercialization and development of our product candidates that receive marketing approval or may elect not to continue or renew commercialization or development programs based on clinical trial results, changes in the partners' or licensees' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- commercialization partners 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;
- commercialization partners or licensees could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the partners 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 commercialization partnership or license with us may be viewed by our partners or licensees as competitive with their own product candidates or products, which may cause partners or licensees to cease to devote resources to the commercialization of our product candidates;
- a commercialization partner 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 commercialization partners 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;
- commercialization partners 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;
- commercialization partners or licensees may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- commercialization partners or licenses may be terminated for the convenience of the partner or licensee and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

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

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

If we are not able to establish additional commercialization partnerships, 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 partner with pharmaceutical or biotechnology companies for the development and potential commercialization of such product candidates, including Vicineum for the treatment of BCG-unresponsive NMIBC. We face significant competition in seeking appropriate partners. Whether we reach a definitive commercialization partnership agreement will depend, among other things, upon our assessment of the partner’s resources and expertise, the terms and conditions of the proposed commercialization partnership and the proposed partner’s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the 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 partner may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a commercialization partnership 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 commercialization partners. Commercialization partnerships 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 partners.

If we are unable to reach agreements with suitable partners 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 partnerships 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 GLP and the Animal Welfare Act requirements. We and our CROs are required to comply with U.S. federal regulations and GCP, 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 and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. Failure to comply with these regulations may require us to repeat pre-clinical studies and clinical trials, which would delay the regulatory approval process.

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

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

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

We rely on domestic and international third-party vendors and CROs for pre-clinical studies and clinical trials related to our product development efforts. Switching or adding additional CROs would involve additional cost and requires management time and focus. Our CROs generally have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements and/or research projects with us

pursuant to such agreements if it can be reasonably demonstrated that the safety of the 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 Vicineum is limited to our pre-clinical studies and clinical trials. We have no experience manufacturing Vicineum 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 Vicineum could be delayed.

Our product candidate, Vicineum, for the treatment of BCG-unresponsive NMIBC, has been produced in our own manufacturing facility for all clinical trials for Vicineum to date, including our ongoing Phase 3 VISTA Trial. In September 2017, we completed the manufacturing of all Vicineum 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 at our facility in Winnipeg and have redirected our resources toward completing the technology transfer process necessary to outsource commercial scale drug supply manufacturing to third-party manufacturers in the event we obtain approval from the FDA to market Vicineum for the treatment of BCG-unresponsive NMIBC.

Any significant disruption in our supplier relationships could harm our business. Any significant delay in the supply of Vicineum or its key materials could considerably delay the commercial launch of Vicineum for the treatment of BCG-unresponsive NMIBC or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of Vicineum.

Our reliance on third-party manufacturers exposes us to certain risks that we would not be subject to if we manufactured Vicineum ourselves, including:

- The development of commercial-scale manufacturing capabilities may require our third-party manufacturers to invest substantial additional funds and hire and retain technical personnel who have the necessary manufacturing experience. Our third-party manufacturers may fail to devote sufficient time and resources to develop the capabilities to manufacture Vicineum.
- Because of the complex nature of Vicineum, our third party manufacturers, 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 manufacturers could default on their agreements with us to meet our requirements for commercialization of Vicineum, or it may terminate or decide not to renew their agreements with us, based on their own business priorities, at a time that is costly or damaging to us. If our third-party manufacturers were to terminate our arrangements or fail to meet our commercial manufacturing demands, we may be delayed in our ability to obtain and maintain regulatory approval of Vicineum or, if approved, commercialize Vicineum for the treatment of BCG-unresponsive NMIBC.
- It may be difficult or impossible for us to find replacement manufacturers 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 the commercial supply of Vicineum, if approved.

Our reliance on third-party manufacturers 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 products candidates and any products that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. Methods of manufacture as well as validation of manufacturing procedures and quality control systems are reviewed by regulatory authorities, such as the FDA and other comparable foreign regulatory authorities, 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. Any failure by our third-party manufacturers to comply with cGMP or similar foreign standards 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, including Vicineum for the treatment of BCG-unresponsive NMIBC. In addition, such failure could be the basis for the FDA or any other foreign regulatory authorities 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.

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 Vicineum and our other proprietary technology and product candidates. 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.

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

Filing, prosecuting and defending patents on Vicineum and our other 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 generic versions or biosimilar versions, respectively, of our products. The FDA has published several 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 Vicineum, 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 Vicineum for the treatment of BCG-unresponsive NMIBC and Vicineum 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 Vicineum for the treatment of BCG-unresponsive NMIBC and Vicineum 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 Vicineum for the treatment of BCG-unresponsive NMIBC and Vicineum for the treatment of SCCHN.

We also have a license agreement with XOMA, which grants us non-exclusive rights,with certain sublicense 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 Vicineum for the treatment of BCG-unresponsive NMIBC and Vicineum 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. 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.

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 partners, 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.

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.

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 Compliance

Even if we obtain marketing approvals for one or more of our product candidates, the terms of such approvals, ongoing regulations and post-marketing restrictions may limit how we manufacture and market such 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 must therefore comply with requirements concerning advertising and promotion for any of our product candidates, including Vicineum for the treatment of BCG-unresponsive NMIBC, for which we 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 and our 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, including Vicineum for the treatment of BCG-unresponsive NMIBC, 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, including Vicineum for the treatment of BCG-unresponsive NMIBC, 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, including Vicineum for the treatment of BCG-unresponsive NMIBC, 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 if they are approved. If new safety information becomes available after approval of our product candidates, including Vicineum for the treatment of BCG-unresponsive NMIBC, the FDA may require labeling changes or establishment of a REMS, and the FDA or comparable foreign regulatory authorities 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 healthcare 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 commercialization partners or licensees;
- 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 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.

The regulatory environment surrounding information security, data collection, and privacy is increasingly demanding. In the United States, we are subject to a number of 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, such as Section 5 of the Federal Trade Commission Act ("FTC Act"), 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 in the United States 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, use 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.

In addition to U.S. data protection laws and regulations, we also may be subject to European and other international data protection requirements. For example, E.U. General Data Protection Regulation ("GDPR") imposes detailed requirements related to the collection, storage, processing and transfer of personal data related to EU data subjects the collection and use of personal health data in the E.U.

In particular, the GDPR prohibits the transfer of personal data to countries outside of the EEA that are not considered by the European Commission to provide an adequate level of data protection, such as the United States, unless there is a suitable data transfer solution in place to safeguard personal data. 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 transfer mechanism or derogation for the transfer of personal data, such as the existence of certain agreements which incorporate the standard contractual clauses as issued by the European Commission, or if there is another appropriate transfer mechanism or derogation in accordance with chapter V GDPR for the transfer of personal data from the EEA to the United States.

Noncompliance with the GDPR can result in fines of up to 4% of total annual worldwide turnover or up to €20 million (whichever is higher).

Many of these laws differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Compliance with these laws and regulations is difficult, constantly evolving, and time consuming. Our failure to comply with these laws, or changes in the way in which these laws are implemented, could lead to unfavorable outcomes, including increased compliance costs, delays or impediments in the development of new products, increased operating costs, diversion of management time and attention, regulatory liability as a result of government enforcement actions and significant penalties against us, civil liability as a result of claims initiated by data subjects (including claims initiated as class actions) contracting parties or other third parties as a result of non-compliance with data protection laws and/or contractual obligations, and adverse publicity that could negatively affect our operating results, financial condition and our overall and business. Federal regulators, state attorneys general, and plaintiffs' attorneys, including class action attorneys, have been and will likely continue to be active in this space. Such liabilities could adversely impact our results of operations, financial condition and our overall 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, 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 of government funds 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;
- 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, teaching hospitals and certain other healthcare providers; 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 healthcare providers, and restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; and state laws that require identification or licensing of sales representatives.

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. See the subsection titled "Other Healthcare Laws and Compliance Requirements" in Item 1. Business above for additional information.

Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of our product candidates, including Vicineum for the treatment of BCG-unresponsive 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 commercialization partners, 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 commercialization partners, 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 and Medicaid programs, also may revise reimbursement and implement coverage restrictions. Any reduction in reimbursement from Medicare, Medicaid 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.

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 70% (as of January 1, 2019) 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 Act'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 payment 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.

Certain provisions of the ACA have been subject to judicial challenges, as well as efforts to repeal, replace, or otherwise modify 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 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 prescription 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, replace, or otherwise modify, or invalidate, the ACA, or portions thereof, will affect our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012, 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 2030 (with the exception of a temporary suspension from May 1, 2020 through March 31, 2021) unless Congress takes additional action. 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 Vicineum for the treatment of BCG-unresponsive NMIBC, which could have a material adverse effect on our financial operations.

Additional legislative changes, regulatory changes, or guidance could be adopted, which may impact the marketing approvals and reimbursement for our product candidates. For example, there has been increasing legislative, regulatory, and enforcement interest in the United States with respect to drug pricing practices. There have been several Congressional inquiries and proposed and enacted federal and state legislation and regulatory initiatives designed to, among other things, bring more transparency to product pricing, evaluate the relationship between pricing and manufacturer patient programs, and reform government healthcare program reimbursement methodologies for drug products. For example, on November 20, 2020, CMS

issued an interim final rule to implement a “Most Favored Nation” demonstration project to test Medicare Part B reimbursement of certain separately payable drugs and biologicals based on international reference prices. The rule has become subject to judicial challenges, and federal courts have enjoined the rule at this time. If the rule survives judicial scrutiny, the Most Favored Nation model will subject certain drugs or biologicals identified by CMS as having the highest annual Medicare Part B spending to an alternative payment methodology based on international reference prices, with the list of products to be updated annually to add more products and products not to be removed absent limited circumstances. There has also been proposed legislation that would establish an international reference price-based Medicare Part B drug and biological payment methodology. 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.

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. We cannot be sure whether additional legislative changes will be enacted in the United States or outside of the United States, or whether regulatory changes, 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 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 available 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. On December 21, 2020, CMS issued a final rule that modified MDRP regulations to permit reporting multiple best price figures with regard to value based purchasing arrangements (beginning in 2022); provide definitions of “line extension,” “new formulation,” and related terms with the practical effect of expanding the scope of drugs considered to be line extensions (beginning in 2022); and revise best price and AMP exclusions of manufacturer-sponsored patient benefit programs, specifically regarding inapplicability of such exclusions in the context of pharmacy benefit manager “accumulator” programs (beginning in 2023).

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.

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 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. HRSA, which administers the 340B 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. HRSA then publishes those prices to 340B covered entities. Moreover, under a final regulation effective January 13, 2021, HRSA newly established an administrative dispute resolution (“ADR”) process for claims by covered entities that a manufacturer has engaged in overcharging, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that could be appealed only in federal court. An ADR proceeding could subject a manufacturer to onerous procedural requirements and could result in additional liability.

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 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.

The United Kingdom ("U.K.")'s withdrawal from the E.U. on January 31, 2020, commonly referred to as Brexit, has created significant uncertainty concerning the future relationship between the U.K. and the E.U. The impact of Brexit on the on-going validity in the U.K. of current E.U. authorizations for medicinal products, whether granted through the centralized procedure, decentralized procedure, or mutual recognition, and on the future process for obtaining marketing authorization for pharmaceutical products manufactured or sold in the U.K. remains uncertain.

On December 24, 2020, the E.U. and U.K. reached an agreement in principle on the framework for their future relationship, the E.U.- U.K. Trade and Cooperation Agreement. This agreement primarily focuses on ensuring free trade between the E.U. and the U.K. in relation to goods, including medicinal products. Although the body of this agreement includes general terms which apply to medicinal products, greater detail on sector-specific issues is provided in an Annex to this agreement. The Annex provides a framework for the recognition of cGMP inspections and for the exchange and acceptance of official cGMP documents.

This agreement does not, however, extend to procedures such as batch release certification. Among the changes that will now occur are that Great Britain (England, Scotland and Wales) will be treated as a country outside and separate from the E.U. Northern Ireland will, with regard to E.U. regulations, continue to follow the E.U. regulatory rules. As part of this agreement, the E.U. and the U.K. will recognize cGMP inspections carried out by the other party and the acceptance of official cGMP documents issued by the other party. This agreement also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release.

The U.K. has unilaterally agreed to accept E.U. batch testing and batch release for a period of at least 2 years until January 1, 2023. However, the E.U. continues to apply E.U. laws that require batch testing and batch release to take place in the E.U. territory. This means that medicinal products that are tested and released in the U.K. must be retested and re-released when entering the E.U. market for commercial use. As regards marketing authorizations, Great Britain will have a separate regulatory submission process, approval process and a separate national marketing authorization. Northern Ireland will, however, continue to be covered by the marketing authorizations granted by the European Commission.

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, failure to provide accurate information to the FDA or comparable non-United States regulatory authorities, including 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 our Business and Operations

The COVID-19 coronavirus could adversely impact our business.

We continue to monitor the effect of the novel strain of coronavirus, COVID-19. The COVID-19 coronavirus has spread to multiple countries, including the United States, and has caused significant disruptions around the world. We may experience disruptions as a result of the COVID-19 pandemic that could severely impact our business, including:

- difficulties in raising additional capital needed to commercialize Vicineum for the treatment of BCG-unresponsive NMIBC due to the slowing of our economy and near term and/or long term negative effects of the pandemic on the financial, banking and capital markets;
- delays in necessary interactions with regulators and other important agencies and contractors due to limitations in employee resources, travel restrictions or forced furlough of government employees;
- interruption of key business activities due to illness and/or quarantine of key individuals and delays associated with recruiting, hiring and training new temporary or permanent replacements for such key individuals, both internally and at our third party service providers;
- evolving changes in local regulations as part of a response to the COVID-19 outbreak that may require us to change the ways in which operate, which may result in unexpected costs;
- interruption of key commercialization, manufacturing, and related activities due to limitations on work and travel imposed or recommended by federal or state governments, employers and others; and
- delays or difficulties related to any future clinical trials that may be required, including delays in clinical trial sites receiving the supplies and materials needed to conduct clinical trials, difficulties in recruiting clinical site investigators and clinical site staff and difficulties in enrolling patients or treating patients in active trials.

The global pandemic of COVID-19 continues to evolve. The extent to which COVID-19 may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the virus. The full impact of the COVID-19 pandemic on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected time frame, will depend on future developments, including the duration of the pandemic and continuing restrictions on travel and transports, and shelter-in-place, social distancing, and similar measures, all of which are uncertain and difficult to predict. The broad-based business and economic disruptions caused by the pandemic could materially affect our business condition, results of operations and cash flows, including our ability to raise additional capital.

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, 2020, we had twenty-seven full-time employees and no part-time employees, eight hold Ph.D. degrees and one is a veterinary doctor. This number consists of eleven employees engaged in administration, five employees engaged in clinical and regulatory activities, five employees engaged in research and development, four employees engaged in operations (two in manufacturing and two in facility/engineering) and two employees engaged in quality and support. Three of our employees are located in our corporate headquarters in Boston, thirteen 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 Vicineum for the treatment of BCG-unresponsive NMIBC, if approved, and to compete effectively will depend, in part, on our ability to effectively manage any future growth. To that end, we must be able to effectively manage our development efforts and clinical trials and hire, train and integrate additional management, administrative and sales and marketing personnel. Our failure to accomplish any of these tasks could prevent us from successfully growing our company.

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

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

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could materially adversely affect our business.

In the ordinary course of business, we rely on information technology networks and systems, some of which are provided, hosted or managed by third parties, to collect, store, process and transmit electronic data. In addition, we handle certain data, including proprietary business information and personal information that is subject to data protection laws and regulations. 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.

Although we have implemented processes, procedures, and controls to help mitigate the risks associated with a cyber security incident, there can be no assurance that these measures will be sufficient for all possible situations. Even security measures that are appropriate, reasonable, and/or in accordance with applicable legal requirements may not be able to protect the networks, systems and information we maintain. Unauthorized parties, whether within or outside our company, may disrupt or gain access to our systems, or those of third parties with whom we do business, through human error, misfeasance, fraud, trickery, or other

forms of deceit, including break-ins, use of stolen credentials, social engineering, phishing, ransomware, computer viruses or other malicious codes, and similar means of unauthorized and destructive tampering. Even the most well protected information, networks, systems and facilities remain potentially vulnerable because the techniques used in such attempted cyber security incidents evolve and generally are not recognized until launched against a target. Accordingly, we may be unable to anticipate these techniques or to implement adequate security barriers or other preventative measures, making it impossible for us to entirely mitigate this risk. While we have experienced, and expect to continue to experience, threats and disruptions to our information technology infrastructure, none of them to date has had a material impact. 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, our product research, development and commercialization of Vicineum for the treatment of BCG-unresponsive NMIBC could be delayed, or we could be subject to regulatory and other government investigations, enforcement actions or incur liability, substantial fines or costs, any of which could materially adversely affect our business, results of operations and financial condition. Although we maintain insurance coverage for various cyber security risks, there can be no guarantee that all costs or losses incurred will be fully insured.

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.

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

As of December 31, 2020, we had United States federal net operating loss ("NOL") carryforwards of $194.1 million, state NOL carryforwards of $134.4 million and United States federal and state research and development credit ("R&D credit") carryforwards of $2.3 million and $0.9 million, respectively. $118.9 million of the United States federal NOL carryforwards and $134.4 million of the state NOL carryforwards expire beginning 2030 through 2040. $75.2 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 2040, 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.

Item 1B. Unresolved Staff Comments.

Not applicable.

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 Vicineum. In September 2017, we completed the manufacturing of all Vicineum 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 at our facility in Winnipeg and have redirected our resources toward completing the technology transfer process necessary to outsource commercial scale drug supply manufacturing to third-party manufacturers in the event we obtain approval from the FDA to market Vicineum for the treatment of BCG-unresponsive NMIBC. We operate our Winnipeg facility under a two-year renewable lease expiring in September 2022, and we have a right to renew the lease for one subsequent three-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 July 2021.

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 November 2021.

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 March 8, 2021, 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 "Item 1A. Risk Factors" 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, Vicineum, 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 BCG-unresponsive NMIBC. On December 18, 2020, we submitted our completed BLA for Vicineum for the treatment of BCG-unresponsive NMIBC to the FDA. On February 12, 2021, the FDA notified us that it has accepted for filing our BLA. The FDA also granted Priority Review for the BLA and the anticipated target PDUFA date for a decision on the BLA is August 18, 2021. In addition to the file acceptance and granting of Priority Review, the FDA also indicated that it is not currently planning to hold an advisory committee meeting to discuss the BLA for Vicineum.

In August 2019, we reported updated preliminary efficacy data from our ongoing single-arm, multi-center, open-label Phase 3 clinical trial of Vicineum as a monotherapy in patients with 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 Vicineum for the treatment of BCG-unresponsive 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 was determined to be refractory or recurred within six months of their last course of adequate BCG;
- Cohort 2 (n=7): Patients with CIS with or without papillary disease that 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 recurred within six months of their last course of adequate BCG.

The primary endpoints of the VISTA Trial were 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") patient 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 patient who completed the induction phase.*

Pooled Cohorts 1 and 2 (n=93) 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 patient 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 patient 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 Vicineum in the VISTA Trial, greater than 75% of all patients are estimated to remain cystectomy-free at 3 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 high 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 Vicineum 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 Vicineum 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 Vicineum 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 Vicineum for the treatment of BCG-unresponsive 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 Vicineum Activity

In August 2018, we received Fast Track designation from the FDA for Vicineum for the treatment of BCG-unresponsive NMIBC.

In May 2019, we met with the FDA for a Type C meeting regarding chemistry, manufacturing and controls (“CMC”) for Vicineum for the treatment of BCG-unresponsive NMIBC 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 Vicineum for the treatment of patients with BCG-unresponsive NMIBC. At the meeting, we reached alignment with the FDA on an accelerated approval pathway for Vicineum along with 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 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 expected that a meeting with the FDA’s Oncologic Drugs Advisory Committee ("ODAC")

will be required as part of the accelerated approval pathway. If Vicineum 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 Vicineum for the treatment of BCG-unresponsive NMIBC. At that meeting, we reached agreement with the FDA that the post-marketing confirmatory trial for Vicineum 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 Vicineum 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 Vicineum to the FDA under Rolling Review. This submission consisted of Modules 1, 2, 4 and 5 only.

On May 7, 2020, we received clinical Scientific Advice from the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA") stating that the Committee agreed that our nonclinical, clinical pharmacology and safety database are all sufficient to support a marketing authorization application ("MAA"). Furthermore, additional clinical trials were not requested by the CHMP in support of the MAA submission for Vicineum for the treatment of BCG-unresponsive NMIBC.

On May 29, 2020, we received CMC Scientific Advice from the CHMP of the EMA, stating that the committee agreed that our comparability plan provides a strong analytical package, and no additional clinical trials to establish comparability are deemed necessary at this time. Furthermore, the CHMP agreed to accept the current Good Manufacturing Practice ("cGMP") inspections conducted by the FDA and will therefore not conduct an independent inspection of the manufacturing facilities.

On June 17, 2020, we were informed that the FDA has conditionally accepted the proprietary brand name VICINEUM™ for our product candidate, oportuzumab monatox. The name VICINEUM was developed in compliance with the FDA's final Guidance for Industry, Contents of a Complete Submission for the Evaluation of Proprietary Names and the FDA's draft Guidance for Industry, Best Practices in Developing Proprietary Name for Drugs. We believe VICINEUM is a proprietary name with strong marketing potential that is also consistent with FDA's goal of preventing medication errors and potential harm to the public by ensuring that only appropriate proprietary names are approved for use. Final approval of the VICINEUM brand name is conditional on FDA approval of our product candidate, oportuzumab monatox. Based upon FDA feedback, we withdrew our previously submitted proposed brand name, VICINIUM®, from consideration due to potential for confusion with ammonium derivative products with the "-ium" suffix as established by the United States Adopted Names Council.

On July 28, 2020, we received notice from the EMA that it has approved our request to review Vicineum under the EMA's centralized authorization procedure drug review process and on September 29, 2020, we received notice from the EMA that it has appointed the Rapporteur and Co-Rapporteur for our MAA. The Rapporteur and Co-Rapporteur are members of EMA's CHMP and will jointly coordinate CHMP's evaluation of our MAA for Vicineum.

On October 23, 2020, we completed a successful pre-submission meeting with the EMA which addressed product specific, legal, regulatory and scientific topics related to Vicineum. The information and insights gained from the meeting will help to facilitate the validation of the MAA and support a smooth evaluation. The agency also provided guidance on various administrative topics which helps to clarify the regulatory path forward.

We held two successful meetings with the assigned Rapporteurs on November 2, 2020 and December 14, 2020 in which we received guidance on the contents of the MAA. The success of these meetings, in addition to the receipt of centralized procedure eligibility confirmation from the EMA, are significant milestones toward our regulatory path forward in Europe and supported our submission of the MAA on March 5, 2021, with potential approval anticipated in early 2022

On December 18, 2020, we submitted the completed BLA, including Module 3 (CMC), to the FDA. After we submitted the BLA to the FDA, we were invited to participate in an Application Orientation Meeting, which is available in certain Center for Drug Evaluation and Research ("CDER") review divisions, at the review team's discretion, for priority applications where early action is expected and/or desired. The objectives of an Application Orientation Meeting include familiarizing the FDA with application datasets, discussing scientific aspects including clinical risk-benefit, and establishing early communication between applicants and the FDA.

On February 12, 2021, the FDA notified us that it has accepted for filing our BLA. The FDA also granted Priority Review for the BLA and the anticipated target PDUFA date for a decision on the BLA is August 18, 2021. In addition to the file acceptance and granting of Priority Review, the FDA also indicated that it is not currently planning to hold an advisory committee meeting to discuss the BLA for Vicineum.

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 Vicineum drug substance production.

In November 2019, we entered into a Commercial Manufacturing and Supply Agreement with Baxter (the "Baxter CSA") for the manufacturing process and technology transfer of Vicineum drug product production.

In April 2019, the first full, commercial-scale cGMP run was completed at Fujifilm. Full quality release testing was completed and all Phase 3 release specifications were met, supporting Fujifilm's ability to produce the bulk drug substance form of Vicineum for commercial purposes if we receive regulatory approval to market Vicineum for the treatment of BCG-unresponsive NMIBC.

In February 2020, manufacturing of the pre-process performance qualification ("pre-PPQ") cGMP batch was completed at Fujifilm. Full quality release testing of the drug substance was completed and all quality acceptance criteria were met.

On August 4, 2020, we completed manufacturing of the drug substance PPQ batches at Fujifilm and in September 2020, we successfully completed the final of three drug product PPQ batches at Baxter. All of the completed drug substance PPQ batches and drug product PPQ batches met all quality acceptance criteria.

In December 2020, we received and analyzed all of the analytical comparability test results from the drug substance and drug product PPQ batches. For analytical comparability, we conducted testing across four categories: release testing, biophysical characterization, forced degradation studies, and stability studies. This approach is in alignment with requirements of the FDA, the EMA and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. The test results for product intended for commercial use were found to be highly comparable to the the Company's clinical supply of Vicineum. Based on these results, we are optimistic that the FDA will determine that the commercial supply of Vicineum is comparable to the clinical supply of Vicineum, and that no additional clinical trials are warranted. The comparability data from the PPQ campaigns for both drug substance and drug product were the final material components of our completed BLA, which was submitted to the FDA on December 18, 2020.

In December 2020, we entered into a commercial manufacturing and supply framework agreement with Qilu (the "Qilu CMO Framework Agreement")for Qilu to be a contract manufacturer for the global commercial supply of Vicineum. We believe that the technology transfer to Qilu for the manufacturing of Vicineum is on track to be completed in mid-2021.

Partnering

Greater China

On July 30, 2020, we and our wholly-owned subsidiary, Viventia Bio, Inc. entered into an exclusive license agreement with Qilu (the "Qilu License Agreement") pursuant to which we granted Qilu an exclusive, sublicensable, royalty-bearing license, under certain intellectual property owned or exclusively licensed by us, to develop, manufacture and commercialize Vicineum for the treatment of NMIBC and other types of cancer in China, Hong Kong, Macau and Taiwan ("Greater China"). We also granted Qilu a non-exclusive, sublicensable, royalty-bearing sublicense, under certain other intellectual property licensed by us to develop, manufacture and commercialize Vicineum in Greater China. We retain (i) development and commercialization rights in the rest of the world excluding Greater China and MENA and (ii) manufacturing rights with respect to Vicineum in the rest of the world excluding Greater China.

We have received a total of $10 million in net proceeds associated with the $12 million upfront payment due pursuant to the Qilu License Agreement . We are also entitled to receive up to an additional $23 million upon the achievement of certain technology transfer, development and regulatory milestones, as well as a 12% royalty based upon annual net sales of Vicineum in Greater China. The royalties are payable upon the first commercial sale of Vicineum in a region and continuing until the latest of (i) twelve years after the first commercial sale of Vicineum in such region, (ii) the expiration of the last valid patent claim covering or claiming the composition of matter, method of treatment, or method of manufacture of such Vicineum in such region, and (iii) the expiration of regulatory or data exclusivity for such Vicineum in such region. The royalty rate is subject to reduction under certain circumstances, including when there is no valid claim of a licensed patent that covers Vicineum in a particular region or no data or regulatory exclusivity of Vicineum in a particular region.

The Investigational New Drug application for Vicineum submitted by Qilu, our partner in Greater China, to the Center for Drug Evaluation of the China National Medical Products Administration was accepted for review in January 2021.

MENA

On November 30, 2020, we entered into an exclusive license agreement with Hikma Pharmaceuticals LLC ("Hikma") (the “Hikma License Agreement”) pursuant to which we granted Hikma an exclusive, sublicensable, royalty-bearing license, under certain intellectual property owned or exclusively licensed by us, to commercialize Vicineum in the Middle East and North Africa region ("MENA") region. We retain development and commercialization rights in the rest of the world excluding Greater China and MENA. In consideration for the rights granted by us, Hikma agreed to pay to us an upfront payment, sales related milestones payments, and royalties and on net sales in the MENA region for the term of the Hikma License Agreement.

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 Vicineum for the treatment of BCG-unresponsive NMIBC, we intend to build a North American specialty urology sales force to market the product in the United States. Outside the United States, we will continue to seek additional 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.

Liquidity and Going Concern

As of December 31, 2020, we had cash and cash equivalents of $52.4 million, net working capital (current assets less current liabilities) of $44.8 million and an accumulated deficit of $315.9 million. We incurred negative cash flows from operating activities of $30.8 million, $37.5 million and $22.8 million for the years ended December 31, 2020, 2019 and 2018, 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 into the follow-up stage of our Phase 3 VISTA Trial of Vicineum for the treatment of BCG-unresponsive NMIBC, seek marketing approval from the FDA and, if approved, commercialize Vicineum for the treatment of BCG-unresponsive NMIBC. 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, out-license and commercialization partnership agreements 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 and, if approved, commercialize our product candidates, including Vicineum for the treatment of BCG-unresponsive NMIBC, and ultimately upon our ability to attain profitable operations. In order to commercialize our product candidates, including Vicineum for the treatment of BCG-unresponsive 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 Vicineum for the treatment of BCG-unresponsive NMIBC, requires substantial working capital, and we expect to seek additional funds through equity or debt financings or through additional commercialization partnerships, licensing transactions or other sources. We may be unable to obtain equity or debt financings or enter into additional commercialization partnerships 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 commercialization

partnerships 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.

We continue to monitor the effect of the outbreak of a novel strain of coronavirus ("COVID-19"). This virus continues to spread globally, has been declared a pandemic by the World Health Organization and has spread to over 200 countries and territories, including the United States disproportionately. 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 are continually assessing the effect of the COVID-19 pandemic on our operations and we are monitoring the spread of COVID-19 and the actions implemented to combat the virus throughout the world.

We do not believe that our cash and cash equivalents of $52.4 million as of December 31, 2020 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 the fourth quarter of 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

License Revenue

License revenue consists of revenue recognized pursuant to our commercialization partnership agreements, including the Qilu License Agreement, which is assessed under ASC Topic 606, *Revenue (*"ASC 606"). In the future, we may generate revenue from a combination of up-front payments, milestone payments and royalties in connection with our commercialization partnership agreements, including the Qilu License Agreement.

Research and Development

Research and development expenses consist primarily of costs incurred for the development of Vicineum for the treatment of BCG-unresponsive NMIBC, 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;
- 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;
- expenses associated with regulatory activities; and
- expenses associated with license milestone fees.

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 Vicineum for the treatment of BCG-unresponsive NMIBC 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 Vicineum for the treatment of BCG-unresponsive NMIBC compared to alternative treatments, including any standard of care;
- the market acceptance of Vicineum for the treatment of BCG-unresponsive NMIBC;

- the cost and timing of the implementation of commercial-scale manufacturing of Vicineum;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation;
- the impact of the COVID-19 pandemic; 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 Vicineum for the treatment of BCG-unresponsive NMIBC could mean a significant change in the costs and timing associated with the development of Vicineum for the treatment of BCG-unresponsive NMIBC. 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 Vicineum for the treatment of BCG-unresponsive NMIBC, we could be required to expend significant additional financial resources and time on the completion of clinical development of Vicineum for the treatment of BCG-unresponsive 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, costs related to manufacturing or purchasing clinical trial materials and technology transfer and license milestone fees, 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 Vicineum for the treatment of BCG-unresponsive NMIBC and other expenses by category. We have deferred further development of Vicineum for the treatment of SCCHN and VB6-845d in order to focus our efforts and our resources on our ongoing development and, if approved, commercialization of Vicineum for the treatment of BCG-unresponsive NMIBC.

We did not allocate research and development expenses to any other specific product program during the periods presented (in thousands):

	Year ended December 31,		
	2020	**2019**	**2018**
Programs:			
Vicineum for the treatment of BCG-unresponsive NMIBC	$ 22,234	$ 16,023	$ 8,942
Total direct program expenses	22,234	16,023	8,942
Personnel and other expenses:			
Employee and contractor-related expenses	5,775	6,513	3,913
Platform-related lab expenses	303	513	250
Facility expenses	442	442	363
Other expenses	437	1,172	609
Total personnel and other expenses	6,957	8,640	5,135
Total Research and Development	**$ 29,191**	**$ 24,663**	**$ 14,077**

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, insurance, investment banking fees, commercial market research, and United States pre-launch market readiness. Future reporting periods may include selling costs pursuant to our commercialization strategy.

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 among 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 and, to a lesser extent, any gains or losses on foreign exchange.

Provision for Income Taxes

Provision for income taxes consists of income taxes paid to foreign jurisdictions pursuant to our commercialization partnership agreements, including the Qilu License Agreement.

Our Results of Operations

Comparison of the Years ended December 31, 2020 and 2019

	Year ended December 31,		Increase/(Decrease)	
	2020	2019	Dollars	Percentage
	(in thousands, except percentages)			
Revenue:				
License revenue	$ 11,236	$ —	$ 11,236	— %
Total revenue	11,236	—	11,236	— %
Operating expenses:				
Research and development	$ 29,191	$ 24,663	$ 4,528	18 %
General and administrative	14,302	12,208	2,094	17 %
Change in fair value of contingent consideration	(11,180)	71,620	(82,800)	(116) %
Total operating expenses	32,313	108,491	(76,178)	(70) %
Loss from Operations	(21,077)	(108,491)	87,414	(81) %
Other income (expense):				
Other income, net	125	991	(866)	(87) %
Net Loss and Comprehensive Loss Before Taxes	**(20,952)**	**(107,500)**	**86,548**	**(81)%**
Provision for income taxes	(1,445)	—	(1,445)	— %
Net Loss and Comprehensive Loss After Taxes	**$ (22,397)**	**$ (107,500)**	**$ 85,103**	**(79)%**

License Revenue

Revenue for the year ended December 31, 2020 was $11.2 million, which was due to the recognition of revenue pursuant to our commercialization partnership agreements, specifically the Qilu License Agreement. The Company did not record any revenue for the year ended December 31, 2019.

Research and Development

Research and development expenses were $29.2 million for the year ended December 31, 2020 compared to $24.7 million for the year ended December 31, 2019. The increase of $4.5 million was due primarily to increased costs associated with technology transfer and manufacturing scale-up for commercial supply ($6.0 million), license milestone fees ($1.2 million), and professional fees in support of regulatory activities ($0.4 million), partially offset by lower employee-related compensation ($1.1 million), lower clinical trial expenses ($1.6 million) as a result of the Company's Phase 3 VISTA Trial winding down, and other decreases ($0.4 million).

General and Administrative

General and administrative expenses were $14.3 million for the year ended December 31, 2020 compared to $12.2 million for the year ended December 31, 2019. The increase of $2.1 million was due primarily to increases in employee-related compensation ($1.3 million), insurance ($0.5 million), legal fees ($0.6 million), and other increases ($0.2 million), partially offset by lower market research ($0.5 million).

Change in Fair Value of Contingent Consideration

The decrease in fair value of contingent consideration was $11.2 million for the year ended December 31, 2020 compared to the increase of $71.6 million for the year ended December 31, 2019. In 2020, discount rates fluctuated significantly as a result of the extreme volatility of financial markets as global economies shut down in order to contain the spread of COVID-19. The discount rate applied to the 2% earnout on all potential commercial net sales of Vicineum through December 2033, upon which a significant portion of the fair value is derived, fluctuated from 5.6% as of December 31, 2019 to 8.8% as of December 31, 2020. As such, changes to discount rates, as well as the refinement of launch timelines in certain markets outside the United States, partially offset by improvements to the competitive landscape, resulted in a decrease in fair value of contingent consideration of $11.2 million for the year ended December 31, 2020.

The increase in fair value of contingent consideration 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 Vicineum 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 Vicineum for the treatment of BCG-unresponsive NMIBC could achieve peak market penetration earlier than previously estimated and that Vicineum 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 attributable primarily to increases in our assumptions for both the estimated United States market share for Vicineum for the treatment of BCG-unresponsive 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 of a competitor's product. As contingent consideration incorporates an earnout 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 Vicineum 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.

Other income, net

Other income, net was $0.1 million for the year ended December 31, 2020 compared to $1.0 million for the year ended December 31, 2019. The change of $0.9 million was due to the decrease in interest income on cash balances.

Provision for Income Taxes

Provision for income taxes was $1.4 million for the year ended December 31, 2020 compared to no provision for income taxes for the year ended December 31, 2019. The increase of $1.4 million was due to income taxes paid to foreign jurisdictions pursuant to our commercialization partnership agreements.

Comparison of the Years ended December 31, 2019 and 2018

For a comparison of our results of operations for the years ended December 31, 2019 and 2018, 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, 2019, filed with the United States Securities and Exchange Commission ("SEC") on March 16, 2020.

Liquidity and Capital Resources

Overview

As of December 31, 2020, we had cash and cash equivalents of $52.4 million, net working capital of $44.8 million and an accumulated deficit of $315.9 million. We incurred negative cash flows from operating activities of $30.8 million, $37.5 million and $22.8 million for the years ended December 31, 2020, 2019 and 2018, 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 into our follow-up stage of our Phase 3 VISTA Trial of Vicineum for the treatment of BCG-unresponsive NMIBC, seek marketing approval from the FDA and EMA for the treatment of BCG-unresponsive NMIBC, and if approved, commercialize Vicineum for the treatment of BCG-unresponsive NMIBC. 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, out-license and commercialization partnership agreements and, to a lesser extent, from a collaboration.

In November 2019, we entered into an Open Market Sale Agreement℠ (the "Sales Agreement") with Jefferies LLC ("Jefferies"), as amended by Amendment No. 1 to Open Market Sale Agreement℠, dated October 30, 2020 and Amendment No. 2 to Open Market Sale Agreement℠, dated February 17, 2021, under which we may issue and sell shares of our common stock from time to time for an aggregate sales price of up to $119.5 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 price. 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.

Through December 31, 2020, we raised $39.9 million of net proceeds from the sale of 35.4 million shares of common stock under the ATM Offering, including $38.0 million in net proceeds from the sale of 33.4 million shares of common stock during the period January 1, 2020 through December 31, 2020. In 2020, we incurred $0.2 million in legal, accounting and printing costs in connection with the ATM Offering. We raised $60.3 million of net proceeds from the sale of 26.3 million shares of common stock under the ATM Offering from January 1, 2021 through March 8, 2021.

We do not believe that our cash and cash equivalents of $52.4 million as of December 31, 2020 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 the fourth quarter of 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.

We continue to monitor the effect of the outbreak of COVID-19. 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 are continually assessing the effect of the COVID-19 pandemic on our operations and we are monitoring the spread of COVID-19 and the actions implemented to combat the virus throughout the world.

Funding Requirements

Our future success is dependent on our ability to develop and, if approved, commercialize our product candidates, including Vicineum for the treatment of BCG-unresponsive NMIBC, and ultimately upon our ability to attain profitable operations. In order to commercialize our product candidates, including Vicineum for the treatment of BCG-unresponsive 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, development and, if approved, commercialization of product candidates, including Vicineum for the treatment of BCG-unresponsive NMIBC, requires substantial working capital, and we expect to seek additional funds through equity or debt financings or through additional commercialization partnerships, licensing transactions or other sources. We may be unable to obtain equity or debt financings or enter into additional commercialization partnerships 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 into our follow-up stage of our Phase 3 VISTA Trial for Vicineum for the treatment of BCG-unresponsive NMIBC;
- seek marketing approvals for Vicineum for the treatment of BCG-unresponsive NMIBC;
- establish and implement 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 Vicineum for the treatment of BCG-unresponsive 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 Vicineum for the treatment of BCG-unresponsive 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 Vicineum for the treatment of BCG-unresponsive NMIBC and our other product candidates;
- the cost and timing of any new clinical trials or studies of Vicineum for the treatment of BCG-unresponsive NMIBC;
- the ongoing COVID-19 pandemic and its impact on our business

- our ability to establish additional commercialization partnerships 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 Vicineum;
- the costs and timing of establishing and implementing sales, marketing and distribution capabilities for Vicineum for the treatment of BCG-unresponsive 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 Vicineum for the treatment of BCG-unresponsive NMIBC, including the potential for the FDA or comparable foreign regulatory authorities 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 our out-license and commercialization partnership agreements;
- the effect of competing technological and market developments; and
- the revenue, if any, received from commercial sales of Vicineum for the treatment of BCG-unresponsive 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 commercialization partnerships and alliances, and licensing arrangements. We do not have any committed external source of funds other than the amounts payable under our out-license and commercialization partnership agreements. 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 commercialization partnerships 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.

The COVID-19 pandemic has negatively impacted the global economy, disrupted business operations and created significant volatility and disruption to financial markets. Significant uncertainty remains as to the potential impact of the COVID-19 pandemic on our operations, and on the global economy as a whole. The extent and duration of the pandemic could continue to disrupt global markets and may affect our ability to raise additional capital in the future.

Cash Flows

The following table sets forth a summary of our cash flows for the years ended December 31, 2020, 2019 and 2018 (in thousands):

	Year ended December 31,		
	2020	**2019**	**2018**
Net Cash Used in Operating Activities	$ (30,837)	$ (37,521)	$ (22,829)
Net Cash Used in Investing Activities	(8)	(136)	(2)
Net Cash Provided by Financing Activities	38,113	35,356	58,583
Net Increase in Cash, Cash Equivalents and Restricted Cash	**$ 7,268**	**$ (2,301)**	**$ 35,752**

Net Cash Used in Operating Activities

Net cash used in operating activities was $30.8 million for the year ended December 31, 2020 and consisted primarily of a net loss of $22.4 million, adjusted for non-cash items, including depreciation of $0.1 million, share-based compensation of $1.8 million, a change in the fair value of the contingent consideration of $11.2 million and a net increase in operating assets and liabilities of $0.9 million.

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 depreciation 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 contingent consideration of $8.8 million and a net increase in operating assets and liabilities of $0.6 million.

Net Cash Used in Investing activities

Net cash used in investing activities consisted of de minimis purchases and sales or property and equipment during each of the years ended December 31, 2020, and 2018 and $0.1 million for the year ended December 31, 2019.

Net Cash Provided by Financing activities

Net cash provided by financing activities was $38.1 million for the year ended December 31, 2020 and consisted primarily of $38.0 million in net proceeds from our ATM Offering and $0.1 million from the exercise of outstanding warrants and options to purchase our common stock.

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.

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 costs; revenue recognition 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 Vicineum 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 the launch of Vicineum in the respective markets, if approved. If regulatory approval to market Vicineum for the treatment of BCG-unresponsive 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, 2020 and 2019.

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, 2020, 2019 and 2018.

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 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, 2020 and 2019, we did not have any uncertain tax positions.

Revenue

We record revenue from our out-license agreements and commercialization partnership agreements, including the Roche License Agreement and the Qilu License Agreement. Under each of these agreements, we granted the counterparty an exclusive license to develop and commercialize the underlying licensed product. These agreements contain up-front license fees, development and regulatory milestone payments, sales-based milestone payments, and sales-based royalty payments.

We determine whether our out-license agreements and commercialization partnership agreements are in scope of ASC 606, which we adopted as of January 1, 2018. Under ASC 606, in determining the appropriate amount of revenue to be recognized as we fulfill our obligations under these out-license agreements and commercialization partnership agreements, we perform the following steps:

1) Identification of the contract;
2) Determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;
3) Measurement of the transaction price, including the constraint on variable consideration;
4) Allocation of the transaction price to the performance obligations;
5) Recognition of revenue when or as the Company satisfies each performance obligation.

Development, Regulatory and Sales-Based Milestones and Other Payments

At the inception of an arrangement that includes development milestone payments, we evaluate whether the development milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated development milestone value is included in the transaction price. Development milestone payments that are not within our control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. For payments pursuant to sales milestones and royalty payments, we will not recognize revenue until the subsequent sale of a licensed product occurs. For arrangements with more than one performance obligation, milestones are generally allocated entirely to the license performance obligation, as (1) the terms of milestone and royalty payments relate specifically to the license and (2) allocating milestones and royalties to the license performance obligation is consistent with the overall allocation objective, because management’s estimate of milestones and royalties approximates the standalone selling price of the license.

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(e) 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, 2020.

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(f), 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 2020 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, 2020 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP.

Changes in Internal Control over Financial Reporting

There have not been changes in our internal control over financial reporting during the quarter ended December 31, 2020 that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

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 2021 Proxy Statement to be filed with the SEC within 120 days of December 31, 2020 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 2021 Proxy Statement to be filed with the SEC within 120 days of December 31, 2020 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 2021 Proxy Statement to be filed with the SEC within 120 days of December 31, 2020 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 2021 Proxy Statement to be filed with the SEC within 120 days of December 31, 2020 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 2021 Proxy Statement to be filed with the SEC within 120 days of December 31, 2020 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	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).
3.3	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 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).
4.4	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).
4.5	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).
4.6	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).
4.7	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+	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).
10.5+	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).
10.6+	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).
10.7+	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).
10.8*	Form of Indemnification Agreement by and between Sesen Bio, Inc. and Each of its Directors and Executive Officers. Incorporated by reference to Exhibit 10.9 to our Annual Report on Form 10-K filed on March 16, 2020 (File. No. 001-36296).
10.9+	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).
10.10†	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).
10.11†	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).
10.12†	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).
10.13†	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).
10.14+	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).
10.15	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).
10.16	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).
10.17+	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).
10.18†	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).
10.19+	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).
10.20+	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).
10.21+	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).
10.22+	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).
10.23	Open Market Sale Agreement℠, dated November 2019, by and between Sesen Bio, Inc. and Jeffries LLC. Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on November 29, 2019 (File No. 001-36296).

10.24	Exclusive License Agreement, dated July 30, 2020, by and among Sesen Bio, Inc., Viventia Bio, Inc. and Qilu Pharmaceutical Co., Ltd. Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q filed with the SEC on November 9, 2020 (File No. 001-36296).
10.25	Amendment No. 1 to the Open Market Sale Agreement℠, dated October 30, 2020, by and between Sesen Bio, Inc. and Jefferies LLC. Incorporated by reference to Exhibit 1.1 to our Current Report on Form 8-K filed on October 30, 2020 (File No. 001-36296).
10.26	Amendment No. 2 to the Open Market Sale Agreement℠, dated February 17, 2021, by and between Sesen Bio, Inc. and Jefferies LLC. Incorporated by reference to Exhibit 1.1 to our Current Report on Form 8-K filed on February 17, 2021 (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	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* 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 15, 2021

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 15, 2021
/s/ Monica Forbes Monica Forbes	Chief Financial Officer (Principal Financial Officer)	March 15, 2021
/s/ Kirstin Anderson Kirstin Anderson	Corporate Controller (Principal Accounting Officer)	March 15, 2021
/s/ Jay S. Duker, M.D. Jay S. Duker, M.D.	Chair of the Board of Directors	March 15, 2021
/s/ Carrie L. Bourdow Carrie L. Bourdow	Director	March 15, 2021
/s/ Jane V. Henderson Jane V. Henderson	Director	March 15, 2021
/s/ Jason A. Keyes Jason A. Keyes	Director	March 15, 2021

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, 2020 and 2019, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

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 Public Company Accounting Oversight Board (United States) (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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purposes of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Fair Value of Contingent Consideration

Description of the Matter	As discussed in Notes 3 and 5 to the consolidated financial statements under the caption "Contingent Consideration," the Company uses a discounted cash flow model to estimate the fair value of the contingent consideration liability each reporting period, which represents the present value of projected future cash flows associated with regulatory approval milestones and royalties on net sales due to the selling shareholders of Viventia Bio Inc. Fluctuations in the fair value of the liability result in a charge to earnings (or loss) during the period. As of December 31, 2020, the Company estimated the fair value of the contingent consideration liability as $108.8 million and recorded the change in fair value of $11.2 million within operating (income) expense for the year ended December 31, 2020. Auditing the fair value of the contingent consideration liability required significant auditor judgment due to the high degree of subjectivity in evaluating certain assumptions used by management to estimate the fair value of the liability. In particular, the fair value measurement was sensitive to the significant assumptions underlying the projected commercial sales of Vicineum and probabilities of success and timing of certain milestone events and achievements.
How We Addressed the Matter in Our Audit	To test the estimated fair value of the contingent consideration liability, our audit procedures included, among others, assessing the terms of the arrangement, evaluating the methodology used and testing the key inputs and significant assumptions discussed above. We evaluated the significant assumptions in light of observable industry and economic trends and standards, external data sources, probability of success benchmarks, and regulatory factors. Our procedures included evaluating the data sources used by management in determining its significant assumptions and included an evaluation of available information that either corroborated or contradicted management's conclusions. In addition, we involved our valuation professionals to assess the methodology used to determine the fair value of the contingent consideration liability, which included performing corroborative fair value calculations.

/s/ Ernst & Young LLP

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

Boston, Massachusetts
March 15, 2021

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

	December 31,	
	2020	**2019**
Assets		
Current assets:		
Cash and cash equivalents	$ 52,389	$ 48,121
Prepaid expenses and other current assets	7,478	6,326
Restricted Cash	3,000	—
Total current assets	62,867	54,447
Restricted cash	20	20
Property and equipment, net	123	238
Intangibles	46,400	46,400
Goodwill	13,064	13,064
Other assets	349	196
Total Assets	**$ 122,823**	**$ 114,365**
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 3,102	$ 1,902
Accrued expenses	3,973	6,169
Deferred revenue	1,500	—
Contingent consideration	8,985	—
Other current liabilities	489	446
Total current liabilities	18,049	8,517
Contingent consideration, net of current portion	99,855	120,020
Deferred revenue, net of current portion	1,500	—
Deferred tax liability	12,528	12,528
Other liabilities	118	—
Total Liabilities	132,050	141,065
Commitments and contingencies		
Stockholders' Deficit:		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized at December 31, 2020 and 2019; no shares issued and outstanding at December 31, 2020 and 2019	—	—
Common stock, $0.001 par value per share; 200,000,000 shares authorized at December 31, 2020 and 2019; 140,449,647 and 106,801,409 shares issued and outstanding at December 31, 2020 and 2019, respectively	140	107
Additional paid-in capital	306,554	266,717
Accumulated deficit	(315,921)	(293,524)
Total Stockholders' Deficit	(9,227)	(26,700)
Total Liabilities and Stockholders' Deficit	**$ 122,823**	**$ 114,365**

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,		
	2020	**2019**	**2018**
Revenue:			
License revenue	$ 11,236	$ —	$ —
Total revenue	11,236	—	—
Operating expenses:			
Research and development	29,191	24,663	14,077
General and administrative	14,302	12,208	11,623
Change in fair value of contingent consideration	(11,180)	71,620	8,800
Total operating expenses	32,313	108,491	34,500
Loss from Operations	(21,077)	(108,491)	(34,500)
Other income (expense):			
Other income, net	125	991	807
Net loss and comprehensive loss, before taxes	**$ (20,952)**	**$ (107,500)**	**$ (33,693)**
Provision for Income Taxes	$ (1,445)	$ —	$ —
Net loss and comprehensive loss	**$ (22,397)**	**$ (107,500)**	**$ (33,693)**
Deemed dividend on adjustment of exercise price on certain warrants	$ (147)	$ —	$ —
Net loss and comprehensive loss attributable to common shareholders	**$ (22,544)**	**$ (107,500)**	**$ (33,693)**
Net loss per common share - basic and diluted	$ (0.19)	$ (1.18)	$ (0.55)
Weighted-average common shares outstanding - basic and diluted	118,221	90,929	61,774

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, 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 vesting 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 pre-funded 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 and vestings of restricted stock awards	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)
Net loss	—	—	—	(22,397)	(22,397)
Share-based compensation	—	—	1,757	—	1,757
Exercises of stock options	12,000	—	13	—	13
Sales of common stock under 2014 ESPP	28,186	—	11	—	11
Exercises of common stock warrants	238,110	—	131	—	131
Issuance of common stock under ATM Offering, net of issuance costs of $1,174	33,369,942	33	37,925	—	37,958
Balance at December 31, 2020	**140,449,647**	**$ 140**	**$ 306,554**	**$ (315,921)**	**$ (9,227)**

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,		
	2020	**2019**	**2018**
Cash Flows from Operating Activities:			
Net loss	$ (22,397)	$ (107,500)	$ (33,693)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	122	219	208
Share-based compensation	1,757	1,237	1,283
Change in fair value of contingent consideration	(11,180)	71,620	8,800
Gain on sale of equipment	—	—	(5)
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(1,304)	(5,188)	(913)
Accounts payable	1,200	535	460
Accrued expenses and other liabilities	(2,035)	1,556	1,031
Deferred revenue	3,000	—	—
Net Cash Used in Operating Activities	**(30,837)**	**(37,521)**	**(22,829)**
Cash Flows from Investing Activities:			
Purchases of property and equipment	(8)	(136)	(2)
Net Cash Used in Investing Activities	**(8)**	**(136)**	**(2)**
Cash Flows from Financing Activities:			
Proceeds from issuance of common stock and common stock warrants, net of issuance costs	—	27,833	50,971
Proceeds from exercises of common stock warrants	131	5,481	7,315
Proceeds from issuance of common stock under ATM Offering, net of issuance costs	37,958	1,936	—
Proceeds from exercises of stock options	13	98	277
Proceeds from sales of common stock under 2014 ESPP	11	8	20
Net Cash Provided by Financing Activities	**38,113**	**35,356**	**58,583**
Net (Decrease) Increase in Cash, Cash Equivalents and Restricted Cash	7,268	(2,301)	35,752
Cash, Cash Equivalents and Restricted Cash - Beginning of Period	48,141	50,442	14,690
Cash, Cash Equivalents and Restricted Cash - End of Period	**$ 55,409**	**$ 48,141**	**$ 50,442**
Reconciliation of cash, cash equivalents, and restricted cash:			
Cash and cash equivalents	$ 52,389	$ 48,121	$ 50,422
Short term restricted cash	3,000	—	$ —
Long term restricted cash	20	20	$ 20
Total cash, cash equivalents, and restricted cash	$ 55,409	$ 48,141	$ 50,442
Supplemental cash flow disclosure:			
Cash paid for amounts included in the measurement of lease liabilities	$ 154	$ 153	$ —
Supplemental disclosure of non-cash operating activities:			
Right-of-use assets related to the adoption of ASC 842	$ —	$ 236	$ —
Right-of-use assets obtained in exchange for lease obligations	$ 290	$ —	$ —
Supplemental disclosure of non-cash financing activities:			
Deemed dividend on adjustment of exercise price on certain warrants	$ 147	$ —	$ —

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, Vicineum™, 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 Vicineum as a monotherapy in patients with 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 Vicineum 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. On December 18, 2020, the Company submitted its completed BLA for Vicineum for the treatment of BCG-unresponsive NMIBC to the FDA.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 Vicineum (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) 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 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. Certain of these payments are payable to individuals or affiliates of individuals that became employees or members of the Company's board of directors, however as of December 31, 2020, none of these individuals are active employees or members of the Company's board of directors.

Liquidity and Going Concern

As of December 31, 2020, the Company had cash and cash equivalents of $52.4 million and an accumulated deficit of $315.9 million. The Company incurred negative cash flows from operating activities of $30.8 million, $37.5 million and $22.8 million for the years ended December 31, 2020, 2019 and 2018, 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 into the follow-up stage of its Phase 3 VISTA Trial of Vicineum for the treatment of BCG-unresponsive NMIBC, seeks marketing approval from the FDA and, if approved, commercialize Vicineum for the treatment of BCG-unresponsive NMIBC. 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 "at-the-market" ("ATM") offerings, commercialization partnership and out-license agreements. 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, obtain marketing approval for and, if approved, commercialize its product candidates, including Vicineum for the treatment of BCG-unresponsive NMIBC, and ultimately upon its ability to attain profitable operations. In order to commercialize its product candidates, including Vicineum for the treatment of BCG-unresponsive 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, marketing approval and, if approved, commercialization 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, development of product candidates, including Vicineum for the treatment of BCG-unresponsive NMIBC, requires substantial working capital, and management expects to seek additional funds through equity or debt financings or through additional commercialization partnerships, licensing transactions or other sources. The Company may be unable to obtain equity or debt financings or enter into additional commercialization partnerships 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 commercialization partnerships 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 $52.4 million as of December 31, 2020 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, Restricted Cash 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 a letter of credit issued related to a license agreement and the credit limit on the Company's corporate credit card, and are classified as short term and long term, respectively. 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, 2020 and 2019, 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, 2020, 2019 and 2018.

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 Vicineum 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 the launch of Vicineum in the respective

markets, if approved. If regulatory approval to market Vicineum for the treatment of BCG-unresponsive 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 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, 2020 and 2019.

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 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, 2020, 2019 and 2018.

Contingent Consideration

The Company uses a discounted cash flow model to estimate the fair value of the contingent consideration liability each reporting period, which represents the present value of projected future cash flows associated with regulatory approval milestones and royalties on net sales due to the selling shareholders of Viventia Bio Inc. as a result of the Viventia Acquisition in September 2016. 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 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, 2020 and 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 and as of December 31, 2020 includes: a property lease for manufacturing, laboratory, warehouse and office space in Winnipeg, Manitoba, 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, 2020, 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, regulatory and financial objectives. 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, 2020, 2019 and 2018 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, including the Company's own volatility, 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, 2020 and 2019, 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 several license agreements, as discussed in "Note 15. License Agreements," pursuant to which the Company received revenue from its commercialization partnership agreements, including the Qilu License Agreement. The Company may receive under each of its commercialization partnership agreements future additional development and regulatory milestone payments, sales-based milestones, and sales-based royalties. The Company recognizes revenue resulting from out-license and commercialization partnership 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 development or regulatory milestones, sales-based milestones or sales-based royalty payments from the counterparties during the years ended December 31, 2020, 2019 and 2018. The Company recognized $11.2 million of license revenue related to the Qilu License Agreement during the year ended December 31, 2020.

4. RECENT ACCOUNTING PRONOUNCEMENTS

Adopted in 2020

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 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. The Company adopted this guidance effective January 1, 2020, and it did not 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. The Company adopted this guidance effective January 1, 2020, and although it resulted in some additional footnote disclosures, it did not have a material impact on the Company's disclosures. For the new disclosures regarding our Level 3 instruments, please read Note 5, Fair Value Measurements and Financial Instruments, to these consolidated financial statements.

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. The amendments in this ASU should be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company adopted this guidance effective January 1, 2020, and it did not have a material impact on the Company's financial position, results of operations or cash flows.

Pending Adoption

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 2019-12 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. The Company 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, 2020 and 2019 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.

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, 2020 and 2019 (in thousands):

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

	December 31, 2020				
			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)	$ 16,374	$ 16,374	$ 16,374	$ —	$ —
Liabilities:					
Contingent consideration, current portion	8,985	$ 8,985	$ —	$ —	$ 8,985
Contingent consideration, net of current portion	$ 99,855	$ 99,855	$ —	$ —	$ 99,855

	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, current portion	—	$ —	$ —	$ —	$ —
Contingent consideration, net of current portion	$ 120,020	$ 120,020	$ —	$ —	$ 120,020

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, 2020.

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 Vicineum forecasted for the United States, Europe, Japan, China and other potential markets and discount rates ranging from 8.4% to 8.8% as of December 31, 2020 and 5.6% to 11.8% as of December 31, 2019. There have been no changes to the valuation methods utilized during the year ended December 31, 2020.

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, 2020 (in thousands):

Balance at December 31, 2019	**$ 120,020**
Change in fair value included in loss	(53,700)
Balance at March 31, 2020	66,320
Change in fair value included in loss	18,480
Balance at June 30, 2020	84,800
Change in fair value included in loss	18,400
Balance at September 30, 2020	103,200
Change in fair value included in loss	5,640
Balance at December 31, 2020	108,840
Balance at December 31, 2020, current portion	8,985
Balance at December 31, 2020, net of current portion	99,855

The fair value of contingent consideration is determined based on the present value of projected future cash flows associated with regulatory approval milestones and earnouts on net sales and is heavily dependent on discount rates to estimate the fair value at each reporting period. Discount rates have fluctuated significantly in 2020 as a result of the extreme volatility of financial markets as global economies shut down in order to contain the spread of COVID-19. Earnouts are determined using a earnout rate of 2% on all commercial net sales of Vicineum through December 2033. The discount rate applied to the 2% earnout is derived from the Company's estimated weighted-average cost of capital ("WACC"), which has fluctuated from 5.6% as of December 31, 2019 to 14.7% as of March 31, 2020, 13.2% as of June 30, 2020, 9.4% as of September 30, 2020 and 8.8% as of December 31, 2020. Milestone payments constitute debt-like obligations, and therefore a high-yield debt index rate is applied to the milestones in order to determine the estimated fair value. This index rate changed from 11.8% as of December 31, 2019 to 17.9% as of March 31, 2020, 14.5% as of June 30, 2020, 11.8% as of September 30, 2020 and 8.4% as of December 31, 2020. These changes in discount rates, as well as the refinement of launch timelines in certain markets outside the United States, partially offset by improvements to the competitive landscape, resulted in an overall $11.8 million decrease in the estimated fair value of contingent consideration during the year ended December 31, 2020. The current portion of total contingent consideration reflects amounts expected to be paid out within twelve months of December 31, 2020.

6. PROPERTY AND EQUIPMENT

The following table sets forth the composition of property and equipment, net as of December 31, 2020 and 2019 (in thousands):

	December 31,	
	2020	**2019**
Lab equipment	$ 570	$ 572
Furniture and fixtures	16	16
Computer equipment	97	87
Software	28	28
Leasehold improvements	293	293
Property and equipment, gross	1,004	996
Less: accumulated depreciation	(881)	(758)
Total Property and Equipment, Net	**$ 123**	**$ 238**

Depreciation expense was $0.1 million, $0.2 million and $0.2 million for the years ended December 31, 2020, 2019 and 2018, respectively.

7. INTANGIBLES AND GOODWILL

Intangibles

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

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, 2020 and 2019 (in thousands):

	December 31,	
	2020	**2019**
IPR&D intangible assets:		
Vicineum United States rights	$ 31,700	$ 31,700
Vicineum 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, 2020 and 2019.

8. ACCRUED EXPENSES

The following table sets forth the composition of accrued expenses as of December 31, 2020 and 2019 (in thousands):

	December 31,	
	2020	2019
Research and development	$ 1,372	$ 3,688
Payroll-related expenses	1,892	1,638
Severance to former Executives and other employees	—	378
Professional fees	684	378
Other	25	87
Total Accrued Expenses	**$ 3,973**	**$ 6,169**

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 were paid through the normal payroll cycle through August 2020, when the Company completed its obligations related to the Fitzgerald Separation Agreement.

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 were paid through the normal payroll cycle through January 2020, when the Company completed its obligations related to the Kim Separation Agreement.

There was no remaining accrued severance as of December 31, 2020.

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 two-year renewable lease through September 2022 with a right to renew the lease for one subsequent three-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 each of the years ended December 31, 2020 and 2019, respectively. Rent expense (under ASC 840), including the related operating costs, was $0.3 million for the year ended December 31, 2018;
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 2021. 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 in rent expense for each of the years ended December 31, 2020, 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 2021. 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 $0.2 million in rent expense for each of the years ended December 31, 2020 and 2019 and $0.1 million in rent expense for the year ended December 31,2018 for this lease.

The asset component of the Company’s operating leases is recorded as operating lease right-of-use assets and reported within other assets on the Company's consolidated balance sheets. The short-term lease liability is recorded in other current liabilities and the long-term lease liability is recorded in other liabilities on the Company’s consolidated balance sheets. Operating lease cost is recognized on a straight-line basis over the lease term.

The components of lease cost for the year ended December 31, 2020 is as follows (in thousands):

	Year Ended December 31, 2020	Year Ended December 31, 2019
Lease Cost:		
Operating lease (including related operating costs)	301	298
Short term property leases	261	263
Total lease costs	562	561

Supplemental Information:	Year Ended December 31, 2020	Year Ended December 31, 2019
Weighted-average remaining lease term (years)	1.75	0.75
Weighted-average discount rate - operating leases	12 %	12 %

The following table sets forth the Company's future minimum lease payments under non-cancelable leases as of December 31, 2020 (in thousands):

Minimum Lease Payments:	Year Ended December 31, 2020
2020	—
2021	162
2022	122
Total future minimum lease payments	284
Less: Amounts representing present value adjustment	(13)
Operating lease liabilities as of December 31, 2020	$ 271

10. STOCKHOLDERS' (DEFICIT) EQUITY

Equity Financings

November 2019 ATM Offering

In November 2019, the Company entered into an Open Market Sale Agreement℠ (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 price. 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 and $0.2 million in legal, accounting and printing costs in 2019 and 2020, respectively, in connection with the ATM Offering. From January 1, 2020 to December 31, 2020, the Company raised $38.0 million of net proceeds from the sale of 33.4 million shares of common stock at a weighted-average price of $1.17 per share under the ATM Offering, including $21.8 million of net proceeds from the sale of 16.6 million shares of common stock at a weighted-average price of $1.36 per share during the three months ended December 31, 2020. Share issue costs, including sales agent commissions, related to the ATM Offering totaled $0.7 million and $1.2 million during the three and twelve months ended December 31, 2020, respectively.

On October 30, 2020, the Company entered into an amendment to the Sale Agreement pursuant to which it may issue and sell an additional $50 million of shares of common stock through Jefferies.

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 had a one-year term that expired 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.

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, 2020 and 2019.

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 140.4 million and 106.8 million shares were issued and outstanding as of December 31, 2020 and 2019, 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, 2020 and 2019 (in thousands):

	December 31,	
	2020	**2019**
Shares of common stock issued	140,450	106,801
Shares of common stock reserved for issuance for:		
Warrants	2,247	22,895
Stock options	10,147	6,236
Shares available for grant under 2014 Stock Incentive Plan	4,863	8,753
Shares available for sale under 2014 Employee Stock Purchase Plan	—	28
Total shares of common stock issued and reserved for issuance	**157,707**	**144,713**

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.

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, 2020 (in thousands):

Issued	Exercise Price	Expiration	December 31, 2019	Issued	(Exercised)	(Cancelled)	December 31, 2020
Jun-2019	$1.47	Jun-2020	20,410	—	—	(20,410)	—
Mar-2018	$0.55*	Mar-2023	1,943	—	(238)	—	1,705
Nov-2017	$0.55*	Nov-2022	487	—	—	—	487
May-2015	$11.83	Nov-2024	28	—	—	—	28
Nov-2014	$11.04	Nov-2024	27	—	—	—	27
			22,895	**—**	**(238)**	**(20,410)**	**2,247**

** 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, 2020, the Company received proceeds of $0.1 million from the exercises of 0.2 million 2018 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. At the time of the modification in October 2019, the 2018 Warrants and 2017 Warrants utilized the same form of warrant, which contained in a prohibition on variable rate transactions (as defined therein). Warrant holders agreed to waive such prohibition in exchange for certain concessions from the Company. 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. Therefore, in the fourth quarter of 2019, 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.

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. During the second quarter of 2020, the anti-dilution provision was triggered; as such, the Company recognized a deemed dividend of approximately $0.1 million which reduced the income available to common stockholders. As the Company has an accumulated deficit balance, there is no overall impact to additional paid-in capital, as the deemed dividend is recorded as offsetting debit and credit entries to additional paid-in capital. Therefore, the amounts were not presented on the Statement of Stockholders' (Deficit) Equity.

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, 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, including ATM offerings, included in the 2017 Warrants was deleted in its entirety 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. As of December 31, 2020, there has been no adjustment to the exercise price of these warrants.

11. LOSS PER SHARE

A net loss cannot be diluted. Therefore, when the Company is in a net loss position, basic and diluted loss per common share are the same. If the Company achieves profitability, the denominator of a diluted earnings per common share calculation includes 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 majority of 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.

Additionally, an entity that presents earnings per share shall recognize the value of the effect of an anti-dilution provision in an equity-classified freestanding financial instrument in the period the anti-dilution provision is triggered. That effect shall be treated as a deemed dividend and as a reduction of income available to common stockholders in basic earnings per share. The deemed dividend is added back to income available to common stockholders when applying the treasury stock method for diluted earnings per share.

For periods with net income, diluted net earnings per share is calculated by either (i) adjusting the weighted-average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period as determined using the treasury stock method or (ii) the two-class method considering common stock equivalents, whichever is more dilutive. The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. The two-class method was not applied for the twelve months ended December 31, 2020, 2019 and 2018 as the Company's participating securities do not have any obligation to absorb net losses.

The following potentially dilutive securities outstanding as of December 31, 2020, 2019 and 2018 have been excluded from the denominator of the diluted loss per share of common stock outstanding calculation (in thousands):

	December 31,		
	2020	**2019**	**2018**
Warrants	2,247	22,895	9,258
Stock options	10,147	6,236	3,942
	12,394	**29,131**	**13,200**

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, 2020, 2019 and 2018 (in thousands):

	Year ended December 31,		
	2020	**2019**	**2018**
Research and development	$ 350	$ 188	$ 505
General and administrative	1,407	1,049	778
Total Share-based Compensation	**$ 1,757**	**$ 1,237**	**$ 1,283**

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 7.9 million stock options outstanding under the 2014 Plan as of December 31, 2020.

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 4.9 million shares of common stock available for issuance under the 2014 Plan as of December 31, 2020.

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, 2020.

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, 2020, 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, 2020, 2019 and 2018:

	Number of Shares under Option (in thousands)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
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
Granted	4,044	$0.87		
Exercised	(12)	$1.13		
Canceled or forfeited	(121)	$1.04		
Outstanding at December 31, 2020	10,147	$1.26	8.50	$ 3,160
Exercisable at December 31, 2020	4,228	$1.63	7.85	$ 931

The Company recognized share-based compensation expense related to stock options of $1.8 million, $1.2 million and $1.3 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, there was $3.6 million of total unrecognized compensation cost related to non-vested stock options which the Company expects to recognize over a weighted-average period of 2.4 years. The weighted-average grant-date fair value of stock options granted during the years ended December 31, 2020, 2019 and 2018 were $0.87, $0.69 and $1.14, respectively. The total intrinsic value of stock options exercised for the years ended December 31, 2020, 2019 and 2018 was de minimis, de minimis and $0.5 million, respectively.

For the years ended December 31, 2020, 2019 and 2018, 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,		
	2020	2019	2018
Fair value of common stock	$0.56	$1.02	$1.71
Exercise price of the option	$0.87	$1.02	$1.71
Expected term (in years)	6.1	6.0	6.0
Risk-free interest rate	1.3%	2.1%	2.8%
Expected volatility	71.5%	78.1%	74.2%
Dividend yield	—%	—%	—%

Performance-Based Grants

Prior to 2018, the Company granted performance-based options to certain employees, and has recognized share-based compensation expense related to such performance-based stock options of de minimis, de minimis and $0.2 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, there was no unrecognized compensation cost related the performance-based stock options granted.

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, 2020, there were no shares of the Company's common stock available for sale under the 2014 ESPP. The Company sold a de minimis number of shares under the ESPP for each of the three years ended December 31, 2020, 2019 and 2018, respectively.

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. The Company contributed a de minimis amount for each of the three years ended December 31, 2020, 2019 and 2018, respectively.

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. The Company contributed a de minimis amount for each of the three years ended December 31, 2020, 2019 and 2018, respectively.

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,		
	2020	**2019**	**2018**
Country:			
United States	$ (35,529)	$ (27,468)	$ (15,977)
Canada	14,577	(80,032)	(17,716)
Total Loss before Income Taxes	**$ (20,952)**	**$ (107,500)**	**$ (33,693)**

The Company's tax provision is comprised of the following components (in thousands):

	Year ended December 31,		
	2020	**2019**	**2018**
Current Tax Provision:			
Federal	$ —	$ —	$ —
State	—	—	—
Foreign	1,445	—	—
Total Current Provision	**$ 1,445**	**$ —**	**$ —**
Deferred Tax Provision:			
Federal	$ —	$ —	$ —
State	—	—	—
Foreign	—	—	—
Total Deferred Provision	**$ —**	**$ —**	**$ —**
Total Tax Provision	**$ 1,445**	**$ —**	**$ —**

The Company did not record current or deferred income tax or benefit for the years ended December 31, 2019 and 2018.

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,		
	2020	2019	2018
United States federal statutory income tax rate	21.0 %	21.0 %	21.0 %
Impact of foreign rate differential	(4.2)	4.4	1.6
State taxes, net of federal benefit	2.0	0.6	1.3
Stock option cancellations	(0.2)	—	(1.2)
Contingent consideration	14.4	(18.0)	(5.5)
General business credits and other credits	6.6	0.4	0.7
Permanent differences	0.2	—	(0.3)
Other	(2.1)	(0.5)	0.5
Foreign taxes	(6.9)	—	—
Change in valuation allowance	(37.7)	(7.9)	(18.1)
Effective Income Tax Rate	**(6.9)%**	**— %**	**— %**

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,	
	2020	2019
Deferred tax assets:		
NOL carryforwards	$ 57,935	$ 50,727
R&D credit carryforwards	3,787	4,385
Accruals and other	3,811	2,464
Capitalized start-up costs	70	91
Other	28	57
Gross deferred tax assets	65,631	57,724
Deferred tax liabilities:		
IPR&D	(12,528)	(12,528)
Property and equipment	—	—
Gross deferred tax liabilities	(12,528)	(12,528)
Valuation allowance	(65,631)	(57,724)
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 $65.6 million and $57.7 million have been established as of December 31, 2020 and 2019, respectively. The $7.9 million increase in the valuation allowance was attributable to the NOL for the year ended December 31, 2020.

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, 2020 (in millions):

	Amount	Expiration Beginning in	Through
United States:			
Federal NOL carryforwards - indefinite	$ 75.2	None	None
Federal NOL carryforwards	$ 118.9	2030	2038
State NOL carryforwards	$ 134.4	2030	2040
Federal R&D credit carryforwards	$ 2.3	2027	2040
State R&D credit carryforwards	$ 0.9	2027	2040
Canada:			
Federal non-capital loss carryforwards	$ 32.2	2035	2040
Federal scientific research and experimental development expense carryforwards	$ 7.0	2032	2040
Federal and provincial investment tax credit carryforwards	$ 0.8	2032	2040

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, 2020, 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 2019 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

Vicineum In-License Agreements

Zurich License Agreement

The Company has a license agreement with the University of Zurich ("Zurich") (the "Zurich License Agreement") 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 Vicineum. The Company may be obligated to pay $0.5 million in milestone payments for the first product candidate that achieves applicable regulatory development milestones. Based on current status, the Company anticipates that these milestones may be triggered by regulatory development pathway of Vicineum. 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. The Company recorded an expense of $0.3 million related to achievement of a development milestone in the three months ended December 31, 2020 due to the submission of the Company's BLA application with the FDA in December 2020.

Micromet License Agreement

The Company has a license agreement with Micromet AG ("Micromet"), now part of Amgen, Inc., (the "Micromet License Agreement") which grants it 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 Vicineum. Under the terms of the Micromet License Agreement, the Company may be obligated to pay up to €2.9 million in milestone payments for the first product candidate that achieves applicable regulatory and sales-based development milestones. Based on current development status, the Company anticipates that certain of these milestones may be triggered by the development pathway of Vicineum. 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 Vicineum. 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. The Company recorded an expense of €0.7 million related to achievement of a development milestone in the three months ended December 31, 2020 due to the submission of the Company's BLA application with the FDA in December 2020.

XOMA License Agreement

The Company has a license agreement with XOMA Ireland Limited ("XOMA") (the "XOMA License Agreement") which grants it non-exclusive rights, with certain sublicense 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 Vicineum. Under the terms of the XOMA License Agreement, 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 the clinical development pathway of Vicineum. The Company is also required to pay a 2.5% royalty on the net sales for products incorporating XOMA's technology, which includes Vicineum. 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.

Out-License Agreement

Roche License Agreement

In June 2016, the Company entered into the Roche License Agreement, 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 Roche License Agreement 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 commercialization 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 (i) $72.5 million in development milestones, the first of which is $20.0 million for initiation of the first Phase II study, (ii), $50.0 million in regulatory milestones and (iii) $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 Roche License Agreement provides for two “option periods” during which Roche may elect to make a one-time payment to the Company and, in turn, terminate its diligence, milestone and royalty payment obligations under the License Agreement. Specifically, (i) Roche may exercise a buy-out option following the first dosing (“Initiation”) in the first Phase 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 Roche License Agreement if the other party breaches any of its material obligations under the Roche License Agreement and does not cure such breach within a specified cure period. Roche may terminate the Roche 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 Roche 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.

Commercialization Partnership Agreements

Qilu License Agreement

On July 30, 2020, the Company and its wholly-owned subsidiary, Viventia Bio, Inc., entered into the Qilu License Agreement pursuant to which the Company granted Qilu an exclusive, sublicensable, royalty-bearing license, under certain intellectual
property owned or exclusively licensed by the Company, to develop, manufacture and commercialize Vicineum (the “Licensed Product”) for the treatment of NMIBC and other types of cancer (the “Field”) in China, Hong Kong, Macau and Taiwan ("Greater China”). The Company also granted Qilu a non-exclusive, sublicensable, royalty-bearing sublicense, under certain other intellectual property licensed by the Company to develop, manufacture and commercialize the Licensed Product in Greater China. The Company retains (i) development and commercialization rights in the rest of the world excluding Greater China and MENA and (ii) manufacturing rights with respect to Vicineum in the rest of the world excluding China.

In consideration for the rights granted by the Company, Qilu agreed to pay to the Company (i) a one-time upfront cash payment of $12 million, subject to certain tax withholdings such as income taxes and value added taxes ("VAT"), payable within 45 business days of the execution date, subject to delivery by the Company of certain know-how and other documentation related to the Licensed Product to Qilu, and (ii) milestone payments totaling up to $23 million upon the achievement of certain technology transfer, development and regulatory milestones. All payments are inclusive of VAT, which are withheld by Qilu upon payment, and for which future recovery of such taxes may be available. In September 2020, the Company received $10.0 million in net proceeds due under the Qilu License Agreement.

Qilu also agreed to pay the Company a 12% royalty based upon annual net sales of Licensed Products in Greater China. The royalties are payable on a Licensed Product-by-Licensed Product and region-by-region basis commencing on the first commercial sale of a Licensed Product in a region and continuing until the latest of (i) twelve years after the first commercial sale of such Licensed Product in such region, (ii) the expiration of the last valid patent claim covering or claiming the composition of matter, method of treatment, or method of manufacture of such Licensed Product in such region, and (iii) the expiration of regulatory or data exclusivity for such Licensed Product in such region (collectively, the “Royalty Term”). The

royalty rate is subject to reduction under certain circumstances, including when there is no valid claim of a licensed patent that covers a Licensed Product in a particular region or no data or regulatory exclusivity of a Licensed Product in a particular region.

Qilu is responsible for all costs related to developing, obtaining regulatory approval of and commercializing the Licensed Products in the Field in Greater China. Qilu is required to use commercially reasonable efforts to develop, seek regulatory approval for, and commercialize at least one Licensed Product in the Field in Greater China. A joint development committee was established between the Company and Qilu to coordinate and review the development, manufacturing and commercialization plans with respect to the Licensed Products in Greater China. The Company and Qilu also executed the terms and conditions of a supply agreement and related quality agreement pursuant to which the Company will manufacture or have manufactured and supply Qilu with all quantities of the Licensed Product necessary for Qilu to develop and commercialize the Licensed Product in the Field in Greater China until the Company has completed manufacturing technology transfer to Qilu and approval of a Qilu manufactured product by the National Medical Products Administration in China for the Licensed Product has been obtained.

The Qilu License Agreement will expire on a Licensed Product-by-Licensed Product and region-by-region basis on the date of the expiration of all applicable Royalty Terms. Either party may terminate the Qilu License Agreement for the other party's material breach following a cure period or upon certain insolvency events. Qilu has the right to receive a refund of all amounts paid to the Company in the event the Qilu License Agreement is terminated under certain circumstances. The Qilu License Agreement includes customary representations and warranties, covenants and indemnification obligations for a transaction of this nature.

The Qilu License Agreement is subject to the provisions of Accounting Standards Codification 606, Revenue from Contracts with Customers ("ASC 606"), which was adopted effective January 1, 2018. The initial transaction price was estimated to be $11.2 million and was based on the up-front fixed consideration of $12 million less amounts withheld for VAT. The Company concluded that its promises under the Qilu License Agreement represented one bundled performance obligation that had been achieved as of September 30, 2020. As such, $11.2 million of the total $11.2 million transaction price was considered earned and the Company recorded $11.2 million of revenue during the three-month period ended September 30, 2020. The Company is reasonably certain that no refund of the upfront payment will be due to Qilu. Additional consideration to be paid to the Company upon the achievement of certain milestones, as well as recoverability of VAT, will be included if it is expected that the amounts will be received and the amounts would not be subject to a constraint. As of December 31, 2020, none of these amounts were reasonably certain to be achieved due to the nature and timing of the underlying activities.

For the three and twelve months ended December 31, 2020, the Company recorded $1.1 million of income tax expense pursuant to the Qilu License Agreement. The income tax expense relates to withholding taxes paid in foreign jurisdictions and is reported as provision for income taxes on the consolidated statement of operations and comprehensive loss for each period.

Other Commercialization Partnership Agreements

On November 30, 2020, the Company entered into an additional license agreement pursuant to which the Company granted an exclusive, sublicensable, royalty-bearing license, under certain intellectual property owned or exclusively licensed by the Company, to commercialize Vicineum in the Middle East and North Africa region ("MENA") region, ("the MENA License Agreement"). The Company retains development and commercialization rights in the rest of the world excluding Greater China and MENA. In consideration for the rights granted by the Company, the counterparty agreed to pay to the Company an upfront payment of $3 million, which would be subject to certain tax withholdings. In addition, the counterparty agreed to pay milestone payments upon the achievement of certain sales-based milestones as well as a royalty based upon annual net sales in the MENA region. During the three months ended December 31, 2020, the Company received $2.7 million under the MENA License Agreement.

The MENA License Agreement is also subject to the provisions of ASC 606. The initial transaction price was estimated by management as $1.5 million as of December 31, 2020 and was based on 50% of the upfront payment, or the amount not subject to a refund if certain regulatory approvals in MENA are not obtained. The Company also concluded that its promises under the MENA License Agreement represented two distinct performance obligations, the first of which is a bundled performance obligation related to the delivery of the license, associated know-how and certain documentation. The second performance obligation relates to the delivery of manufactured product. Both performance obligations were not achieved as of December 31, 2020; as such, no revenue has been recognized under this agreement during 2020. Additional variable consideration, determined to be allocated entirely to the bundled license performance obligation, to be paid to the Company based upon future sales levels will be recognized as revenue when the underlying sales of the licensed product occurs. In addition, variable

consideration related to any future delivery of product will be recognized in future periods as the product is delivered. As of December 31, 2020, none of these additional amounts were reasonably certain to be achieved due to the nature and timing of the underlying activities. The Company has recorded a contract liability of $3.0 million which is recorded within deferred revenue on its consolidated balance sheets as of December 31, 2020, of which $1.5 million is expected to be recognized within twelve months of the period ended December 31, 2020 and is therefore classified in current liabilities. For the three months ended December 31, 2020, the Company recorded $0.3 million of income tax expense pursuant to this license agreement. The income tax expense relates to withholding taxes paid in foreign jurisdictions and is reported as provision for income taxes on the consolidated statement of operations and comprehensive loss for the three months ended December 31, 2020.

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, 2020, 2019 and 2018, 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. 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, 2020, 2019 and 2018, the Company paid $0.1 million under this license agreement.

The Company previously leased office space in Toronto, Ontario from Mr. Dan. The lease was terminated by the Company in December 2018. For the year ended December 31, 2018, the Company paid $18,000 of rent.

Due to his retirement in July 2019, Mr. Dan was not deemed a related party during the twelve month period ended December 31, 2020; as such, only payments made through the nine month period ended September 30, 2019 are considered payments to a related party.

17. SUBSEQUENT EVENTS

On January 13, 2021, the Company issued a press release announcing that the Investigational New Drug application for Vicineum submitted by the Company’s licensee in China, Qilu Pharmaceutical Co., Ltd., was accepted for review by the China National Medical Products Administration.

On February 16, 2021, the Company announced that the FDA has accepted for filing the Company’s BLA for Vicineum, for the treatment of BCG-unresponsive NMIBC, and granted the application Priority Review. With Priority Review, the anticipated target Prescription Drug User Fee Act (“PDUFA”) date for a decision on the BLA is August 18, 2021. In addition, the FDA stated that it is not currently planning to hold an advisory committee meeting to discuss the BLA for Vicineum.

On February 17, 2021, the Company entered into Amendment No. 2 (the “Second Amendment”) to the Sale Agreement with Jefferies, dated November 29, 2019, as amended by Amendment No. 1 to the Sale Agreement. The Second Amendment allows for the Company to issue and sell through Jefferies up to an additional $34.5 million of shares of its common stock, par value $0.001 per share, under the Sale Agreement. As of the effective date of the Second Amendment, the Company had approximately $35.5 million in total remaining capacity under the Sale Agreement.

On March 8, 2021, the Company issued a press release announcing the March 5, 2021 submission of the Marketing Authorization Application to the EMA for Vicineum for the treatment of BCG-unresponsive NMIBC under the EMA’s centralized procedure.

The Company raised $60.3 million of net proceeds from the sale of 26.3 million shares of common stock under the ATM Offering from January 1, 2021 through March 8, 2021.

Stock Options Granted

In February 2021, the Company's board of directors granted 4.1 million stock options with an exercise price of $3.17 to employees and officers under the Company's 2014 Plan. These stock options had a grant-date fair value of $2.06 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 28, 2021, there were 165,803,480 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 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

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 report dated March 15, 2021, with respect to the consolidated financial statements of Sesen Bio, Inc. included in this Annual Report (Form 10-K) of Sesen Bio, Inc. for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 15, 2021

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, 2020 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 15, 2021

By: _____
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, 2020 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 15, 2021

By: _____
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, 2020 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 15, 2021

By: _____
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, 2020 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 15, 2021

By: _____
Name: Monica Forbes
Title: Chief Financial Officer
(Principal Financial Officer)