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, 2021

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, 2021, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $870.7 million.

There were 199,463,645 shares of the registrant's common stock outstanding as of February 21, 2022.

Documents Incorporated by Reference

Portions of the registrant’s Definitive Proxy Statement relating to the 2022 Annual Meeting of Stockholders ("2022 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, 2021, 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, 2021

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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,” "contemplate," “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 resolve the issues identified in the complete response letter (“CRL”) we received from the US Food and Drug Administration (“FDA”) regarding our Biologics License Application (“BLA”) for Vicineum™ for the treatment of bacillus Calmette-Guérin (“BCG”)-unresponsive non-muscle invasive bladder cancer (“NMIBC”);
- our plans and ability to resolve the concerns identified in the European Medicines Agency’s (“EMA”) Withdrawal Assessment Report related to our marketing authorization application (“MAA”) for Vysyneum™ (the “EMA Withdrawal Report”);
- our belief that we have a clear understanding of what additional information regarding chemistry, manufacturing and controls ("CMC") is required for potential resubmission of a BLA for Vicineum;
- our ability to utilize Vicineum manufactured during process validation for any future clinical trials needed to address issues raised in the CRL, including an additional Phase 3 clinical trial, and that any such future clinical trials can proceed while addressing CMC issues raised in the CRL;
- our expectation to discuss the study protocol for an additional Phase 3 clinical trial for Vicineum for the treatment of non-muscle invasive carcinoma in situ (“CIS”) of the bladder in patients previously treated with adequate or less than adequate BCG in a Type C Meeting with the FDA scheduled for March 28, 2022 (“Type C Meeting”);
- our expectations regarding an additional Phase 3 clinical trial for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG to address questions related to clinical matters raised in the CRL;
- our intentions to use the information from the Type A Meetings following the CRL we received regarding our BLA for Vicineum to determine the appropriate path forward with regulators;
- our plans and ability to resubmit a BLA for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG to the FDA following the issuance of the CRL by the FDA, and if approved by the FDA, our ability to commercialize Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG;
- our plans and ability to resume pursuing regulatory approval of Vysyneum™ (the proprietary brand name that was conditionally approved by the EMA for oportuzumab monatox in the European Union) of BCG-unresponsive NMIBC in the European Union when there is more clarity from the FDA on next steps for Vicineum in the US;
- our intentions to work closely with the FDA to understand next steps for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG in the US;
- our intentions to work closely with the EMA to understand next steps for Vysyneum™ for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG in the European Union;
- 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG in the United States, the European Union and other non-US jurisdictions, and the labeling under any approval we may obtain;
- our projected financial position and estimated cash burn rate;
- our belief that we will have sufficient future cash flows from additional geographic regions outside the US to support the value of our goodwill and EU indefinite-lived, acquired in-process research and development ("IPR&D");
- our plans to continue to evaluate timelines for commercialization and probability of success of development of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG;
- our estimations regarding any remeasurement of contingent consideration liability in the future;

- our estimations regarding any potential impairment to our goodwill and indefinite-lived intangible asset in the future;
- our estimates regarding expenses, future revenues, capital requirements and needs for, and ability to obtain, additional financing;
- our need to raise substantial additional capital to fund our operations;
- the success, cost and timing of our pre-clinical studies and clinical trials in the United States and other non-US jurisdictions;
- our dependence on third parties, including contract research organizations (“CROs”) in the conduct of our pre-clinical studies and clinical trials, including an additional Phase 3 clinical trial for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG;
- the timing and costs associated with our manufacturing process and technology transfer to Qilu Pharmaceutical Co., Ltd. (“Qilu”) for the production of Vicineum drug substance and drug product, and our reliance on Qilu to perform under our agreement with Qilu;
- market acceptance of our product candidates, including Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG;
- the size and growth of the potential markets for our product candidates, and our ability to serve those markets;
- our ability to obtain and maintain intellectual property protection for our product candidates and our proprietary technology;
- our strategic operating plan to sublicense Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG to business development partners in all regions outside the US, including the European Union, to earn a potential combination of upfront, milestone, and royalty payments, and the business development partner to bear the majority of regulatory and commercialization costs;
- our belief that the probability of success of future approval in the European Union for Vysyneum increases if FDA approval for Vicineum has already been obtained;
- our beliefs regarding key advantages of our targeted fusion protein therapeutics (“TFPT”) platform;
- our expectation that Vicineum may work via a dual mechanism of action to directly kill cancer cells and activate a local inflammatory process that stimulates T-cells, which then proliferate and destroy the cancer cells;
- our expectation that there may be potential for a synergistic effect when Vicineum is given in combination with checkpoint inhibitors;
- our expectations regarding the amount and timing of milestone and royalty payments pursuant to our out-license agreements and OUS business development partnership agreements, including our license agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (collectively, “Roche”), (the “Roche License Agreement”) and our exclusive license agreement with Qilu for the development, manufacture and commercialization of Vicineum in China, Hong Kong, Macau and Taiwan ("Greater China");
- our ability to regain compliance with Nasdaq’s minimum bid price requirement;
- our plans to seek additional OUS business development partnerships; and
- the success of competing therapies and products that are or become available.

The forward-looking statements in this Annual Report on Form 10-K are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and involve known and unknown risks, uncertainties, assumptions and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, among others, the following:

- we may not be able to resolve the issues raised in the CRL we received from the FDA regarding our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC;
- we may not be able to resolve the concerns identified in the EMA Withdrawal Assessment Report;
- we may not determine a viable path forward for continued clinical development of Vicineum, which would prevent us from resubmitting a BLA for Vicineum;
- we may not achieve profitable operations or access needed capital;
- we may experience delays or difficulties related to the continued clinical development of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, 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 due to COVID-19 or otherwise;

- clinical trials of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, including an additional Phase 3 clinical trial for Vicineum, or any of our other product candidates, may not demonstrate safety and efficacy to the satisfaction of the FDA, EMA or other non-US regulatory authorities or otherwise produce favorable results;
- we may not obtain marketing approval of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG in the United States, the European Union or other non-US jurisdictions;
- Vicineum may not gain market acceptance for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG in the United States, the European Union or other non-US jurisdictions;
- the market opportunity for Vicineum may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed;
- we may experience issues or delays with third-party disposition, labelling and packaging of clinical supply of Vicineum;
- our competitors may discover, develop or commercialize products before, or more successfully than, we do;
- we may be unable to obtain, maintain, defend and enforce patent claims and other intellectual property rights;
- we may be unable to defend against pending or threatened litigation, which may be costly and time-consuming;
- we may fail to comply with all regulatory requirements or experience unanticipated problems with our products;
- we may recognize impairment of our goodwill and indefinite-lived intangible asset;
- we may not meet the Nasdaq minimum bid price requirement during any compliance period or in the future;
- we may not be granted relief from delisting from Nasdaq if necessary; and
- such other factors described in “Item 1A. Risk Factors” and “Item 5. Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this Annual Report on Form 10-K.

Our product candidates are investigational biologics undergoing clinical development and have not been approved by the FDA, EMA or other comparable non-US regulatory authorities. On August 13, 2021, we received a CRL from the FDA indicating that the FDA had determined that it could not approve the BLA for Vicineum in its present form. On August 20, 2021, we withdrew our MAA to the EMA for Vysyneum for the treatment of BCG-unresponsive NMIBC in order to pause our plans to pursue regulatory approval of Vysyneum in the European Union until there is more clarity from the FDA on next steps for Vicineum in the United States. In October and December 2021, we participated in a CMC Type A Meeting and a Clinical Type A Meeting, respectively, with the FDA to discuss issues raised in the CRL and design elements of an additional Phase 3 clinical trial for Vicineum, which the FDA confirmed will be required for a potential resubmission of a BLA. Following these Type A Meetings, we believe we have greater clarity of the requirements for potential resubmission of a BLA. A Type C Meeting has been scheduled with the FDA for March 28, 2022 in which we expect to discuss the study protocol for the additional Phase 3 clinical trial that we plan to conduct for potential resubmission of a BLA for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG.

The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. 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. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for us to predict all risks and uncertainties. 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. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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

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 OUS business development partnership agreements, we currently have no source of 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. If we are unable to obtain marketing approval for or successfully commercialize our lead product candidate, either alone or through an out-license or an OUS business development partnership, or experience significant delays in doing so, our business could be materially harmed.
- If additional clinical trials of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG fail to demonstrate safety and efficacy to the satisfaction of the FDA, the EMA or other non-US regulatory authorities or do not otherwise produce favorable results, we will be unable to complete the development and potential commercialization of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG.
- We may not be able to develop a more sensitive bioanalytical assay which is needed for the additional Phase 3 clinical trial for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG.
- If we experience any of a number of possible unforeseen events in connection with our clinical trials, potential marketing approval or commercialization of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG could be delayed or prevented.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.
- Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG 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 will need to obtain regulatory authority approval of any proposed names for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, and any failure or delay associated with such naming approval may adversely impact our business.
- 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG or any other product candidate.
- Failure to obtain marketing approval in non-US 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 non-US jurisdictions.
- Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, if approved.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

Risks Related to Our Dependence on Third Parties

- We will depend on Qilu for the development and commercialization of Vicineum in Greater China.
- 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 are dependent on third parties to formulate and manufacture Vicineum, which exposes us to a number of risks that may delay development, regulatory approval and commercialization of our products or result in higher product costs.

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

- 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, and affect the prices we may obtain.
- 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.

Risks Related to Our Business and Operations

- The COVID-19 coronavirus could adversely impact our business.
- Our future success depends on our ability to attract, retain and motivate qualified personnel.
- 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.
- We and certain of our officers have been named as defendants in three pending securities class action lawsuits and three related shareholder derivative lawsuits have been filed. These lawsuits, and potential similar or related lawsuits, could result in substantial damages, divert management’s time and attention from our business, and have a material adverse effect on our results of operations. These lawsuits, and any other lawsuits to which we are subject, will be costly to defend and are uncertain in their outcome.
- 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.

Risks Related to Ownership of Our Common Stock

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

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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG.

In December 2020, we submitted our completed BLA for Vicineum for the treatment of BCG-unresponsive NMIBC to the FDA, which was accepted for filing by the FDA in February 2021. The FDA granted Priority Review for the BLA and set a target PDUFA date for a decision on the BLA of August 18, 2021. On August 13, 2021, we received a CRL from the FDA indicating that the FDA had determined that it could not approve the BLA for Vicineum in its present form and provided recommendations specific to additional clinical/statistical data and analyses in addition to CMC issues pertaining to a recent pre-approval inspection and product quality. On August 20, 2021, we withdrew our MAA to the EMA for Vysyneum for the treatment of BCG-unresponsive NMIBC in order to pause our plans to pursue regulatory approval of Vysyneum in the European Union until there is more clarity from the FDA on next steps for Vicineum in the United States. Vysyneum is the proprietary brand name that was conditionally approved by the EMA for oportuzumab monatox in the European Union. In October 2021, the EMA issued its Withdrawal Assessment Report relating to our MAA for Vysyneum, as is consistent with the EMA's standard practice when an MAA is withdrawn. The EMA Withdrawal Assessment Report reflects the initial assessment and corresponding questions from the EMA and identifies major objections in the areas of quality, good clinical practice, efficacy and safety. Due to the high concordance between FDA and European Commission approvals, we believe that the probability of success of future approval in the European Union for Vysyneum increases if FDA approval for Vicineum has already been obtained.

On October 29, 2021, we participated in a Type A Meeting with the FDA to discuss questions related to CMC raised in the CRL (the "CMC Type A Meeting"). During the CMC Type A Meeting, we and the FDA reviewed issues related to CMC to be further discussed during the review of a BLA for Vicineum upon potential resubmission. We believe we have a clear understanding of what additional information regarding CMC is required for a potential resubmission of a BLA. Additionally, although not an issue raised in the CRL, the FDA confirmed at the CMC Type A Meeting that Vicineum manufactured using the proposed commercial process is comparable to Vicineum used in prior clinical trials. The FDA also confirmed that we can utilize Vicineum manufactured during process validation for any future clinical trials needed to address issues raised in the CRL, and that these potential trials can proceed while addressing CMC issues.

On December 8, 2021, we participated in a Type A Meeting with the FDA to discuss design elements of an additional Phase 3 clinical trial for Vicineum (the "Clinical Type A Meeting"), which the FDA confirmed will be required for a potential resubmission of a BLA. The trial design may include these elements:

- A randomized clinical trial assessing the safety and efficacy of Vicineum compared to investigators' choice of intravesical chemotherapy;
- Trial may include both patients who have received adequate BCG[1] and patients who have received less than adequate BCG;
- The FDA encouraged us to submit the final results from the Phase 3 VISTA trial for Vicineum with a BLA resubmission.

[1]As per the 2018 FDA guidance on NMIBC, adequate BCG is defined as at least one of the following: (i) at least five of six doses of an initial induction course plus at least two of three doses of maintenance therapy or (ii) at least five of six doses of an initial induction course plus at least two of six doses of a second induction course.

On January 7, 2022, the FDA granted our request for a Type C Meeting to discuss the study protocol for an additional Phase 3 clinical trial that we plan to conduct for potential resubmission of a BLA for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. The Type C Meeting has been scheduled for March 28, 2022.

One of the items we expect to be discussed in the Type C Meeting is the patient population for the additional Phase 3 clinical trial, which may be different than the patient population studied in previous clinical trials for Vicineum for the treatment of NMIBC in two primary ways.

First, the additional Phase 3 clinical trial may include patients with only non-muscle invasive carcinoma in situ (CIS) of the bladder, and may not include patients with only papillary disease of the bladder. This change would lead to a smaller overall patient population than previously studied, as some of our past clinical trials of Vicineum in NMIBC have included patients with CIS or high-grade papillary disease of the bladder.

Second, the additional Phase 3 clinical trial may include patients who have received less than adequate BCG in addition to those who have received adequate BCG, per the FDA's guidance. Receipt of less than adequate BCG could be due to (i) failure of, or intolerance to, a BCG therapy prior to reaching the FDA's definition of adequate BCG or (ii) supply shortages of BCG, among other reasons. This change would lead to a larger patient population than previously studied, as past clinical trials of Vicineum in NMIBC only included patients who had previously been treated with adequate BCG.

Potential changes related to the additional Phase 3 clinical trial for Vicineum will be discussed at the upcoming Type C Meeting with the FDA scheduled for March 28, 2022.

Our TFPT 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, 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 TFPT product candidate is Vicineum, in development for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG and recurrent, locally advanced or metastatic EpCAM-expressing squamous cell carcinoma of the head and neck ("SCCHN"). This TFPT 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG.*** In December 2020, we submitted our completed BLA for Vicineum to the FDA for the treatment of BCG-unresponsive NMIBC, which was accepted for filing by the FDA in February 2021. The FDA granted Priority Review for the BLA and set a target PDUFA date for a decision on the BLA of August 18, 2021. On August 13, 2021, we received a CRL from the FDA indicating that the FDA had determined that it could not approve the BLA for Vicineum in its present form. On August 20, 2021, we withdrew our MAA to the EMA for Vysyneum for the treatment of BCG-unresponsive NMIBC in order to pause our plans to pursue regulatory approval of Vysyneum in the European Union until there is more clarity from the FDA on next steps for Vicineum in the United States. In October and December 2021, we participated in a CMC Type A Meeting and a Clinical Type A Meeting, respectively, with the FDA to discuss issues raised in the CRL and design elements of an additional Phase 3 clinical trial for Vicineum, which the FDA confirmed will be required for a potential resubmission of a BLA. Following these Type A Meetings, we believe we have greater clarity of the requirements for potential resubmission of a BLA. We have a Type C Meeting scheduled with the FDA for March 28, 2022 in which we expect to discuss the study protocol for the additional Phase 3 clinical trial that we plan to conduct for potential resubmission of a BLA for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG.
- ***Maximize the commercial potential Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG.*** We own exclusive, worldwide rights to Vicineum and we have out-licensed the rights to Vicineum in Greater China, the Middle East and North Africa region (“MENA”) and Turkey. If Vicineum receives marketing approval from the FDA for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, 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 business development 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. In 2020 and 2021, we entered into license agreements to support such commercialization efforts outside the United States for Greater China, MENA and Turkey.
- ***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 National Cancer Institute ("NCI") for the development of Vicineum in combination with AstraZeneca’s immune checkpoint inhibitor durvalumab for the treatment of NMIBC. Vicineum is believed to work via a dual

mechanism of action to directly kill cancer cells and activate a local inflammatory process that stimulates T-cells, which then proliferate and destroy the cancer cells. Because of this second mechanism, there may be potential for a synergistic effect when given in combination with checkpoint inhibitors. Under the terms of the CRADA, this hypothesis is being tested by the NCI in Phase 1 clinical trial in patients with BCG-unresponsive NMIBC to evaluate the safety, efficacy and biological correlates of Vicineum in combination with durvalumab ("NCI Trial"). On September 10, 2021, preliminary results from an interim analysis of 12 patients in the NCI Trial ("Interim Analysis") were presented at a conference hosted by the American Urological Association. Enrollment in the Phase 1 clinical trial is ongoing. Based on the Interim Analysis, the combination of Vicineum and durvalumab has been generally well-tolerated with no new safety signals emerging (no Grade 4 or 5 treatment-related adverse events) and has a similar safety profile compared to both agents used individually. The Interim Analysis also indicated a 3-month complete response rate of 42% (5/12) and a 12-month complete response rate of 17% (2/12).

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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG and have deferred further development of our other product candidates. The following table sets forth our current development stage programs:

SESEN BIO PIPELINE

PRODUCT CANDIDATE	INDICATION	NCT	PRECLINICAL	Ph I	Ph II	Ph III
Locally-administered TFPTs						
Vicineum™ (Anti-EpCAM + ETA)	Non-muscle invasive carcinoma in situ (CIS) of the bladder[1]	TBD	Anticipated			
Vicineum™ (Anti-EpCAM + ETA)	BCG-unresponsive non-muscle invasive bladder cancer	NCT02449239	Ongoing[2]			
Vicineum™ (Anti-EpCAM + ETA)[3]	SCCHN	OUS*	Completed[4]			
Systemically-administered TFPTs						
VB6-845d (Anti-EpCAM (Fab) + deBouganin)[3]	Solid tumors	N/A	Completed			

SESEN BIO PARTNERSHIPS[5]

PRODUCT CANDIDATE	INDICATION	NCT	PRECLINICAL	Ph I	Ph II	Ph III
Vicineum™ (Qilu Pharmaceutical)	BCG-unresponsive non-muscle invasive bladder cancer	NCT04859751	Ongoing			
EBI-031 / RG6179 (Roche[6])	Diabetic macular edema	NCT05151731	Ongoing			
EBI-031 / RG6179 + Ranibizumab (Roche[6])	Diabetic macular edema	NCT05151744	Ongoing			
VB5-845d[7] + NIR Fluorescence Dye (Leiden University Medical Center)	Tumor imaging during surgery	OUS*	Completed			
Vicineum™ + Durvalumab (National Cancer Institute)	BCG-unresponsive non-muscle invasive bladder cancer	NCT03258593	Ongoing			

[1]In patients previously treated with adequate or less than adequate BCG; [2]Trial is in follow-up stage; [3]Development has been deferred in order to focus efforts and resources on ongoing development of Vicineum for treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less-than-adequate BCG; [4]Ph II and Ph III were initiated but terminated early, and enrolled patients completed the full study course; [5]Clinical trials for Sesen Bio's partnerships are sponsored by the Partner; [6]Roche = F. Hoffmann-La Roche Ltd and Hoffman-La Roche Inc.; [7]VB5-845d is a deimmunized Fab containing the anti-EpCAM antibody binding domains of Vicineum™

BCG = Bacillus Calmette-Guérin; TFPT=Targeted Fusion Protein Therapeutics; ETA=Pseudomonas Exotoxin A; SCCHN=Squamous Cell Carcinoma of the Head and Neck; OUS=Outside the US; NIR=Near Infrared

*OUS studies not registered on ClinicalTrials.gov

Vicineum for the Treatment of Non-Muscle Invasive CIS of the Bladder in Patients Previously Treated with Adequate or Less Than Adequate BCG

Overview

We are developing Vicineum, oportuzumab monatox, for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. Vicineum is given via 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. In August 2018, we received Fast Track designation from the FDA for Vicineum for the treatment of BCG-unresponsive NMIBC. The FDA has conditionally accepted the proprietary brand name VICINEUM™ for our product candidate, oportuzumab monatox.

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 occurs in the lining of the bladder, 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 occurs in the bladder, has a strong tendency to invade the muscular wall of the bladder, spread to other parts of the body and is more likely to result in death. Bladder cancer is also divided into muscle-invasive and non-muscle invasive, 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. Evaluable 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%.

According to World Cancer Research Fund International figures, bladder cancer is the tenth most common cancer diagnosed worldwide and the second most common malignancy of the genitourinary system, which refers to cancers of the urinary system of men and women and the reproductive organs of men. In 2020, there were an estimated 573,000 new cases of bladder cancer diagnosed and 213,000 deaths worldwide, according to data from the Global Cancer Observatory. The 5-year global prevalence of bladder cancer, or the number of individuals with bladder cancer in a 5-year period, is estimated at 1.7 million individuals. The most recent data from the NCI's Surveillance, Epidemiology and End-Result Program ("SEER") estimated that approximately 84,000 new cases of bladder cancer would be diagnosed in 2021 and there would be approximately 17,000 deaths due to bladder cancer in the United States during 2021. 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 and 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 ten people with bladder cancer are over the age of 55 years). The median age at diagnosis is approximately 73 years of age. 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. Our initial target market includes the approximately 6,000 patients in the US diagnosed annually, including those patients with non-muscle invasive CIS of the bladder previously treated with adequate or less than adequate BCG. We would expect that, if Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG is approved by the FDA, patients would receive treatment until the earlier of 2 years and disease recurrence.

Current Approaches to Treatment

Within non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, 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 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, surgical removal of the bladder, or a 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 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 hospital readmission for surgery-related complications within 90 days following surgery. 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.

Keytruda was approved by the FDA in January 2020 for the treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy and is the only approval of Keytruda in the NMIBC space. Keytruda has been on the market for the treatment of BCG-unresponsive CIS (+/- Ta/T1) patients since January 2020. 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 directly into the bladder once a week for six weeks. Due to drug resistance and toxicities, Valstar has had limited clinical 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). Another route of administration for checkpoint inhibitor is currently being evaluated by Pfizer with the subcutaneous administration of Sasanlimab (PF-06801591) for the treatment of BCG-unresponsive NMIBC patients.

Regulatory Update

United States

In December 2020, we submitted our completed BLA for Vicineum for BCG-unresponsive NMIBC to the FDA, which was accepted for filing by the FDA in February 2021. The FDA granted Priority Review for the BLA and set a target PDUFA date for a decision on the BLA of August 18, 2021. On August 13, 2021, we received a CRL from the FDA indicating that the FDA had determined that it could not approve the BLA for Vicineum in its present form and provided recommendations specific to additional clinical/statistical data and analyses in addition to CMC issues pertaining to a recent pre-approval inspection and product quality.

On October 29, 2021, we participated in a CMC Type A Meeting with the FDA. During the CMC Type A Meeting, we and the FDA reviewed issues related to CMC to be further discussed during the review of a BLA for Vicineum upon potential resubmission. We believe we have a clear understanding of what additional information regarding CMC is required for a potential resubmission of a BLA. Additionally, although not an issue raised in the CRL, the FDA confirmed at the CMC Type A Meeting that Vicineum manufactured using the proposed commercial process is comparable to Vicineum used in prior clinical trials. The FDA also confirmed that we can utilize Vicineum manufactured during process validation for any future clinical trials needed to address issues raised in the CRL, and that any of these future trials can proceed while addressing CMC issues raised in the CRL.

On December 8, 2021, we participated in a Clinical Type A Meeting with the FDA to discuss design elements of an additional Phase 3 clinical trial for Vicineum, which the FDA confirmed will be required for a potential resubmission of a BLA. The FDA encouraged us to include the Vista Trial data in a BLA resubmission.

On January 7, 2022, the FDA granted our request for a Type C Meeting to discuss the study protocol for an additional Phase 3 clinical trial that we plan to conduct for potential resubmission of a BLA for Vicineum for the treatment of non-muscle invasive

CIS of the bladder in patients previously treated with adequate or less than adequate BCG. The Type C Meeting has been scheduled for March 28, 2022.

Although the FDA previously conditionally accepted the name Vicineum for our product candidate, oportuzumab monatox, in the United States, this approval is subject to further and final review by FDA upon potential resubmission of a BLA. If the FDA objects to our proposed proprietary product name, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable laws, not infringe the existing rights of third parties and be acceptable to the FDA.

European Union

On March 5, 2021, we submitted a MAA to the EMA for Vysyneum for the treatment of BCG-unresponsive NMIBC under the EMA's centralized procedure. On March 31, 2021, we were informed that the Committee for Medicinal Products for Human Use of the EMA had conditionally accepted the proprietary brand name Vysyneum for our product candidate, oportuzumab monatox, in the European Union.

On August 20, 2021, we withdrew our MAA to the EMA for Vysyneum for the treatment of BCG-unresponsive NMIBC in order to pause our plans to pursue regulatory approval of Vysyneum in the European Union until there is more clarity from the FDA on next steps for Vicineum in the United States.

On October 20, 2021, the EMA issued its Withdrawal Assessment Report relating to our MAA for Vysyneum, as is consistent with the EMA's standard practice when an MAA is withdrawn. The Assessment Report reflects the initial assessment and corresponding questions from the EMA and identifies major objections in the areas of quality, good clinical practice, efficacy and safety. Due to the high concordance between FDA and European Commission approvals, we believe that the probability of success of future approval in the European Union for Vysyneum increases if FDA approval for Vicineum has already been obtained.

Although the EMA previously conditionally accepted the name Vysyneum for our product candidate, oportuzumab monatox, in the European Union, this approval is subject to further and final review by the EMA upon potential resubmission of the MAA. If the EMA objects to our proposed proprietary product name, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable laws, not infringe the existing rights of third parties and be acceptable to the EMA.

China

On July 30, 2020, we and our wholly-owned subsidiary, Viventia Bio, Inc., entered into an exclusive license agreement with Qilu Pharmaceutical, Co., Ltd. ("Qilu") 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 BCG-unresponsive NMIBC and other types of cancer in Greater China. The Investigational New Drug application ("IND") 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 and approved in March 2021.

On June 1, 2021, we entered into a Global Supply Agreement with Qilu pursuant to which Qilu will be part of the manufacturing network for, if approved, global commercial supply of Vicineum drug substance and drug product.

On July 20, 2021 we and Qilu announced the enrollment of the first patient in China in a Phase 3 clinical trial to assess the efficacy and safety of Vicineum in patients with BCG-unresponsive NMIBC. The open-label, single-arm, multi-center bridging trial will evaluate the efficacy and safety of Vicineum in approximately 53 patients with carcinoma in situ (CIS) with or without papillary disease, high-grade Ta papillary disease or T1 papillary disease of any grade. Patients will be required to have failed previous treatment with BCG for inclusion in the trial. The primary endpoints are the complete response rate (for CIS patients) and the recurrence-free rate (for papillary patients) at six months, with the complete response rate and the recurrence-free rate at three months, safety and tolerability as the secondary endpoints. Based on the partnership agreement between Sesen Bio and Qilu Pharmaceutical, the trial is being run at the sole cost of Qilu Pharmaceutical.

MENA

On November 30, 2020, we and our wholly owned subsidiary, Viventia Bio, Inc., entered into an exclusive license agreement with Hikma Pharmaceuticals LLC, to develop and commercialize Vicineum for the treatment of BCG-unresponsive NMIBC in the MENA region (20 countries in the Middle East and North Africa). No submission for registration has taken place in any of the countries as approvals are contingent on FDA or EMA approval.

Turkey

On August 5, 2021, we entered into an exclusive license agreement with EİP Eczacıbaşı İlaç Pazarlama A.Ş., to develop and commercialize Vicineum for the treatment of BCG-unresponsive NMIBC in Turkey and Northern Cyprus. No submission for registration has taken place in either region as approvals are contingent on FDA or EMA approval.

Internal Review

In September 2021 we disclosed that our Board of Directors (the “Board”) initiated an independent internal review conducted by outside counsel with the assistance of subject matter experts focusing on the conduct of, and data generated from, the clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC, and the overall safety of Vicineum (the “Review”). The Review took place over the course of five months, involved full cooperation from our management team, a review of more than 600,000 documents, and 39 interviews of current and former employees and consultants. It is now complete. As a result of the Review, the Board continues to fully support our current management team and believes no changes or amendments relating to our prior disclosures to the Securities and Exchange Commission (“SEC”) or the FDA relating to Vicineum, the Phase 3 VISTA trial for Vicineum for the treatment of BCG-unresponsive NMIBC, or the BLA for Vicineum are warranted. We intend to work cooperatively with the FDA in preparing for an additional Phase 3 clinical trial for Vicineum.

New Proposed Phase 3 Clinical Trial

On January 7, 2022, the FDA granted our request for a Type C Meeting to discuss the study protocol for an additional Phase 3 clinical trial that we plan to conduct for potential resubmission of a BLA for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. The Type C Meeting has been scheduled for March 28, 2022.

Prior Phase 3 Clinical Trial – VISTA Trial

We, through our subsidiary Viventia, commenced our single-arm, multi-center, open-label Phase 3 clinical trial ("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 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 the VISTA Trial, in which the primary endpoints were complete response ("CR") and duration of response ("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.

The primary and secondary endpoints for the VISTA Trial were 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 at 3 months (post-induction).

Patients with CIS were considered to have a CR if at the time of any disease status evaluation (per protocol every 13 weeks or any unscheduled evaluation) there was 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 was not considered a treatment failure in these patients, and they could 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 one of the following (i) at least five of six doses of an initial induction course plus at least two of three doses of maintenance therapy or (ii) at least five of six doses of an initial induction course plus at least two of six doses of a second induction course):

- 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 DoR for BCG-unresponsive CIS patients who experience a 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 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	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. These additional 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.

Data is as of the May 29, 2019 data cut from the Phase III VISTA trial. The clinical data shown are based on the data submitted in the BLA on December 18, 2020. Final numbers are pending. On August 13, 2021, the FDA issued a CRL for the BLA that included requests for additional clinical and statistical data.

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 or death). There were no age-related increases in adverse events observed in the VISTA Trial.

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 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.

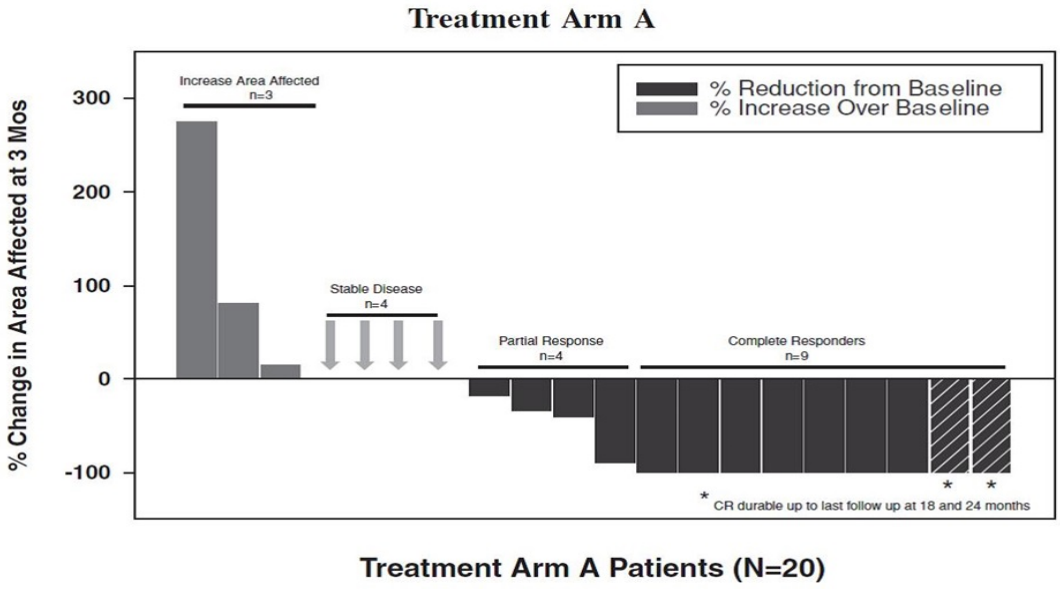
A CR was defined in this Phase 1 clinical trial as non-positive urine cytology and either normal cystoscopy or abnormal cystoscopy with negative biopsy. Of the 64 patients enrolled, only 61 were considered to be evaluable for efficacy as two patients were excluded from the analysis due to an absence 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.

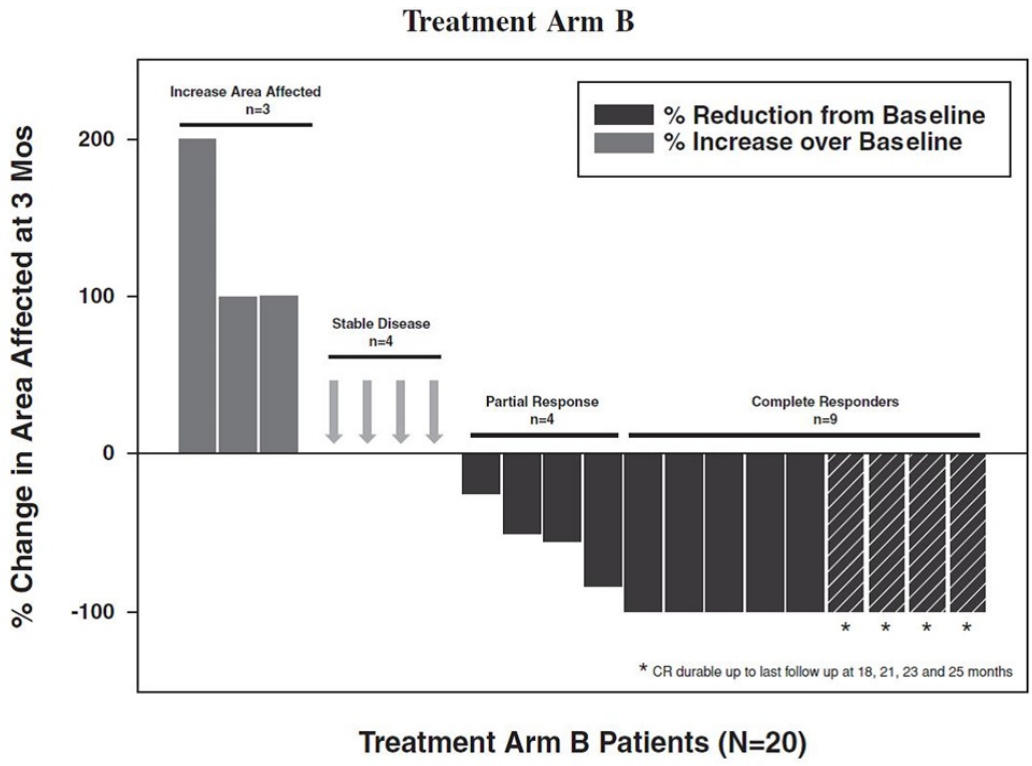
Phase 2 Clinical Trial. Based on our Phase 1 clinical trial conducted in Canada, we submitted the IND for Vicineum for the treatment of BCG-unresponsive NMIBC to the FDA in August 2005, and we initiated an open-label Phase 2 clinical trial of Vicineum in March 2007 at 20 sites in Canada and the United 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:





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, which ended up being our Phase 3 VISTA Trial.

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.

Outside of United States ("OUS") Business Development Partnering

Greater China

On July 30, 2020, we and our wholly-owned subsidiary, Viventia Bio, Inc., entered into an exclusive license agreement with Qilu Pharmaceutical, Co., Ltd. ("Qilu") 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 BCG-unresponsive NMIBC and other types of cancer in China, Hong Kong, Macau and Taiwan. 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, the Middle East and North Africa region ("MENA") and Turkey and (ii) manufacturing rights with respect to Vicineum in the rest of the world excluding Greater China.

During 2020, we received a total of $10 million in net proceeds associated with 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 Vicineum in such region, and (iii) the expiration of regulatory or data exclusivity for 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.

Qilu is responsible for all costs related to developing, obtaining regulatory approval of and commercializing Vicineum for the prevention and treatment of cancers including, but not limited to, NMIBC and various sub-types of NMIBC (the "Field") in Greater China. Qilu is required to use commercially reasonable efforts to develop, seek regulatory approval for, and commercialize Vicineum in the Field in Greater China. A joint development committee was established between us and Qilu to coordinate and review the development, manufacturing and commercialization plans with respect to Vicineum in Greater China. We and Qilu also executed the terms and conditions of a supply agreement and related quality agreement pursuant to which we will manufacture or have manufactured and supply Qilu with all quantities of Vicineum necessary for Qilu to develop and commercialize Vicineum in the Field in Greater China until we have completed manufacturing technology transfer to Qilu and approval of a Qilu manufactured product by the National Medical Products Administration in China ("NMPA") for Vicineum 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 us 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 Investigational New Drug application ("IND") 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 and approved in March 2021, resulting in a $3 million milestone payment from Qilu, the first milestone payment out of the $23 million in potential milestone payments. We recorded $2.8 million (net of VAT) as license revenue during the three-month period ended March 31, 2021.

In June 2021, the Qilu License Agreement was recognized by Shandong Province, Bureau of Science and Technology as "Technology Transfer". An agreement that is designated as a Technology Transfer shall be entitled to a tax incentive of value-added tax ("VAT") recovery. As such, we recorded $0.9 million of revenue during the three months ended June 30, 2021 for additional purchase price resulting from Qilu's obligation to pay Sesen an amount equal to its recovery of VAT. We will not be subject to VAT on future potential milestone payments.

On July 20, 2021 we and Qilu announced the enrollment of the first patient in China in a Phase 3 clinical trial to assess the efficacy and safety of Vicineum in patients with BCG-unresponsive NMIBC. The open-label, single-arm, multi-center bridging trial will evaluate the efficacy and safety of Vicineum in approximately 53 patients with carcinoma in situ (CIS) with or without papillary disease, high-grade Ta papillary disease or T1 papillary disease of any grade. Patients will be required to have failed previous treatment with BCG for inclusion in the trial. The primary endpoints are the complete response rate (for CIS patients) and the recurrence-free rate (for papillary patients) at six months, with the complete response rate and the recurrence-free rate at three months, safety and tolerability as the secondary endpoints. Based on the Qilu License Agreement, the trial is being run at the sole cost of Qilu.

MENA

On November 30, 2020, we and our wholly owned subsidiary, Viventia Bio, Inc., entered into an exclusive license agreement with Hikma Pharmaceuticals LLC, to develop and commercialize Vicineum for the treatment of BCG-unresponsive NMIBC in the MENA region (20 countries in the Middle East and North Africa). 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.

Turkey

On August 5, 2021, we entered into an exclusive license agreement with EIP pursuant to which we granted EIP an exclusive license to register and commercialize Vicineum for the treatment of BCG-unresponsive NMIBC in Turkey and Northern Cyprus. Under the terms of the license agreement, we are entitled to receive an upfront payment of $1.5 million. We are in the process of amending the license agreement to defer payment of the upfront payment to coincide with the potential FDA approval of Vicineum. We are also eligible to receive additional regulatory and commercial milestone payments of $2.0 million and are entitled to receive a 30% royalty on net sales in Turkey and Northern Cyprus.

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. 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.

In our clinical trials involving Vicineum for the treatment of SCCHN, there were no Grade 5 serious adverse events that were considered by the clinical investigator to be related to Vicineum. The serious adverse events (Grade 3 and Grade 4) that were reported in the clinical trials of Vicineum for the treatment of SCCHN and were considered to be possibly, probably or definitely related to treatment consisted of abnormal tumor growth, anorexia, cancer pain, decrease in red blood cells, difficulty swallowing, elevated calcium levels, facial pain, fatigue, high blood sugar, influenza like illness, injection site pain, liver function abnormalities, low albumin level, low sodium concentration, nausea, rash, swelling, tumor hemorrhage and tumor necrosis.

For the combined Phase 1 (VB4-101 and VB4-101A) and Phase 2 (VB4-845-01-IIA) studies, seven subjects died during the clinical trials of Vicineum for the treatment of SCCHN, but none of the deaths were deemed to be Vicineum-related. Out of the four patients who discontinued treatment due to liver function test abnormalities, 2 subjects were in study VB4-101 and 2 were subjects were in VB4-101A). Four subjects withdrew from the clinical trials. Three of the four subjects withdrew at their request and one of the four subjects withdrew at the request of the investigator.

Phase 3 (VB4-845-01-lllA) VB4-845-01-lllA was a randomized, multicentre therapeutic confirmatory study evaluating the safety and efficacy of Vicineum plus BSC versus BSC alone in the treatment of patients with advanced SCCHN who had received at least 1 anti-cancer treatment regimen for advanced disease. One hundred and sixty-six of the approximately 292 patients were enrolled at 75 sites. The primary endpoint for the study was overall survival. A total of 166 patients had been randomized into the study. Of the 166 patients, 82 were randomized to the Vicineum treatment plus BSC arm and 84 patients were randomized to the BSC arm.

VB4-845-01-IIIA was terminated early due to a corporate decision unrelated to safety or efficacy. At the time of study termination, survival data was available for 133 of 142 patients that had been randomized. A total of 66 were enrolled on the BSC arm and 67 enrolled in the Vicineum plus BSC treatment arm. Of the 66 BSC patients enrolled in the BSC arm, there were 43 documented deaths in this treatment arm; the date of death was known for 36 patients and unknown for 7. Of the patients treated with Vicineum, 41 deaths were documented with the date of death known for 37 patients and unknown for 4.

Interim safety data was available for 132 of 139 patients that had been randomized. One hundred and eleven patients reported at least 1 AE. Thirty-six patients reported 205 adverse events (AEs) that were treatment related. Most of the treatment-related AEs were mild to moderate in severity. Of the 205 treatment-related AEs reported, there were 23 Grade 3 events and 2 Grade 4 events. There were no Grade 5 related AEs reported. The 2 related Grade 4 events were 2 occurrences of tumour necrosis in 1 patient; both were considered probably related to the treatment. Most related AEs resolved on their own and did not require additional treatment. Others were treated with concomitant medications.

Four patients in the Vicineum plus BSC group reported Grade 3 increases in both ALT and AST. One patient reported a Grade 3 increase in ALT and another patient reported a Grade 3 increase in AST. All of the Grade 3 increases in ALT/AST occurred in the Vicineum plus BSC group. No Grade 4 increases in ALT/AST were reported. In 1 patient, Vicineum was discontinued due to liver function test abnormalities, in 1 patient Vicineum was interrupted due to liver function test abnormalities and in the last patient Vicineum was discontinued due to disease progression.

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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. 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 provides for 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. DeBouganin acts by inhibiting protein synthesis and helps circumvent multi-drug resistance mechanisms. 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 antibody responses directed against the Fab 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. 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 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. 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, we 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.

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 our patent rights and know-how related to our monoclonal antibody EBI-031 and all other IL-6 anti-IL antagonist monoclonal antibody technology owned by us (collectively, the "Licensed Intellectual Property"). Under the 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 an IL-6 antagonist anti-IL monoclonal antibody (the "Roche 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 next of which is $30.0 million for initiation of the first Phase III 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.

In December 2021, a $20 million milestone was achieved due to Roche initiating a Phase II clinical trial. We invoiced Roche $20 million with payment terms of 30 days following the achievement of the corresponding milestone event, pursuant to the Roche License Agreement. In January 2022 the payment of $20 million was received.

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 Roche Licensed Product until the day before Initiation of the first Phase 3 study for a Roche 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 Roche 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 Roche Licensed Product in either the United States or in the EU, 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 Roche Licensed Product has issued in the EU.

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 Roche 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.

In December 2021, Roche reported that it started enrollment of two Phase 2 clinical trials in patients with diabetic macular edema (“DME”). The first clinical trial, BP43445 (NCT05151731), is a multicenter, randomized, double-masked, active comparator-controlled trial to investigate the efficacy, safety, tolerability, pharmacokinetics, and pharmacodynamics of EBI-031 administered intravitreally in patients with DME. The second clinical trial, BP43464 (NCT05151744), is a combination trial to assess the efficacy, safety, tolerability, pharmacokinetics, and pharmacodynamics of EBI-031 with ranibizumab (an anti-vascular endothelial growth factor inhibitor) compared with ranibizumab alone in DME patients. For both trials, only one eye will be chosen as the trial eye and the duration of the trial will be 52 weeks.

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 pending applications in the United States. The expiry dates of the patents in this family are April 2024 and June 2025, subject to any applicable patent term adjustment or extension that may be available on a jurisdictional basis. See "Our Vicineum License Agreements" below for additional information.

In addition to the Zurich portfolio, we own two issued US patents related to Vicineum. The expiry date of these patents is 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, Australia and Japan and patent applications in Canada, Europe and Hong Kong. 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 February 28, 2022, 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 February 25, 2022, 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, New Zealand, Russia and South Africa, that expire in November 2033;
- patent applications covering the IL-6 antagonistic anti-IL6 monoclonal antibodies and active fragments thereof, including IL-6 antibody EBI-029, filed in Brazil, Canada, Europe, India, Mexico, United States 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 Australia, Austria, Belgium, Bulgaria, Chile, China, Columbia, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hong Kong, Hungary, Indonesia, Ireland, Italy, Japan, Lithuania, Macau, Malaysia, Mexico, Morocco, Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovenia, Slovakia, South Africa, Spain, Sweden, Switzerland, Turkey, Ukraine, United States 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, Bahrain, Brazil, Canada, Costa Rica, Europe, Egypt, India, Israel, Korea, New Zealand, Oman, Peru, Philippines, Qatar, Saudi Arabia, Singapore, Thailand, United Arab Emirates, United States and Vietnam, and, if granted, are expected to expire in 2035; and
- patent applications in China, Europe, Japan and the United States, each corresponding to a United States provisional application covering the IL-6 antibody EBI-031 formulation, which, if granted, are expected to expire in 2037.

Our Vicineum License Agreements

In-License Agreement with Zurich

Overview and Exclusivity

We have a License Agreement with the University of Zurich ("Zurich") which grants us exclusive license rights, with the right to sublicense, to make, have made, use and sell under certain patents primarily directed to our targeting agent, including an EpCAM chimera and related immunoconjugates and methods of use and manufacture of the same. These patents cover some key aspects of Vicineum. Upon receipt of the CRL regarding our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC, we became obligated to pay $0.5 million in a milestone payment to Zurich. We are 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 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. For the year ended December 31, 2020, we recorded an expense of $0.3 million for the achievement of the development milestone related to the submission of our BLA for Vicineum with the FDA. For the year ended December 31, 2021, we recorded an expense of $0.5 million for the regulatory milestone related to receipt of the CRL from the FDA in August 2021.

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

We have a License Agreement with Micromet AG ("Micromet"), now part of Amgen, Inc., which grants us nonexclusive rights, with certain sublicense rights, for know-how and patents allowing exploitation of certain single chain antibody products. These patents cover some key aspects of Vicineum. Under the terms of the License Agreement with Micromet, as of December 31, 2021, we may be obligated to pay up to €2.4 million in milestone payments for the first product candidate that achieves applicable regulatory and sales-based development milestones (approximately $2.7 million at exchange rates in effect on December 31, 2021). 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 (approximately $56,625 at exchange rates in effect as of December 31, 2021), which can be credited towards any royalty payment we owe to Micromet. We recorded an expense of €0.7 million ($0.9 million) related to achievement of a development milestone in the three months ended December 31, 2020, due to the submission of our BLA for Vicineum with the FDA in December 2020. We recorded an expense of €0.5 million ($0.6 million) related to the submission of the MAA to the EMA for Vysyneum™ in the first quarter of 2021.

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

We have a License Agreement with XOMA Ireland Limited ("XOMA") which grants us non-exclusive rights to certain XOMA patent rights and know-how related to certain expression technology, including plasmids, expression strains, plasmid maps and production systems. These patents and related know-how cover some key aspects of Vicineum. Under the terms of the License Agreement with XOMA, 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 Vicineum's clinical development pathway. We are also required to pay a 2.5% royalty on the net sales for products incorporating XOMA's technology, which includes 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.

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 XOMA 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.

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 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 completed the technology transfer process to outsource future Vicineum clinical and commercial to third-party manufacturers.

Fujifilm and Baxter

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 August 2020, we completed manufacturing of the drug substance process performance qualification (“PPQ”) batches at Fujifilm and in September 2020, we successfully completed the 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 Vicineum produced by Fujifilm and Baxter were found to be highly comparable to our supply of Vicineum produced at our Winnipeg facility.

On October 29, 2021, at the CMC Type A Meeting, the FDA confirmed that Vicineum manufactured using the proposed commercial process is comparable to Vicineum used in prior clinical trials and confirmed that we can utilize Vicineum manufactured during process validation for any future clinical trials needed to address issues raised in the CRL regarding the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC, and that any of these future trials can proceed while addressing CMC issues raised in the CRL.

In January 2022, we signed a Scope of Work ("SOW #11") with Fujifilm under the Fujifilm MSA for the manufacturing of commercial batches of Vicineum in 2022 and 2023.

We intend to use Vicineum produced by Fujifilm and Baxter for any future clinical trials of Vicineum, including the additional Phase 3 clinical trial, and, if approved, for commercial supply.

Qilu

In June 2021, we entered into a Global Supply Agreement with Qilu pursuant to which Qilu will be part of the manufacturing network for, if approved, global commercial supply of Vicineum drug substance and drug product.

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); Pfizer, Inc. (Sasanlimab);
- 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 EU 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 ("EU 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 non-US statutes and regulations require the expenditure of substantial time and financial resources, and we may not be successful in any given jurisdiction.

US 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 a 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. Non-US 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.

Under the 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.

The FDA may not complete its review or approve a BLA within these established goal review times. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure, and potent for its intended use, and whether the product is being manufactured in compliance with cGMP. The FDA may also refer applications for novel product candidates which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will inspect the facilities at which the product candidate is manufactured or the facilities that are significantly involved in the product development and distribution process and will not approve the product candidate unless cGMP compliance is satisfactory. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with 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 CRL. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. On August 13, 2021, we received a CRL from the FDA indicating that the FDA had determined that it could not approve the BLA for Vicineum in its present form and provided recommendations specific to additional clinical/statistical data and analyses in addition to CMC issues pertaining to a recent pre-approval inspection and product quality. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of a 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 deemed ‘‘interchangeable’’ by the FDA, in fact, will be readily substituted by pharmacies, which are governed by state pharmacy law.

After an innovator has marketed its product for four years, a manufacturer may file an application for approval of a ‘‘biosimilar’’ version of the innovator product. However, although an application for approval of a biosimilar may be filed four years after approval of the innovator product, qualified innovative biological products receive 12 years of regulatory exclusivity, meaning that the FDA may not approve a biosimilar version until 12 years after the innovative biological product was first approved by the FDA under the PHSA. The BPCIA also provides a mechanism for innovators to enforce the patents that protect innovative biological products and for biosimilar applicants to challenge the patents. Such patent litigation may begin as early as four years after the innovative biological product is first approved by the FDA. Although the patents for the reference biologic may be challenged by the biosimilar applicant during that time period pursuant to the BPCIA statutory patent challenge framework, no biosimilar or interchangeable product will be licensed by the FDA until the end of the exclusivity period. The first biologic product candidate submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against any other determinations of interchangeability to the reference product for the lesser of (i) one year after first commercial marketing of the interchangeable biosimilar product, (ii) 18 months after approval of the interchangeable biosimilar product if there is no legal challenge, (iii) 18 months after the resolution in the interchangeable biosimilar product applicant’s favor of a lawsuit challenging the reference product’s patents, and (iv) 42 months after approval of the interchangeable biosimilar product if a lawsuit is ongoing within the 42-month period.

The objectives of the BPCIA are conceptually similar to those of the Hatch-Waxman Act, which established abbreviated pathways for the approval of generic drugs. The FDA has published several guidance documents providing direction on developing and obtaining approval of biosimilar product candidates. The guidance documents to date explain, among other things, that the FDA will approve a biosimilar product if there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency. A determination of biosimilarity may be based upon: (1) analytical studies showing that the biological product is highly similar to, with no clinically meaningful differences from, the reference product, (2) animal studies, including toxicity assessments, and/or (3) a clinical trial or trials (including assessment of immunogenicity and PKs) that are sufficient to demonstrate safety, purity and potency 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. 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 US 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 non-US official, political party or candidate

for the purpose of influencing any act or decision of the non-US 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 countries outside of the United States 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 EU, for example, a CTA must be submitted to the competent authorities of the EU 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 product under EU regulatory systems, we must submit a marketing authorization application.

In the EU, 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 EU Member States and three of the four European Free Trade Association States - Iceland, Liechtenstein and Norway. Under the centralized procedure in the EU, 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 EU, 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 non-US 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 EU, the advertising and promotion of our products will also be subject to EU laws and EU Member States' national laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. Other EU 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 EU. The applicable laws at the EU level and in the individual EU 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 EU 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 EU, 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 EU; 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 EU. 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 EU 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, nor 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.

Under the Centralized Procedure in the EU, 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 NMIBC and Fast Track designation from the FDA for the treatment of SCCHN.

Healthcare Reform

In the United States and some non-US 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.

The Centers for Medicare & Medicaid Services ("CMS"), the agency that administers the Medicare and Medicaid programs, 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, 2022). On December 10, 2021, President Biden signed a law that provides for 1% Medicare sequestration in the second quarter of 2022 and allows the full 2% sequestration thereafter until 2030. To offset the temporary suspension during the COVID-19 pandemic, in 2030, the sequestration will be 2.25% for the first half of the year, and 3% in the second half of the year.

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, Congress is currently considering changes that could affect our overall rebate liability. Changes under consideration include a drug price negotiation program, Medicare Part B and Part D inflation rebates, under which manufacturers would owe rebates if the average sales price or average manufacturer price of a drug were to increase faster than the pace of inflation, and Part D benefit redesign, including a proposed new manufacturer discount program.

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 non-US 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 non-US 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 non-US 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 creating 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 or modify manufacturer discounts. For example, Congress is currently considering legislation that would sunset the current Part D discount program and replace it with a new manufacturer discount program, effective 2024. Congress further could enact a Medicare Part D inflation rebate, under which manufacturers would owe rebates if the average manufacturer price of a drug were to increase faster than the pace of inflation.

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 EU, 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 EU Member States. The EU 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 EU Member States may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other EU 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 EU Member States and other non-US 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 EU 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 non-US 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 EU Member States. These EU 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 EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product vary between EU 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG 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 non-US jurisdictions in which we conduct our business. We have described below some of the key federal, state and non-US healthcare laws and regulations that may affect our ability to operate.

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

The federal civil False Claims Act prohibits, among other things, any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds; knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government; or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. The False

Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the statute and to share in any monetary recovery. Pharmaceutical and other healthcare companies have faced enforcement actions under the federal civil False Claims Act for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product and for allegedly causing false claims to be submitted because of the companies’ marketing of the product for unapproved, and thus non-reimbursable, uses. In addition, a claim can be deemed to be false due to failure to comply with legal or regulatory requirements material to the government’s payment decision. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and significant mandatory penalties per false claim or statement. Pharmaceutical and other healthcare companies also are subject to other federal false claims laws, including, among others, federal criminal healthcare fraud and false statement statutes.

The fraud provisions of the federal Health Insurance Portability and Accountability Act of 1996 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 our 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, including with respect to the potential 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. CMS uses these submissions to determine payment rates for drugs under Medicare Part B. For calendar quarters beginning January 1, 2022, manufacturers will be required to report the average sales price for certain drugs under the Medicare program regardless of whether they participate in the Medicaid Drug Rebate Program. In addition, starting in 2023, manufacturers must pay refunds to Medicare for single source drugs or biologicals, or biosimilar biological products, reimbursed under Medicare Part B and packaged in single-dose containers or single-use packages for units of discarded drug reimbursed by Medicare Part B in excess of 10 percent of total allowed charges under Medicare Part B for that drug. Manufacturers that fail to pay refunds could be subject to civil monetary penalties of 125 percent of the refund amount.

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. HRSA further could terminate a manufacturer’s agreement to participate in the 340B program for a failure to comply with 340B program requirements. In the event that HRSA were to terminate such an 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.

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. We also expect to participate in the Tricare Retail Pharmacy Program, under which we would pay quarterly rebates to DoD for prescriptions of innovator drugs dispensed to Tricare beneficiaries through Tricare Retail network pharmacies. 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 non-US country, we may be subject to similar non-US 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 EU, 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 EU 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 EU Member States and by the United Kingdom's Bribery Act 2010.

The national laws of certain EU 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 EU Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the individual EU Member States.

If we fail to comply with applicable non-US 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 Bio, Inc., a corporation incorporated under the laws of the Province of Ontario, Canada, the shareholders of Viventia named therein (collectively, 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"), 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. Clairmark is an affiliate of Leslie L. Dan, who served on our board of directors until his retirement in July 2019.

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 (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

Our 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 our corporate 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 our 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, 2021, we had thirty-five full-time employees and no part-time employees, nine hold Ph.D. degrees and one is a veterinary doctor. This number consists of fifteen employees engaged in administration and twenty employees engaged in research and development (eight in clinical and regulatory, three in supply chain, five in manufacturing/engineering, and four in quality and support). Two of our employees are located in our corporate headquarters in Cambridge, fifteen of our employees are located in our Winnipeg facility, and five 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 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. 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 clinical development of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG and seek marketing approval from the FDA. We had net losses of $0.3 million, $22.4 million and $107.5 million for the years ended December 31, 2021, 2020 and 2019, respectively. We incurred negative cash flows from operating activities of $68.9 million, $30.8 million and $37.5 million for the years ended December 31, 2021, 2020 and 2019, respectively. As of December 31, 2021, we had cash and cash equivalents of $162.6 million, net working capital (current assets less current liabilities) of $194.0 million and an accumulated deficit of $316.3 million. We have financed our operations to date primarily through private placements of our common stock, preferred stock, common stock warrants and convertible bridge notes, venture debt borrowings, our initial public offering ("IPO"), our follow-on public offerings, sales effected in at-the-market ("ATM") offerings and, our out-licensing and OUS business development partnership agreements. The majority of our revenue to date has been from milestone payments received under our out-licensing and OUS business development 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:

- continue our clinical development of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG;
- seek marketing approval for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG in the United States and the European Union;
- establish a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, if approved;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed drugs;
- seek and conduct combination trials of one or more of our product candidates;
- seek to develop additional product candidates;
- in-license or acquire the rights to other products, product candidates or technologies; and
- maintain, expand and protect our intellectual property portfolio;

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 trials 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 OUS business development partnership agreements, we currently have no source of 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 OUS business development partnership agreements, neither we nor any of our business development 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 business development partners obtain marketing approval for, and commercialize, Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. Our ability to generate revenue from Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG will depend on a number of factors, including:

- our ability to obtain regulatory approval for, and successfully commercialize, Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG;
- our ability to complete and submit applications to, and obtaining regulatory approval from, non-US regulatory authorities;
- the size of the markets in the territories for which we or our business development 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 business development partners' ability to successfully complete development activities, including necessary clinical trials, for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG.

Even if Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG 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 a new Phase 3 clinical trial for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, and functions associated with operating as a public company. We expect to continue to spend substantial amounts to continue the clinical development of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, and, if approved, commercialize Vicineum. 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 costs and timing of continuing the clinical development of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG;
- the success of our commercialization of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, if approved;
- the outcome, timing and cost of the regulatory approval process for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG by the FDA and comparable non-US regulatory authorities, 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG;

- 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 clinical development or commercialization of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG in the United States and other markets;
- delay, limit, reduce or terminate the clinical development of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG; or
- significantly curtail our operations.

Based on our current operating plan, we believe that our cash and cash equivalents of $162.6 million as of December 31, 2021, will be sufficient to fund our operations into 2024; 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.

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 OUS business development 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 OUS business development 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.

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, 2021, we had an aggregate of 15.8 million stock options and RSUs outstanding under the 2014 Plan, our prior equity plan and inducement awards granted outside of our equity plans. In addition, as of December 31, 2021, we had 8.9 million 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 OUS business development 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. If we are unable to obtain marketing approval for or successfully commercialize our lead product candidate, either alone or through an out-license or OUS business development 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. On August 13, 2021, we received a CRL from the FDA indicating that the FDA had determined that it could not approve the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC in its present form. On August 20, 2021, we withdrew our MAA to the EMA for Vysyneum for the treatment of BCG-unresponsive NMIBC in order to pause

our plans to pursue regulatory approval of Vysyneum in the European Union until there is more clarity from the FDA on next steps for Vicineum in the United States. In October and December 2021, we participated in a CMC Type A Meeting and a Clinical Type A Meeting, respectively, with the FDA to discuss issues raised in the CRL and to discuss design elements of an additional Phase 3 clinical trial for Vicineum, which the FDA confirmed will be required for a potential resubmission of a BLA. Following these Type A Meetings, we believe we have greater clarity of the requirements for potential resubmission of a BLA. We have a Type C Meeting scheduled with the FDA for March 28, 2022, in which we expect to discuss the study protocol for the additional Phase 3 clinical trial that we plan to conduct for potential resubmission of a BLA for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG.

We may be unable to address the issues identified in the CRL from the FDA or resubmit a BLA for Vicineum, or address the concerns identified in the EMA Withdrawal Assessment Report or resubmit our MAA for Vysyneum, including because of a lack of capital or otherwise.

Even if the issues identified in the CRL or the concerns identified in the EMA Withdrawal Assessment Report are resolved to the satisfaction of the FDA or the EMA, respectively, the FDA and the European Commission retain the right not to approve a BLA or MAA, respectively, or to require additional information, or to raise additional issues with regard to regulatory approval, which could further delay or prevent its approval or limit product labelling claims.

Our prospects are substantially dependent on our ability and the ability of our out-licensing and OUS business development partners to obtain marketing approval for and commercialize Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. In addition, either the substance of the issues identified by the FDA in the CRL, or the CRL itself, or the concerns identified in the EMA Withdrawal Assessment Report could have an adverse impact on future efforts to obtain marketing authorization for Vicineum from other non-US regulatory authorities, or on our future efforts to commercialize Vicineum and gain acceptance of Vicineum from third party payors. The success of Vicineum will depend on several factors, including the following:

- successfully completing the clinical development of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG;
- addressing the issues identified in the CRL we received from the FDA and the concerns identified in the EMA Withdrawal Assessment Report;
- receiving marketing approvals from the FDA, the European Commission or comparable non-US regulatory authorities, including our ability to address the issues identified by the FDA in the CRL or the EMA Withdrawal Assessment Report;
- developing and maintaining the commercial manufacturing supply and distribution chain for Vicineum;
- performance of our current and future out-licensing or OUS business development partners;
- the 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;
- protecting our rights in our intellectual property portfolio;
- launching commercial sales, if and when marketing approval is received;
- demonstrating an acceptable safety profile prior to and following any marketing approval;
- obtaining marketplace acceptance, if 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 OUS business development partners are unable to develop, receive marketing approval for, or successfully commercialize Vicineum or experience delays as a result of any of these factors or otherwise, our business could be materially harmed.

If additional clinical trials of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG fail to demonstrate safety and efficacy to the satisfaction of the FDA, the EMA or other non-US regulatory authorities or do not otherwise produce favorable results, we will be unable to complete the development and potential commercialization of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG.

Before obtaining marketing approval from regulatory authorities for the sale of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, we must complete pre-clinical development and conduct extensive clinical trials to demonstrate the safety and efficacy of Vicineum in humans. In order to address the issues identified in the CRL we received from the FDA for the BLA for Vicineum and the concerns

identified in the EMA Withdrawal Assessment Report, we will need to complete one or more additional clinical trials. Such trials will require us to incur substantial additional costs and will delay the potential commercialization of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. 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. Further, 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.

Even if such clinical trials are successfully completed as planned, the results may not support approval of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG under the laws and regulations of the FDA, the European Commission or comparable non-US regulatory authorities. We cannot be certain that additional clinical data will demonstrate Vicineum is both safe and effective for its intended uses to the satisfaction of the FDA, the EMA or comparable non-US regulatory authorities. Pre-clinical and clinical data and analyses are often able to be interpreted in different ways. Even if we view our results favorably, we may be unable to demonstrate safety and efficacy of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG to the satisfaction of the FDA, the EMA or other non-US regulatory authorities. If a regulatory authority has a different view, we may still fail to obtain regulatory approval of Vicineum. This, in turn, would prevent us from commercializing Vicineum and our ability to generate revenues in the future would be materially impaired.

We may not be able to develop a more sensitive bioanalytical assay which is needed for the additional Phase 3 clinical trial for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG.

We will need to develop a more sensitive bioanalytical assay for the additional Phase 3 clinical trial for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG than was used in our prior VISTA Trial for Vicineum. This bioanalytical assay will be used to measure levels of Vicineum in the blood. The development of a new bioanalytical assay for a novel biologic like Vicineum can be complex. There is risk that an adequately sensitive bioanalytical assay may not be scientifically or economically feasible or that any new bioanalytical assay developed by us or a third party will not be accepted by the FDA or other comparable regulatory bodies. As a result, further development of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG may be negatively impacted or delayed, which would have an adverse impact on our business.

If we experience any of a number of possible unforeseen events in connection with our clinical trials, potential marketing approval or commercialization of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG could be delayed or prevented.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG that we may develop, including:

- clinical trials of Vicineum may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon the development of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG;
- enrollment in these clinical trials may be slower or more challenging than we anticipate, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements, including GCP or meet their contractual obligations to us in a timely manner, or at all;
- inspection of the clinical trial operations, trial sites or manufacturing facilities by the FDA or other comparable non-US regulatory authorities could result in findings of non-compliance and the imposition of a clinical suspension or termination;
- regulators or IRBs/Ethics Committees may delay or not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays or fail to reach agreement with the FDA or a comparable non-US regulatory authority on a trial design that we are able to execute;
- we may be unable to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including for the same indications as our clinical trials;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;

- trial sites and investigators may deviate from clinical trial protocols or otherwise fail to conduct the trial in accordance with regulatory requirements, and investigators may drop out of the clinical trial;
- trial sites may withdraw from our clinical trials, including as a result of changing standards of care or ineligibility of a site to participate in our clinical trials;
- we may decide, or regulators or IRBs/Ethics Committees or other reviewing entities, including comparable non-US regulatory authorities, may require us to suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements including GCP or a finding that the patients are being exposed to unacceptable health risks;
- the cost of clinical trials of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG may be greater than we anticipate;
- we may receive feedback from DSMBs or the FDA, or a comparable non-US regulatory authority, that might require modification to the protocol for the clinical trial or performance of additional studies before clinical trials may continue;
- as a clinical trial proceeds, or as the results of earlier stage studies or concurrent studies become available, we may determine that we need to modify the protocol and/or other aspects of the clinical trial before it may continue;
- the FDA, a comparable non-US regulatory authority, or we may decide to, or a DSMB may recommend to, suspend or terminate clinical trials at any time for safety issues or for any other reason;
- the supply or quality of Vicineum or other materials necessary to conduct clinical trials of Vicineum may be insufficient or inadequate;
- Vicineum may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs/Ethics Committees to suspend or terminate the trials;
- lack of adequate funding to continue a clinical trial, including the occurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical trials or increased expenses associated with the services of our CROs and other third parties; and
- changes in applicable laws, governmental regulations or administrative actions.

We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their activities, we have limited control over their actual performance. Any delays in completing our clinical trials will increase our costs, slow down our development and regulatory submission process for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG and jeopardize our ability to obtain regulatory approval, commence commercial sales and generate revenues, if Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG is ultimately approved.

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

If we are required to conduct additional clinical trials or other testing of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of Vicineum or other testing, if the results of these trials or tests are not favorable or are only modestly favorable or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, or is subject to a REMS;
- be subject to additional post-marketing testing requirements; or
- have Vicineum removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our pre-clinical studies or clinical trials will begin as planned, will need to be restructured or will be completed

on schedule, or at all. Significant pre-clinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG.

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

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

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

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

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

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

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

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

Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG 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 non-US 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. 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 or death). 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, if approved, could lead to the FDA's or other comparable non-US 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 non-US regulatory authorities could order us to cease further development or deny approval of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG;
- 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG;
- 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG;
- 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, if approved.

We will need to obtain regulatory authority approval of any proposed names for oportuzumab monatox for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, and any failure or delay associated with such naming approval may adversely impact our business.

Although the FDA previously conditionally accepted the name Vicineum, and EMA previously conditionally accepted the name Vysyneum, for our product candidate, oportuzumab monatox, these approvals are subject to further and final review by FDA and EMA upon potential resubmission of our respective applications and at the time of regulatory authority review of such applications. If the FDA or EMA object to any proposed proprietary product name, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable laws, not infringe the existing rights of third parties and be acceptable to the FDA and EMA, as applicable.

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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG or any other product candidate.

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. 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. In October and December 2021, we participated in a CMC Type A Meeting and Clinical Type A Meeting, respectively, with the FDA to discuss issues raised in the CRL and design elements of an additional Phase 3 clinical trial for Vicineum, which the FDA confirmed will be required for a potential resubmission of a BLA. We have a Type C Meeting scheduled with the FDA for March 28, 2022, in which we expect to discuss the study protocol for the additional Phase 3 clinical trial that we plan to conduct for potential resubmission of a BLA for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG.

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 comparable non-US 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 non-US 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 non-US 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 non-US 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. For example, on March 5, 2021, we submitted our MAA to the EMA for Vicineum for the treatment of BCG-unresponsive NMIBC under the EMA's centralized procedure. On August 20, 2021, we withdrew our MAA to the EMA for Vysyneum for the treatment of BCG-unresponsive NMIBC. We have decided to pause our plans to pursue regulatory approval of Vysyneum in the European Union until there is more clarity from the FDA on the next steps for Vicineum in the United States. Additionally, on October 20, 2021, the EMA issued its Withdrawal Assessment Report relating to our MAA for Vysyneum, as is consistent with the EMA's standard practice when an MAA is withdrawn. The Assessment Report reflects the initial assessment and corresponding questions from the EMA and identifies major objections in the areas of quality, good clinical practice, efficacy and safety. 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.

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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG 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 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. On May 17, 2020, the FDA issued a CRL that indicated outstanding questions regarding CMC = issues of Adstiladrin. 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 first quarter of 2022. 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. Finally, another route of administration for checkpoint inhibitors is currently being evaluated by Pfizer with the subcutaneous administration of Sasanlimab (PF-06801591) for the treatment of BCG-unresponsive NMIBC patients. 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 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, 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.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, if approved.

We face an inherent risk of product liability exposure related to the use of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. If we cannot successfully defend ourselves against claims that Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG;
- 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG.

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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG 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 Greater China.

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

We have sought and may seek additional third-party partners or licensees for development and commercialization of our product candidates, including Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. Our current and likely commercialization partners or licensees include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. Our ability to generate revenues from these arrangements depend and will depend on our partners' or licensees' abilities and efforts to successfully perform the functions assigned to them in these arrangements.

OUS business development partnerships and licenses involving our product candidates pose a number of risks, including the following:

- 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;
- partners or licensees may not perform their obligations as expected;
- 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;
- 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 any such partner’s or licensee’s strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- 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 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;
- partners or licensees 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;
- partners or licensees could become involved in a business combination, which might deemphasize or terminate the commercialization or development of any product candidate licensed to it by us;
- disagreements with 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;
- 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;
- 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.

OUS business development 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 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 OUS business development partners and licensees.

Additionally, 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 unable to reach agreements with suitable new partners or licensees 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 US 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 non-US 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 non-US regulatory authorities may require us to perform additional clinical trials before approving our marketing applications.

On October 27, 2021, the FDA published a Warning Letter (the “FDA Warning Letter”) issued to a former clinical investigator in our VISTA trial for Vicineum arising from a 2021 FDA inspection related to the review of our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. We discontinued use of the clinical site and the clinical investigator over four years ago when we learned of professional misconduct by the clinical investigator that was unrelated to the VISTA trial. The FDA Warning Letter indicated that the clinical investigator did not comply with applicable statutory requirements and applicable regulations regarding conduct of clinical investigations. The clinical investigator's medical license was temporarily suspended on May 29, 2017, due to inaccurate recordkeeping, which was unassociated with Sesen Bio and the patients in the VISTA trial. We notified the FDA of the misconduct at that time. There was no evidence found that patients were harmed by the clinical investigator’s actions. We included the corresponding patient data from the clinical site in the BLA submission to the FDA, which were thoroughly analyzed and discussed during the BLA review.

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 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.

We are dependent on third parties to formulate and manufacture Vicineum, which exposes us to a number of risks that may delay development, regulatory approval and commercialization of our products or result in higher product costs.

In September 2017, we completed the manufacturing of all Vicineum necessary for our 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 completed the technology transfer process to outsource future Vicineum clinical and commercial to third-party manufacturers.

On August 13, 2021, we received a CRL from the FDA indicating that the FDA had determined that it could not approve the BLA for Vicineum in its present form and, among other things, raised CMC issues pertaining to a recent pre-approval inspection and product quality. At the CMC Type A Meeting held in October 2021, the FDA confirmed that Vicineum manufactured using the proposed commercial process is comparable to Vicineum used in prior clinical trials and that we can utilize Vicineum manufactured during process validation for any future clinical trials needed to address issues raised in the CRL, and that such trials can proceed while addressing CMC issues. Therefore, we have no current plans to re-build internal manufacturing capacity for Vicineum and we expect to continue to rely on third-party expertise in this area.

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 manufacturing capabilities to produce clinical supply of Vicineum 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 our clinical supply demands, 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 supply of Vicineum, or they 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 manufacturing demands, we may be delayed in our ability to obtain and maintain regulatory approval of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG.
- 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 clinical supply of Vicineum.
- If any third-party manufacturer makes improvements in the manufacturing process for Vicineum, we may not own, or may have to share, the intellectual property rights to such improvements.
- A third-party manufacturer may gain knowledge from working with us that could be used to supply one of our competitors with a product that competes with ours.

Our reliance on third-party manufacturers reduces our control over production and supply of Vicineum but does not relieve us of our responsibility to ensure compliance with applicable legal and regulatory standards. The FDA and other non-US

regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP and similar non-US 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 non-US 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 non-US standards, 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. For example, we may be unable to resolve the issues raised in the CRL pertaining to a recent pre-approval inspection and product quality.

In addition, a failure by our third-party manufactures to comply with cGMP or similar non-US standards could be the basis for the FDA or any other non-US 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.

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.

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 non-US 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 countries outside the United States 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 non-US 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 non-US 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 countries outside of the US may not protect our rights to the same extent as the laws of the United States, and such 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 EU 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 non-US 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 non-US 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 Zurich License 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG 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 Zurich 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 Zurich License Agreement could result in our loss of rights to practice the patent rights licensed to us under the Zurich 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG 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 Micromet 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 Micromet License Agreement could result in our loss of rights to practice the patent rights licensed to us under the Micromet 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG 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 XOMA 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 XOMA License Agreement could result in our loss of rights to practice the patent rights licensed to us under the XOMA 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG 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

If and when we commercialize, 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 non-US jurisdictions in which we conduct our business.

For a full discussion of these laws, see the subsection titled “Other Healthcare Laws and Compliance Requirements” in Item 1.

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

Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of our product candidates, including Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, and affect the prices we may obtain.

In the United States and some non-US 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.

CMS, the agency that administers the Medicare and Medicaid programs, 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, 2022). On December 10, 2021, President Biden signed a law that provides for 1% Medicare sequestration in the second quarter of 2022 and allows the full 2% sequestration thereafter until 2030. To offset the temporary suspension during the COVID-19 pandemic, in 2030, the sequestration will be 2.25% for the first half of the year, and 3% in the second half of the year.

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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, 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, Congress is currently considering changes that could affect our overall rebate liability. Changes under consideration include a drug price negotiation program, Medicare Part B and Part D inflation rebates, under which manufacturers would owe rebates if the average sales price

or average manufacturer price of a drug were to increase faster than the pace of inflation, and Part D benefit redesign, including a proposed new manufacturer discount program. 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.

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, 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 US data protection laws and regulations, we also may be subject to European and other international data protection requirements, such as the EU General Data Protection Regulation. Our failure to comply with data privacy and security laws and regulations, 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.

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.

For our current and future operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we 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 non-US official, political party or candidate for the purpose of influencing any act or decision of the non-US 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 us 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 non-US 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.

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 EU 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 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:

- delays or difficulties related to the continued clinical development of Vicineum for non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, 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;
- difficulties in raising additional capital needed for the continued development of Vicineum for non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG and if approved, commercialization for Vicineum due to the 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; and
- 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.

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 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 and those of third parties with which we contract. 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 on our business or operations. 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, if approved, commercialization of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG 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, our reputation, 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.

Our restructuring plan and the associated headcount reduction may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

On August 30, 2021, we approved a restructuring plan to reduce operating expenses and better align our workforce with the needs of our business following receipt of the CRL from the FDA regarding our BLA for Vicineum for the treatment of BCG-

unresponsive NMIBC. The restructuring plan included a reduction in our workforce by 18 positions (approximately 35%) as well as additional cost-saving initiatives intended to preserve capital while we continue development of Vicineum. Restructuring expenses for the year ended December 31, 2021 were approximately $5.5 million, consisting primarily of severance and other employee-related costs of $2.8 million and contract termination costs of $2.7 million.

We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. Furthermore, our restructuring plan may be disruptive to our operations. For example, our headcount reductions could yield unanticipated consequences, such as increased difficulties in implementing our business strategy, including retention of our remaining employees.

We and certain of our officers have been named as defendants in three pending securities class action lawsuits and three related shareholder derivative lawsuits have been filed. These lawsuits, and potential similar or related lawsuits, could result in substantial damages, divert management's time and attention from our business, and have a material adverse effect on our results of operations. These lawsuits, and any other lawsuits to which we are subject, will be costly to defend and are uncertain in their outcome.

On August 19, 2021, August 31, 2021 and October 7,2021, three substantially identical securities class action lawsuits captioned Bibb v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-07025, Cizek v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-07309 and Markman v. Sesen Bio, Inc. et al., Case No. 1:21-cv-08308 were filed against us and certain of our officers in the US District Court for the Southern District of New York. The three complaints allege violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder based on statements made by us concerning our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. The three complaints seek compensatory damages and costs and expenses, including attorneys' fees. On October 29, 2021, the court consolidated the three cases under the caption In re Sesen Bio, Inc. Securities Litigation, Master File No. 1:21-cv-07025-AKH (the "Securities Litigation"), and appointed Ryan Bibb, Rodney Samaan, Lionel Dreshaj and Benjamin Dreshaj ("Lead Plaintiffs") collectively as the lead plaintiffs under the Private Securities Litigation Reform Act. On November 1, 2021, two stockholders filed motions to reconsider asking the court to appoint a different lead plaintiff. The court has not ruled on those motions at this time. On November 24, 2021, defendants filed a motion to transfer venue to the US District Court for the District of Massachusetts. That motion was fully briefed as of December 13, 2021, but the court has not yet ruled on that motion. On December 6, 2021, the Lead Plaintiffs filed an amended class action complaint (the "Amended Complaint"). The Amended Complaint alleges the same violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder on the same theory as the prior complaints. Defendants' response to the Amended Complaint is due to be filed on March 7, 2022.

On September 20, 2021 and September 24, 2021, two substantially similar derivative lawsuits captioned Myers v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-11538 and D'Arcy v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-11577 were filed against our board of directors and certain of our officers in the US District Court for the District of Massachusetts, with Sesen Bio, Inc. named as a nominal defendant. On January 12, 2022, a third derivative complaint captioned Tang v. Sesen Bio, Inc., et al., was filed in Superior Court in Massachusetts against our board of directors and certain of our officers in the US District Court for the District of Massachusetts, with us named as nominal defendant, but no defendant has yet been served. The three derivative complaints allege breach of fiduciary duties, waste of corporate assets, and violations of federal securities laws based on statements made by us concerning our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. The D'Arcy complaint further alleges unjust enrichment, abuse of control, gross mismanagement and aiding and abetting thereof. The three derivative complaints seek unspecified damages, restitution and disgorgement of profits, benefits and compensation obtained by the defendants and costs and expenses, including attorneys' fees. On October 18, 2021, the court consolidated the two federal court cases under the caption In re Sesen Bio, Inc. Derivative Litigation, Lead Case No. 1:21-cv-11538 (the "Federal Derivative Litigation"). On December 22, 2021, the court entered a joint stipulation among the parties to stay the Federal Derivative Litigation until after a ruling on any motion to dismiss filed by defendants in the Securities Litigation. Defendants intend to seek a similar stay of the state court derivative litigation in the event any defendant is served.

We believe that these lawsuits are without merit and intend to vigorously defend against these actions. However, whether or not the claims are successful, litigation is often expensive and can divert management's attention and resources from other business concerns, which could adversely affect our business.

We currently are not able to estimate the possible cost to us from these actions, as the pending lawsuits are currently at an early stage, and we cannot be certain how long it may take to resolve the pending lawsuits or the possible amount of any damages that we may be required to pay. If we are ultimately required to pay significant defense costs, damages or settlement amounts, such payments could adversely affect our operations.

We may be the target of similar litigation in the future. The market price of our common stock has experienced and may continue to experience volatility, and in the past, companies that have experienced volatility in the market price of their stock

have been subject to securities litigation. Any future litigation could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business. We maintain liability insurance; however, if any costs or expenses associated with the pending lawsuits or any other litigation exceed our insurance coverage, we may be forced to bear some or all costs and expenses directly, which could adversely affect our business, financial condition, results of operations or stock price.

Risks Related to Ownership of Our Common Stock

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

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

On January 24, 2022, we received notice (the "Notice") from the Nasdaq Stock Market LLC ("Nasdaq") that we are not currently in compliance with the $1.00 minimum bid price requirement for continued listing on the Nasdaq Global Market, as set forth in Nasdaq Listing Rule 5450(a)(1). The Notice indicated that, consistent with Nasdaq Listing Rule 5810(c)(3)(A), we have 180 calendar days, or until July 25, 2022, to regain compliance with the minimum bid price requirement by having the closing bid price of our common stock meet or exceed $1.00 per share for at least ten consecutive business days. The notification had no immediate effect on the listing of our common stock, and our common stock will continue to trade on the Nasdaq Global Market under the symbol "SESN" at this time.

If we do not regain compliance by July 25, 2022, we may be eligible for an additional 180 calendar day grace period. If we fail to regain compliance during the applicable period, we will receive notification from Nasdaq that our common stock is subject to delisting. At that time, we may then appeal the delisting determination to a Nasdaq hearings panel. Such notification will have no immediate effect on our listing on the Nasdaq Global Market, nor will it have an immediate effect on the trading of our common stock pending such hearing. There can be no assurance, however, that we will be able to regain compliance with Nasdaq's minimum bid price requirement. If we regain compliance with the Nasdaq's minimum bid price requirement, there can be no assurance that we will be able to maintain compliance with the continued listing requirements for the Nasdaq Global Market or that our common stock will not be delisted from the Nasdaq Global Market in the future. In addition, we may be unable to meet other applicable listing requirements of the Nasdaq Global Market, including maintaining minimum levels of stockholders' equity or market values of our common stock in which case, our common stock could be delisted notwithstanding our ability to demonstrate compliance with the minimum bid price requirement.

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

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

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

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

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not retain our listing on Nasdaq and if the price of our common stock is less than $5.00, our common stock may be deemed a penny stock. The

penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stockholders may have difficulty selling their shares.

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 affected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our Certificate of Incorporation or bylaws.

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

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 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 completed the technology transfer process to outsource future Vicineum clinical and commercial to third-party manufacturers. 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 June 2022.

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 May 2022.

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.

On August 19, 2021, August 31, 2021, and October 7, 2021, three substantially identical securities class action lawsuits captioned Bibb v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-07025, Cizek v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-07309 and Markman v. Sesen Bio, Inc. et al., Case No. 1:21-cv-08308 were filed against us and certain of our officers in the US District Court for the Southern District of New York. The three complaints allege violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder, based on statements made by us concerning the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. The three complaints seek compensatory damages and costs and expenses, including attorneys' fees. On October 29, 2021, the court consolidated the three cases under the caption In re Sesen Bio, Inc. Securities Litigation, Master File No. 1:21-cv-07025-AKH (the "Securities Litigation"), and appointed Ryan Bibb, Rodney Samaan, Lionel Dreshaj and Benjamin Dreshaj ("Lead Plaintiffs") collectively as the lead plaintiffs under the Private Securities Litigation Reform Act. On November 1, 2021, two stockholders filed motions to reconsider asking the court to appoint a different lead plaintiff. The court has not ruled on those motions at this time. On November 24, 2021, defendants filed a motion to transfer venue to the US District Court for the District of Massachusetts. That motion was fully briefed as of December 13, 2021, but the court has not yet ruled on that motion. On December 6, 2021, the Lead Plaintiffs filed an amended class action complaint (the "Amended Complaint"). The Amended Complaint alleges the same violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder on the same theory as the prior complaints. Defendants' response to the Amended Complaint is due to be filed on March 7, 2022.

On September 20, 2021 and September 24, 2021, two substantially similar derivative lawsuits captioned Myers v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-11538 and D'Arcy v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-11577 were filed against our board of directors and certain of our officers in the US District Court for the District of Massachusetts, with us named as nominal defendant. On January 12, 2022, a third derivative complaint captioned Tang v. Sesen Bio, Inc., et al., was filed in Superior Court in Massachusetts against our board of directors and certain of our officers in the US District Court for the District of Massachusetts, with us named as nominal defendant, but no defendant has yet been served. The three derivative complaints allege breach of fiduciary duties, waste of corporate assets and violations of federal securities laws, based on statements made by us concerning the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. The D'Arcy complaint further alleges unjust enrichment, abuse of control, gross mismanagement and aiding and abetting thereof. The three derivative complaints seek unspecified damages, restitution and disgorgement of profits, benefits and compensation obtained by the defendants and costs and expenses, including attorneys' fees. On October 18, 2021, the court consolidated the two federal court cases under the caption In re Sesen Bio, Inc. Derivative Litigation, Lead Case No. 1:21-cv-11538 (the "Federal Derivative Litigation"). On December 22, 2021, the court entered a joint stipulation among the parties to stay the Federal Derivative Litigation until after a ruling on any motion to dismiss filed by defendants in the Securities Litigation. Defendants intend to seek a similar stay of the state court derivative litigation in the event any defendant is served.

We believe that these lawsuits are without merit and intends to vigorously defend against them. The lawsuits are in the early stages, and, at this time, no assessment can be made as to the likely outcome or whether the outcome will be material to us.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Stock Price

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

Holders

As of February 21, 2022, there were 17 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. [Reserved.]

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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG.

In December 2020, we submitted our completed BLA for Vicineum for the treatment of BCG-unresponsive NMIBC to the FDA, which was accepted for filing by the FDA in February 2021. The FDA granted Priority Review for the BLA and set a target PDUFA date for a decision on the BLA of August 18, 2021. On August 13, 2021, we received a CRL from the FDA indicating that the FDA had determined that it could not approve the BLA for Vicineum in its present form and provided recommendations specific to additional clinical/statistical data and analyses in addition to CMC issues pertaining to a recent pre-approval inspection and product quality. On August 20, 2021, we withdrew our MAA to the EMA for Vysyneum for the treatment of BCG-unresponsive NMIBC in order to pause our plans to pursue regulatory approval of Vysyneum in the European Union until there is more clarity from the FDA on next steps for Vicineum in the United States. Vysyneum is the proprietary brand name that was conditionally approved by the EMA for oportuzumab monatox in the European Union. In

October 2021, the EMA issued its Withdrawal Assessment Report relating to our MAA for Vysyneum, as is consistent with the EMA's standard practice when an MAA is withdrawn. The EMA Withdrawal Assessment Report reflects the initial assessment and corresponding questions from the EMA and identifies major objections in the areas of quality, good clinical practice, efficacy and safety. Due to the high concordance between FDA and European Commission approvals, we believe that the probability of success of future approval in the European Union for Vysyneum increases if FDA approval for Vicineum has already been obtained.

On October 29, 2021, we participated in a Type A Meeting with the FDA to discuss questions related to CMC raised in the CRL (the "CMC Type A Meeting"). During the CMC Type A Meeting, we and the FDA reviewed issues related to CMC to be further discussed during the review of a BLA for Vicineum upon potential resubmission. We believe we have a clear understanding of what additional information regarding CMC is required for a potential resubmission of a BLA. Additionally, although not an issue raised in the CRL, the FDA confirmed at the CMC Type A Meeting that Vicineum manufactured using the proposed commercial process is comparable to Vicineum used in prior clinical trials. The FDA also confirmed that we can utilize Vicineum manufactured during process validation for any future clinical trials needed to address issues raised in the CRL, and that these potential trials can proceed while addressing CMC issues.

On December 8, 2021, we participated in a Type A Meeting with the FDA to discuss design elements of an additional Phase 3 clinical trial for Vicineum (the "Clinical Type A Meeting"), which the FDA confirmed will be required for a potential resubmission of a BLA. The trial design may include these elements:

- A randomized clinical trial assessing the safety and efficacy of Vicineum compared to investigators' choice of intravesical chemotherapy;
- Trial may include both patients who have received adequate BCG[1] and patients who have received less than adequate BCG;
- The FDA encouraged us to submit the final results from the Phase 3 Vista Trial for Vicineum with a BLA resubmission.

[1]As per the 2018 FDA guidance on NMIBC, adequate BCG is defined as at least one of the following: (i) at least five of six doses of an initial induction course plus at least two of three doses of maintenance therapy or (ii) at least five of six doses of an initial induction course plus at least two of six doses of a second induction course.

On January 7, 2022, the FDA granted our request for a Type C Meeting to discuss the study protocol for an additional Phase 3 clinical trial that we plan to conduct for potential resubmission of a BLA for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. The Type C Meeting has been scheduled for March 28, 2022.

One of the items we expect to be discussed in the Type C Meeting is the patient population for the additional Phase 3 clinical trial, which may be different than the patient population studied in previous clinical trials for Vicineum for the treatment of NMIBC in two primary ways.

First, the additional Phase 3 clinical trial may include patients with only non-muscle invasive carcinoma in situ (CIS) of the bladder, and may not include patients with only papillary disease of the bladder. This change would lead to a smaller overall patient population than previously studied, as some of our past clinical trials of Vicineum in NMIBC have included patients with CIS or high-grade papillary disease of the bladder.

Second, the additional Phase 3 clinical trial may include patients who have received less than adequate BCG in addition to those who have received adequate BCG, per the FDA's guidance. Receipt of less than adequate BCG could be due to (i) failure of, or intolerance to, a BCG therapy prior to reaching the FDA's definition of adequate BCG or (ii) supply shortages of BCG, among other reasons. This change would lead to a larger patient population than previously studied, as past clinical trials of Vicineum in NMIBC only included patients who had previously been treated with adequate BCG.

Potential changes related to the additional Phase 3 clinical trial for Vicineum will be discussed at the upcoming Type C Meeting with the FDA scheduled for March 28, 2022.

The single-arm, multi-center, open-label Phase 3 clinical trial ("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:

- 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 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	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. These additional 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.

Data is as of the May 29, 2019 data cut from the Phase III VISTA trial. The clinical data shown are based on the data submitted in the BLA on December 18, 2020. Final numbers are pending. On August 13, 2021, the FDA issued a CRL for the BLA that included requests for additional clinical and statistical data.

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 or death). There were no age-related increases in adverse events observed in the VISTA Trial.

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 for the manufacturing process and technology transfer of Vicineum drug product production.

In August 2020, we completed manufacturing of the drug substance process performance qualification (“PPQ”) batches at Fujifilm and in September 2020, we successfully completed the 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 Vicineum produced by Fujifilm and Baxter were found to be highly comparable to supply of Vicineum at our Winnipeg facility.

In June 2021, we entered into a Global Supply Agreement with Qilu pursuant to which Qilu will be part of the manufacturing network for, if approved, global commercial supply of Vicineum drug substance and drug product.

On October 29, 2021, at the CMC Type A Meeting, the FDA confirmed that Vicineum manufactured using the proposed commercial process is comparable to Vicineum used in prior clinical trials and confirmed that we can utilize Vicineum manufactured during process validation for any future clinical trials needed to address issues raised in the CRL regarding the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC, and that any of these future trials can proceed while addressing CMC issues raised in the CRL.

In January 2022, we signed a Scope of Work ("SOW #11") with Fujifilm under the Fujifilm MSA for the manufacturing of commercial batches of Vicineum in 2022 and 2023.

We intend to use Vicineum produced by Fujifilm and Baxter for any future clinical trials of Vicineum and, if approved, for commercial supply.

Outside of United States ("OUS") Business Development Partnering

Greater China

On July 30, 2020, we and our wholly-owned subsidiary, Viventia Bio, Inc., entered into an exclusive license agreement with Qilu Pharmaceutical, Co., Ltd. ("Qilu") 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 BCG-unresponsive 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, the Middle East and North Africa region (“MENA”) and Turkey and (ii) manufacturing rights with respect to Vicineum in the rest of the world excluding Greater China.

During 2020, we received a total of $10 million in net proceeds associated with 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 Vicineum in such region, and (iii) the expiration of regulatory or data exclusivity for 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 ("IND") 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 and approved in March 2021, resulting in a $3 million milestone payment from Qilu, the first milestone payment out of the $23 million in potential milestone payments. We recorded $2.8 million (net of VAT) as license revenue during the three-month period ended March 31, 2021.

In June 2021, the Qilu License Agreement was recognized by Shandong Province, Bureau of Science and Technology as "Technology Transfer". An agreement that is designated as a Technology Transfer shall be entitled to a tax incentive of value-added tax ("VAT") recovery. As such, we recorded $0.9 million of revenue during the three months ended June 30, 2021, for additional purchase price resulting from Qilu's obligation to pay Sesen an amount equal to its recovery of VAT. We will not be subject to VAT on future potential milestone payments to Qilu.

On July 20, 2021 we and Qilu announced the enrollment of the first patient in China in a Phase 3 clinical trial to assess the efficacy and safety of Vicineum in patients with BCG-unresponsive NMIBC. The open-label, single-arm, multi-center bridging trial will evaluate the efficacy and safety of Vicineum in approximately 53 patients with carcinoma in situ (CIS) with or without papillary disease, high-grade Ta papillary disease or T1 papillary disease of any grade. Patients will be required to have failed previous treatment with BCG for inclusion in the trial. The primary endpoints are the complete response rate (for CIS patients)

and the recurrence-free rate (for papillary patients) at six months, with the complete response rate and the recurrence-free rate at three months, safety and tolerability as the secondary endpoints. Based on the Qilu License Agreement, the trial is being run at the sole cost of Qilu.

MENA

On November 30, 2020, we and our wholly owned subsidiary, Viventia Bio, Inc., entered into an exclusive license agreement with Hikma Pharmaceuticals LLC, to develop and commercialize Vicineum for the treatment of BCG-unresponsive NMIBC in MENA region (20 countries in Middle East and North Africa) (the "MENA License Agreement"). 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.

Turkey

On August 5, 2021, we entered into an exclusive license agreement with EİP Eczacıbaşı İlaç Pazarlama A.Ş., ("EIP") pursuant to which we granted EIP an exclusive license to register and commercialize Vicineum for the treatment of BCG-unresponsive NMIBC in Turkey and Northern Cyprus. Under the terms of the licensing agreement, we are entitled to receive an upfront payment of $1.5 million. We are in the process of amending the license agreement to defer payment of the upfront payment to coincide with the potential FDA approval of Vicineum. We are also eligible to receive additional regulatory and commercial milestone payments of $2.0 million and are entitled to receive a 30% royalty on net sales in Turkey and Northern Cyprus.

Internal Review

In September 2021 we disclosed that our Board of Directors (the "Board") initiated an independent internal review conducted by outside counsel with the assistance of subject matter experts focusing on the conduct of, and data generated from, the clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC, and the overall safety of Vicineum (the "Review"). The Review took place over the course of five months, involved full cooperation from our management team, a review of more than 600,000 documents, and 39 interviews of current and former employees and consultants. It is now complete. As a result of the Review, the Board continues to fully support our current management team and believes no changes or amendments relating to our prior disclosures to the Securities and Exchange Commission ("SEC") or the FDA relating to Vicineum, the Phase 3 VISTA trial for Vicineum for the treatment of BCG-unresponsive NMIBC, or the BLA for Vicineum are warranted. We intend to work cooperatively with the FDA in preparing for an additional Phase 3 clinical trial for Vicineum.

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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, 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, including the additional Phase 3 clinical trial for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG;
- 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG 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, including the additional Phase 3 clinical trial, and other research and development activities;
- the efficacy and potential advantages of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG compared to alternative treatments, including any standard of care;
- the market acceptance of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG;
- 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG could mean a significant change in the costs and timing associated with the development of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, we could be required to expend significant additional financial resources and time on the completion of clinical development of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG.

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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG.

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

	Year ended December 31,		
	2021	**2020**	**2019**
Programs:			
Vicineum for the treatment of BCG-unresponsive NMIBC	$ 15,110	$ 22,234	$ 16,023
Total direct program expenses	15,110	22,234	16,023
Personnel and other expenses:			
Employee and contractor-related expenses	8,977	5,775	6,513
Platform-related lab expenses	172	303	513
Facility expenses	524	442	442
Other expenses	529	437	1,172
Total personnel and other expenses	10,202	6,957	8,640
Total Research and Development	**$ 25,312**	**$ 29,191**	**$ 24,663**

General and Administrative

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

Restructuring Charge

On August 30, 2021, we approved a restructuring plan to reduce operating expenses and better align our workforce with the needs of our business following receipt of the CRL from the FDA regarding the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC (the “Restructuring Plan”). The Restructuring Plan included a reduction in our workforce by 18 positions (or approximately 35% of our workforce) as well as additional cost-saving initiatives intended to preserve capital while we continue development of Vicineum. Restructuring costs related to the Restructuring Plan were recorded in operating expenses in our Consolidated Statements of Operations and Comprehensive Loss.

Intangibles Impairment Charge

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 acquisition of Viventia 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. 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. If an impairment indicator is identified, an interim impairment assessment is performed. The fair value of the acquired intangible assets for the US and EU rights of Vicineum is determined using a risk-adjusted discounted cash flow approach, which includes probability adjustments for projected revenues and operating expenses based on the success rates assigned to each stage of development for each geographical region as well as discount rates applied to the projected cash flows.

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

Benefit for income taxes is driven by the intangible impairment charge, changing the value of deferred tax liabilities. Provision for income taxes consists of income taxes incurred to non-US jurisdictions pursuant to our OUS business development partnership agreements, including the Qilu License Agreement.

Our Results of Operations

Comparison of the Years ended December 31, 2021 and 2020

	Year ended December 31,		Increase/(Decrease)	
	2021	2020	Dollars	Percentage
	(in thousands, except percentages)			
Revenue:				
License and related revenue	$ 26,544	$ 11,236	$ 15,308	136 %
Total revenue	26,544	11,236	15,308	136 %
Operating expenses:				
Research and development	$ 25,312	$ 29,191	$ (3,879)	(13) %
General and administrative	29,393	14,302	15,091	106 %
Restructuring charge	5,528	—	5,528	— %
Intangibles impairment charge	31,700	—	31,700	— %
Change in fair value of contingent consideration	(56,840)	(11,180)	(45,660)	408 %
Total operating expenses	35,093	32,313	2,780	9 %
Loss from Operations	(8,549)	(21,077)	12,528	(59) %
Other (expense) income:				
Other (expense) income, net	(60)	125	(185)	(148) %
Net Loss and Comprehensive Loss Before Taxes	**(8,609)**	**(20,952)**	**12,343**	**(59)%**
Benefit (provision) for income taxes	8,273	(1,445)	9,718	(673) %
Net Loss and Comprehensive Loss After Taxes	**$ (336)**	**$ (22,397)**	**$ 22,061**	**(98)%**

License Revenue

Revenue for the year ended December 31, 2021 was $26.5 million, primarily due to the $20 million milestone achieved pursuant to the Roche License Agreement upon initiating a Phase II clinical trial, $5.0 million related to the Qilu License Agreement (achievement of the IND milestone, clinical supply revenue, and license revenue for additional purchase price due to the recovery of VAT), and $1.5 million upfront milestone revenue achieved pursuant to the MENA License Agreement. Revenue for the year ended December 31, 2020 was $11.2 million, which was due to the recognition of revenue pursuant to the Qilu License Agreement.

Research and Development

Research and development expenses were $25.3 million for the year ended December 31, 2021, compared to $29.2 million for the year ended December 31, 2020. The decrease of $3.9 million was primarily due to lower costs associated with technology transfer and manufacturing ($7.4 million). This was partially offset by increases in employee-related compensation driven by increased headcount as part of the commercial build and the retention program implemented after receipt of the CRL in August 2021 ($2.1 million), regulatory and clinical consulting fees ($1.0 million) and certain other R&D expense, none of which were individually material ($0.5 million). We anticipate that R&D expenses will increase beginning in 2022 due to additional clinical trial activity costs related to our plans to conduct an additional Phase 3 clinical trial for Vicineum.

General and Administrative

General and administrative expenses were $29.4 million for the year ended December 31, 2021, compared to $14.3 million for the year ended December 31, 2020. The increase of $15.1 million was primarily due to increases in employee-related compensation ($5.0 million), legal costs ($4.8 million), and marketing and commercial expenses ($4.1 million) driven by preparation for the commercial launch of Vicineum prior to the issuance of the CRL in August 2021. Additionally, increases in accounting services ($0.4 million), insurance expenses ($0.4 million), IT expenses ($0.3 million) and others ($0.1 million) contributed to the increase.

Restructuring Charge

On August 30, 2021, we approved a restructuring plan to reduce operating expenses and better align our workforce with the needs of our business following receipt of the CRL from the FDA regarding the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC (the “Restructuring Plan”). The Restructuring Plan included a reduction in our workforce by 18 positions

(or approximately 35% of our workforce) as well as additional cost-saving initiatives intended to preserve capital while we continue development of Vicineum.

Restructuring expenses were $5.5 million for the year ended December 31, 2021, compared to no restructuring expenses for the year ended December 31, 2020. The increase was due to one-time costs associated with the Restructuring Plan implemented in response to the CRL for severance and other employee-related costs ($2.8 million) and termination of certain contracts ($2.7 million).

Intangibles Impairment Charge

We recorded an intangibles impairment charge of $31.7 million during the year ended December 31, 2021. We did not record any impairment charges during the year ended December 31, 2020. In August 2021, we received a CRL from the FDA regarding our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. The impairment charge of $31.7 million for the year ended December 31, 2021 relates to the full impairment of our US in-process research and development asset due to expected delays in the start of commercialization and lower probabilities of success, combined with higher operating expenses expected to be incurred prior to commercialization, resulting in lower expected future cash flows estimated in the US market at this time.

Change in Fair Value of Contingent Consideration

The non-cash change in fair value of contingent consideration was income of $56.8 million for the year ended December 31, 2021, compared to income of $11.2 million for the year ended December 31, 2020. The decrease in the fair value of contingent consideration of $45.7 million from the year ended December 31, 2020 to the year ended December 31, 2021, was driven by the receipt of a CRL from the FDA, regarding our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. Due to the inherent uncertainty in the path forward for Vicineum at this time, we reassessed the underlying assumptions used to develop the revenue projections upon which the fair value of the contingent consideration is based. The most significant and impactful assumptions in our revenue projection models are timing of product launch and probabilities of clinical and regulatory success POS; we expect delays in the start of commercialization and estimate lower POS as a direct result of the CRL and our withdrawal of the MAA. We will need to conduct an additional clinical trial, which will lead to delays in the start of commercialization globally. We have assessed a range of commercialization timeline assumptions and applied a probability to each outcome based on management’s best estimate. In addition, we now assume a lower POS in achieving certain clinical and regulatory milestones in the range of approximately 45% to 55% globally. We participated in Type A Meetings with the FDA on October 29, 2021 and December 8, 2021 to discuss questions related to CMC and clinical issues raised in the CRL. Both meetings helped us determine the appropriate path forward for Vicineum. Any changes in these assumptions and estimates or other information obtained, may have a significant impact on the remeasurement of the contingent consideration liability in the future

The change in fair value of contingent consideration was income of $11.2 million for the year ended December 31, 2020. This was primarily attributable to significantly higher discount rates as a result of financial market conditions as of the year ended December 31, 2020, offset by changes to the competitive landscape.

Other (expense) income, net

Other expense, net was $0.1 million for the year ended December 31, 2021, compared to other income of $0.1 million for the year ended December 31, 2020. The change of $0.2 million was due primarily to lower interest income.

Provision for Income Taxes

For the twelve months ended December 31, 2021, we recorded a benefit from income taxes of $8.3 million. In the third quarter of 2021, we determined that the fair value of the Vicineum United States in-process research and development asset was zero, which resulted in an impairment charge of $31.7 million. In connection with this impairment charge, in the third quarter of 2021, we wrote-down the associated deferred tax liability by $8.6 million as a benefit. Please refer to Note 8, "Intangible Assets and Goodwill," for further information regarding the impairment charge. For the twelve months ended December 31, 2020, we recorded a provision for income taxes of $1.4 million. This provision consisted of income taxes paid to non-US jurisdictions pursuant to our commercialization partnership agreements.

Comparison of the Years ended December 31, 2020 and 2019

For a comparison of our results of operations for the years ended December 31, 2020 and 2019, 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, 2020, filed with the United States Securities and Exchange Commission ("SEC") on March 15, 2021.

Liquidity and Capital Resources

Overview

As of December 31, 2021, we had cash and cash equivalents of $162.6 million, net working capital of $194.0 million and an accumulated deficit of $316.3 million. We incurred negative cash flows from operating activities of $68.9 million, $30.8 million and $37.5 million for the years ended December 31, 2021, 2020 and 2019, respectively. We believe that our cash and cash equivalents of $162.6 million as of December 31, 2021, are sufficient to fund our operating plan into 2024.

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 seek to address the issues raised in the CRL we received for our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC and the concerns identified in the EMA Withdrawal Assessment Report, complete an additional Phase 3 clinical trial for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, and seek marketing approval from the FDA and the European Commission and, if approved, commercialize Vicineum. We have financed our operations to date primarily through private placements of our common stock, preferred stock, common stock warrants and convertible bridge notes, venture debt borrowings, our IPO, follow-on public offerings, sales effected in ATM offerings, our OUS business development partnerships and license agreements and, to a lesser extent, from a collaboration.

In November 2019, we entered into an Open Market Sale Agreement (the "Sale Agreement") with Jefferies LLC ("Jefferies"), under which we may issue and sell shares of our common stock, par value $0.001 per share from time to time for an aggregate sales price of up to $35 million through Jefferies (the "ATM Offering"). In October 2020 and February 2021, we entered into Amendments No. 1 and No. 2 to the Sale Agreement, respectively. Amendments No. 1 and No.2 modified the Sale Agreement to reflect that we may issue and sell shares of our common stock from time to time for an aggregate sales price of up to an additional $50.0 million and $34.5 million, respectively. In June 2021, we entered into Amendment No. 3 to the Sale Agreement, which modified the Sale Agreement to remove the maximum dollar amount of shares of common stock that may be sold pursuant to the Sale Agreement. In June and July 2021, we filed prospectus supplements with the SEC in connection with the offer and sale of up to an aggregate of $200 million of our common stock pursuant to the Sale Agreement. Sale of common stock under the Sale 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, 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. As of December 31, 2021, we have $97.8 million in available ATM capacity. We may sell shares of our common stock efficiently from time to time but have no obligation to sell any of our common stock and may at any time suspend offers under the Sale Agreement or terminate the Sale Agreement. Subject to the terms and conditions of the Sale 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 minimum price set by us from time to time. 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 under the Sale Agreement. We raised $175.0 million of net proceeds from the sale of 56.9 million shares of common stock at a weighted-average price of $3.17 per share during the year ended December 31, 2021. We 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 during the year ended December 31, 2020. Share issue costs, including sales agent commissions, related to the ATM Offering totaled $5.4 million and $1.2 million for the year ended December 31, 2021 and December 31, 2020, respectively.

We continue to monitor the effect of the outbreak of COVID-19. 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, and ultimately upon our ability to attain profitable operations. In order to commercialize our product candidates, including Vicineum, 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, requires substantial working capital, and we expect to seek additional funds through equity or debt financings or through additional OUS business development partnerships, collaborations, licensing transactions or other sources. We may be unable to obtain equity or debt financings or enter into additional OUS business development partnerships, collaborations, 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:

- address the issues identified in the CRL we received from the FDA for our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC and the concerns identified in the EMA Withdrawal Assessment Report, including the completion of an additional Phase 3 clinical trial;
- seek marketing approvals for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG;
- 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG and our other product candidates, including an additional Phase 3 clinical trial for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG;
- the ongoing COVID-19 pandemic and its impact on our business
- our ability to establish additional OUS business development partnerships, collaborations, or licensing arrangements on favorable terms, if at all, particularly manufacturing, marketing and distribution arrangements for our product candidates;
- the costs and timing of the implementation of commercial-scale manufacturing activities;
- the costs and timing of establishing and implementing sales, marketing and distribution capabilities for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, 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, EMA, and comparable non-US regulatory authorities for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, including the potential for the FDA or comparable non-US 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 OUS business development 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, 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 OUS business development partnerships, alliances, and licensing arrangements. We do not have any committed external source of funds other than the amounts payable under our out-license and OUS business development 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 OUS business development partnerships, 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.

Contractual and Other Obligations

For information related to our cash requirements from known contractual and other obligations, see the description of Contingent Consideration in Note 5 “Fair Value Measure and Financial Instruments,” as well as the description of our leases in Note 7 “Property and Equipment”, and the description of our license agreement and collaborations in Note 17, “License Agreements” of Part IV - Item 15. Exhibits and Financial Statements - Notes to Consolidated Financial Statements.

Cash Flows

The following table sets forth a summary of our cash flows for the years ended December 31, 2021, 2020 and 2019 (in thousands):

	Year ended December 31,		
	2021	**2020**	**2019**
Net Cash Used in Operating Activities	$ (68,878)	$ (30,837)	$ (37,521)
Net Cash Used in Investing Activities	(4)	(8)	(136)
Net Cash Provided by Financing Activities	176,129	38,113	35,356
Net Increase in Cash, Cash Equivalents and Restricted Cash	**$ 107,247**	**$ 7,268**	**$ (2,301)**

Net Cash Used in Operating Activities

Net cash used in operating activities was $68.9 million for the year ended December 31, 2021 and consisted primarily of a net loss of $0.3 million, which includes $26.5 million of revenue recognized pursuant to the Roche License Agreement upon Roche initiating a Phase II clinical trial, achievement of the IND milestone in China pursuant to the Qilu License Agreement, clinical supply revenue resulting from the delivery of drug product to Qilu, our OUS partner for Greater China, and license revenue for additional purchase price due to the recovery of VAT by our OUS business development partner for Greater China, adjusted for non-cash items, including share-based compensation of $5.1 million, a decrease in the fair value of contingent consideration of $56.8 million, impairment charge of $31.7 million and a net decrease in operating assets and liabilities of $48.6 million.

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 contingent consideration of $71.6 million and a net decrease in operating assets and liabilities of $3.1 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, 2021, and 2020 and $0.1 million for the year ended December 31, 2019.

Net Cash Provided by Financing activities

Net cash provided by financing activities was $176.1 million for the year ended December 31, 2021 and consisted of $175.0 million in net proceeds from the sale of common stock under the ATM Offering and $1.1 million in proceeds from the exercise of common stock warrants.

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

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.

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 involve a significant level of estimation uncertainty and have had or are reasonably likely to have a material impact on our financial condition or results of operations. Management has determined that our most critical accounting policies are those relating to the fair value of indefinite-lived intangible assets, goodwill; contingent consideration; revenue recognition; development and regulatory milestone payments and other costs; and research and development costs.

Fair Value of 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 acquisition of Viventia 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 Vicineum's commercial launch in the respective markets, if approved. If regulatory approval to market Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG 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. If an impairment indicator is identified, an interim impairment assessment is performed.

In August 2021, we received a CRL from the FDA regarding our BLA for Vicineum for the treatment of NMIBC, our lead product candidate. In the CRL, the FDA determined that it could not approve the BLA for Vicineum in its present form and provided recommendations specific to additional clinical/statistical data and analyses in addition to CMC issues pertaining to a recent pre-approval inspection and product quality. Given the inherent uncertainty in the development plans for Vicineum as a result of the CRL and our withdrawal of the MAA, an impairment analysis was conducted in the third quarter of 2021, which concluded that the carrying value of our intangible asset of Vicineum United States rights was fully impaired as of September 30, 2021. The $31.7 million of impairment charges are due to delays in the expected start of commercialization and lower probabilities of success, combined with higher operating expenses expected to be incurred prior to commercialization, resulting in lower expected future cash flows estimated in the US market. At this time, we have assessed that the carrying value of the Vicineum EU rights is not at significant risk of impairment in the future within the current range of commercialization timelines and POS assumptions. This is primarily due to the fact that we expect the Vicineum sales outside of the US to be two to three times the expected sales volume in the US, based on our reassessment of the total addressable global market for high-risk NMIBC during the quarter ended June 30, 2019, wherein we determined that both the global market size and the estimated potential Vicineum commercial sales within the global market were likely higher than the Company's previous estimate. In addition, the EU asset is burdened with significantly less expense than the US asset, as our strategic operating plan is to sublicense Vicineum to business development partners in all regions outside the US, including the EU, with it earning a potential combination of upfront, milestone, and royalty payments, and the business development partner bearing the majority of regulatory and commercialization costs.

In October and December 2021, we participated in a CMC Type A Meeting and a Clinical Type A Meeting, respectively, with the FDA to discuss issues raised in the CRL and to discuss design elements of an additional Phase 3 clinical trial for Vicineum, which the FDA confirmed will be required for a potential resubmission of a BLA. Following these Type A Meetings, we believe we have greater clarity of the requirements for potential resubmission of a BLA. We have a Type C Meeting scheduled with the FDA for March 28, 2022, in which we expect to discuss the study protocol for the additional Phase 3 clinical trial that we plan to conduct for potential resubmission of our a BLA for Vicineum for the treatment of non-muscle invasive CIS of the

bladder in patients previously treated with adequate or less than adequate BCG. We performed the annual impairment test, which incorporated the impact of the CRL and the subsequent Type A Meetings in the fourth quarter of 2021 and concluded that the carrying value of our intangible asset of Vicineum EU rights was not impaired as of December 31, 2021.

Goodwill

Goodwill on our consolidated balance sheets is the result of our acquisition of Viventia 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. If an impairment indicator is identified, an interim impairment assessment is performed. Given the inherent uncertainty in the development plans for Vicineum as a result of the CRL and our withdrawal of the MAA, an impairment analysis was conducted in the third quarter of 2021. While an impairment was recognized in one of our intangible assets, Vicineum US Rights, we concluded that the carrying value of our goodwill of $13.1 million was not impaired as of September 30, 2021. In October and December 2021, we participated in a CMC Type A Meeting and a Clinical Type A Meeting, respectively, with the FDA to discuss issues raised in the CRL and to discuss design elements of an additional Phase 3 clinical trial for Vicineum, which the FDA confirmed will be required for a potential resubmission of a BLA. Following these Type A Meetings, we believe we have greater clarity of the requirements for potential resubmission of a BLA. We have a Type C Meeting scheduled with the FDA for March 28, 2022, in which we expect to discuss the study protocol for the additional Phase 3 clinical trial that we plan to conduct for potential resubmission of our a BLA for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. We performed the annual goodwill impairment test, which incorporated the impact of the CRL and the subsequent Type A Meetings in the fourth quarter of 2021 and concluded that there was no goodwill impairment as of December 31, 2021. While our stock price has declined since December 31, 2021, this is consistent with the general biotech sector overall, as world economic conditions continue to be impacted by the highly contagious Omicron variant. We believe that we have sufficient future cash flows from additional geographic regions outside the US to support the value of its goodwill. We project future cash flows based on various timeline assumptions and applies a probability to each outcome based on management's best estimate. In addition, probabilities of success in achieving certain clinical and regulatory success can also have a material effect on the estimated fair value of the equity of its reporting unit as of the impairment assessment date. We will continue to evaluate timelines for commercialization and probability of success of development of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG.

Contingent Consideration

Contingent consideration on our consolidated balance sheets is the result of our acquisition of Viventia in September 2016 and represents the discounted present value of future commercial launch milestones and net sales royalties due to the former shareholders of Viventia pursuant to the Share Purchase Agreement. For additional information on how contingent consideration has changed over the relevant period, see "Part IV - Item 15. Financial Statements - Notes to Consolidated Financial Statements - Note 1. Description of Business" of this Annual Report on Form 10-K. Contingent consideration is measured at its estimated fair value on a recurring basis at each reporting period, with fluctuations in value resulting in a non-cash charge to earnings (or loss) during the period. The estimated fair value measurement is based on significant unobservable inputs (Level 3 within the fair value hierarchy), including internally developed financial forecasts, probabilities of success and timing of certain milestone events and achievements, which are unpredictable and inherently uncertain. Actual future cash flows may differ from the assumptions used to estimate the fair value of contingent consideration. The valuation of contingent consideration requires the use of significant assumptions and judgments, which management believes are consistent with those that would be made by a market participant. Management reviews its assumptions and judgments on an ongoing basis as additional market and other data is obtained, and any future changes in the assumptions and judgments utilized by management may cause the estimated fair value of contingent consideration to fluctuate materially, resulting in earnings volatility. In October and December 2021, we participated in a CMC Type A Meeting and a Clinical Type A Meeting, respectively, with the FDA to discuss issues raised in the CRL and to discuss design elements of an additional Phase 3 clinical trial for Vicineum, which the FDA confirmed will be required for a potential resubmission of a BLA. Following these Type A Meetings, we believe we have greater clarity of the requirements for potential resubmission of a BLA. We have a Type C Meeting scheduled with the FDA for March 28, 2022, in which we expect to discuss the study protocol for the additional Phase 3 clinical trial that

we plan to conduct for potential resubmission of our a BLA for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. We reassessed the underlying assumptions used to develop the revenue projections upon which the fair value of its contingent consideration is based. The most significant and impactful assumptions in our revenue projection models are timing of product launch and probabilities of clinical and regulatory success (POS); we expect delays in the start of commercialization and estimate lower POS as a direct result of the CRL. We plan to conduct an additional clinical trial, which will lead to delays in the start of commercialization globally and any significant changes or delays could have a significant impact on the fair value of contingent consideration. We have assessed a range of commercialization timeline assumptions and applied a probability to each outcome based on management's best estimate. In addition, we now assume a lower POS in achieving certain clinical and regulatory milestones in the range of approximately 45% to 55% globally. Any changes in these assumptions and estimates, or other information obtained, may have a significant impact on the remeasurement of the contingent consideration liability in the future. The fair value of the Company's contingent consideration is determined based on the present value of projected future cash flows associated with sales-based milestones and earnouts on net sales and is heavily dependent on discount rates to estimate the fair value at each reporting period. Earnouts are determined using an 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 8.8% as of December 31, 2020, to 7.8% as of March 31, 2021, 6.8% as of June 30, 2021, 8.6% as of September 30, 2021, and 9.3% as of December 31, 2021. 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 8.4% as of December 31, 2020, to 7.4% as of March 31, 2021, 6.6% as of June 30, 2021, 7.5% as of September 30, 2021, and 8.0% as of December 31, 2021.

Development and Regulatory 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 note recognize revenue until the subsequent sale of a licensed product occurs. For arrangements with one than one performance obligations, the 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.

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

Not applicable.

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, 2021.

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 2021 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, 2021 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP.

The effectiveness of our ICFR as of December 31, 2021 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included immediately below.

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control over Financial Reporting

We have audited Sesen Bio Inc.'s internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Sesen Bio, Inc. (the "Company") maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2021 and 2020, 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, 2021, and the related notes and our report dated February 28, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

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

Definition and Limitations of Internal Control Over Financial Reporting

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

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 28, 2022

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, 2021 that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

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 2022 Proxy Statement to be filed with the SEC within 120 days of December 31, 2021 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 2022 Proxy Statement to be filed with the SEC within 120 days of December 31, 2021 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 2022 Proxy Statement to be filed with the SEC within 120 days of December 31, 2021 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 2022 Proxy Statement to be filed with the SEC within 120 days of December 31, 2021 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 2022 Proxy Statement to be filed with the SEC within 120 days of December 31, 2021 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 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	Certificate of Amendment of Certificate of Incorporation. Incorporated by reference to Exhibit 3.3 to our Quarterly Report on Form 10-Q filed on May 10, 2021 (File No. 001-36296).
3.4	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).
4.1*	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.
4.2	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).
4.3	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 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 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 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 on 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 on 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.
10.9+	2014 Employee Stock Purchase Plan. Incorporated by reference to Exhibit 10.13 to our Registration Statement on Form S-1/A filed 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 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 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 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 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 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 on 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 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 Jefferies 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	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).
10.25†	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 on November 9, 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).
10.27+	Amendment No. 2 to the Sesen Bio, Inc. 2014 Stock Incentive Plan. Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on May 3, 2021 (File No. 001-36296).
10.28+	Amendment No. 1 to the Sesen Bio, Inc. 2014 Employee Stock Purchase Plan. Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed on May 3, 2021 (File No. 001-36296).
10.29	Amendment No. 3 to the Open Market Sale AgreementSM, dated June 1, 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 June 1, 2021 (File No. 001-36296).
10.30*+	Form of RSU Award Agreement for Retention Awards
10.31*+	Form of PSU Award Agreement for Retention Awards
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: February 28, 2022

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)	February 28, 2022
/s/ Monica Forbes Monica Forbes	Chief Financial Officer (Principal Financial Officer)	February 28, 2022
/s/ Elly Ryu Elly Ryu	Corporate Controller (Principal Accounting Officer)	February 28, 2022
/s/ Jay S. Duker, M.D. Jay S. Duker, M.D.	Chair of the Board of Directors	February 28, 2022
/s/ Carrie L. Bourdow Carrie L. Bourdow	Director	February 28, 2022
/s/ Jason A. Keyes Jason A. Keyes	Director	February 28, 2022
/s/ Peter K Honig, M.D. Peter K Honig, M.D.	Director	February 28, 2022
/s/ Michael A.S. Jewett, M.D. Michael A.S. Jewett, M.D.	Director	February 28, 2022

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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, 2021 and 2020, 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, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 28, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were 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 critical audit matters 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 matters below, providing a separate opinion on the critical audit matters or on the accounts or disclosures to which they relate.

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, 2021, the Company estimated the fair value of the contingent consideration liability as $52.0 million and recorded the change in fair value of $56.8 million as operating income for the year ended December 31, 2021.

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 to estimate the fair value. 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

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the development of the significant assumptions over the Company’s process to estimate the fair value of the contingent consideration liability. This included testing controls over management’s review of the significant estimation assumptions and methods used to develop the fair value estimate, the accuracy of the calculations included within the fair value model, and the underlying data used in the model.

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.

Impairment Evaluation of Goodwill and Indefinite-Lived Intangible Assets

Description of the Matter

As discussed in Notes 3 and 8 to the consolidated financial statements under the captions “Indefinite-Lived Intangible Assets” and “Goodwill,” 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 acquisition of Viventia in 2016. Goodwill on the Company's consolidated balance sheets is the result of the Company’s acquisition of Viventia 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. 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. 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 IPR&D requires management to estimate the future discounted cash flows of the underlying asset. Impairment testing of goodwill requires management to estimate the future discounted cash flows of the Company’s one reporting unit.

Auditing management’s impairment assessments required significant auditor judgment due to the high degree of subjectivity in evaluating certain assumptions used to estimate the fair value of the reporting unit for and the IPR&D. In particular, the fair value estimates of goodwill and of IPR&D were sensitive to the significant assumptions underlying the projected commercial sales of Vicineum.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the development of the significant assumptions over the Company's goodwill and indefinite-lived intangible asset impairment review processes. This included testing controls over management's review of the quantitative impairment analyses of goodwill and IPR&D, including the significant estimation assumptions and methods used, the accuracy of the calculations included within the valuation models, and the underlying data used in those models.

To test the impairment evaluations over goodwill and IPR&D assets, our audit procedures included, among others, evaluating the methodology and valuation models 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 inspected the Company's reconciliation of the fair value of the reporting unit to the market capitalization of the Company and assessed the results. We involved our valuation professionals to assess the methodology and valuation of the discounted cash flow models, including evaluating the reasonableness of certain significant assumptions.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2010.
Boston, Massachusetts
February 28, 2022

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

	December 31,	
	2021	**2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 162,636	$ 52,389
Accounts receivables	21,011	—
Other receivables	3,482	—
Prepaid expenses and other current assets	18,476	7,478
Restricted Cash	—	3,000
Total current assets	205,605	62,867
Non-current assets:		
Restricted cash	20	20
Property and equipment, net	43	123
Intangible assets	14,700	46,400
Goodwill	13,064	13,064
Long term prepaid expenses	7,192	—
Other assets	123	349
Total non-current assets	**$ 35,142**	**$ 59,956**
Total Assets	**$ 240,747**	**$ 122,823**
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,853	$ 3,102
Accrued expenses	8,255	3,973
Deferred revenue	—	1,500
Contingent consideration	—	8,985
Other current liabilities	460	489
Total current liabilities	11,568	18,049
Non-current liabilities:		
Contingent consideration, net of current portion	52,000	99,855
Deferred tax liability	3,969	12,528
Deferred revenue, net of current portion	1,500	1,500
Other non-current liabilities	—	118
Total non-current liabilities	57,469	114,001
Total Liabilities	69,037	132,050
Stockholders' Equity (Deficit):		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized at December 31, 2021 and 2020; no shares issued and outstanding at December 31, 2021 and 2020	—	—
Common stock, $0.001 par value per share; 400,000,000 and 200,000,000 shares authorized at December 31, 2021 and 2020; 199,463,645 and 140,449,647 shares issued and outstanding at December 31, 2021 and 2020, respectively	199	140
Additional paid-in capital	487,768	306,554
Accumulated deficit	(316,257)	(315,921)
Total Stockholders' Equity (Deficit)	171,710	(9,227)
Total Liabilities and Stockholders' Equity	**$ 240,747**	**$ 122,823**

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,		
	2021	**2020**	**2019**
Revenue:			
License and related revenue	$ 26,544	$ 11,236	$ —
Total Revenue	26,544	11,236	—
Operating expenses:			
Research and development	25,312	29,191	24,663
General and administrative	29,393	14,302	12,208
Restructuring charge	5,528	—	—
Intangibles impairment charge	31,700	—	—
Change in fair value of contingent consideration	(56,840)	(11,180)	71,620
Total operating expenses	35,093	32,313	108,491
Loss from Operations	$ (8,549)	$ (21,077)	$ (108,491)
Other (expense) income, net	(60)	125	991
Loss Before Taxes	$ (8,609)	$ (20,952)	$ (107,500)
Benefit (provision) from income taxes	$ 8,273	$ (1,445)	$ —
Net Loss and Comprehensive Loss After Taxes	$ (336)	$ (22,397)	$ (107,500)
Deemed dividend on adjustment of exercise price of certain warrants	$ —	$ (147)	$ —
Net loss attributable to common stockholders - basic and diluted	$ (336)	$ (22,544)	$ (107,500)
Net loss per common share - basic and diluted	$ —	$ (0.19)	$ (1.18)
Weighted-average common shares outstanding - basic and diluted	$ 182,323	$ 118,221	$ 90,929

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Equity (Deficit)
	Shares	Amount			
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 vesting of RSAs	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 $2.2 million	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 $0.2 million	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 $1.2 million	33,369,942	33	37,925		37,958
Balance at December 31, 2020	140,449,647	140	306,554	(315,921)	(9,227)
Net loss	—	—	—	$ (336)	(336)
Share-based compensation	—	—	5,143	—	5,143
Exercises of stock options	33,610	—	42	—	42
Exercises of common stock warrants	2,048,059	2	1,124	—	1,126
Issuance of common stock under ATM Offering, net of issuance costs of $5.4 million	56,932,329	57	174,905	—	174,962
Balance at December 31, 2021	**199,463,645**	**$ 199**	**$ 487,768**	**$ (316,257)**	**$ 171,710**

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,		
	2021	**2020**	**2019**
Cash Flows from Operating Activities:			
Net loss	$ (336)	$ (22,397)	$ (107,500)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	85	122	219
Share-based compensation	5,143	1,757	1,237
Change in fair value of contingent consideration	(56,840)	(11,180)	71,620
Intangibles impairment charge	31,700	—	—
Changes in operating assets and liabilities:			
Accounts receivable (net)	(24,493)	—	—
Prepaid expenses and other assets	(17,964)	(1,304)	(5,188)
Accounts payable	(249)	1,200	535
Accrued expenses and other liabilities	(4,424)	(2,035)	1,556
Deferred revenue	(1,500)	3,000	—
Net cash used in operating activities	**(68,878)**	**(30,837)**	**(37,521)**
Cash Flows from Investing Activities:			
Purchases of equipment	(4)	(8)	(136)
Net cash used in investing activities	**(4)**	**(8)**	**(136)**
Cash Flows from Financing Activities:			
Proceeds from issuance of common stock and common stock warrants, net of issuance costs	—	—	27,833
Proceeds from exercises of common stock warrants	1,126	131	5,481
Proceeds from issuance of common stock under ATM Offering, net of issuance costs	174,962	37,958	1,936
Proceeds from exercises of stock options	42	13	98
Proceeds from sale of common stock pursuant to ESPP	—	11	8
Net cash provided by financing activities	**176,129**	**38,113**	**35,356**
Net increase (decrease) in cash, cash equivalents and restricted cash	107,247	7,268	(2,301)
Cash, cash equivalents and restricted cash - beginning of period	55,409	48,141	50,442
Cash, cash equivalents and restricted cash - end of period	**$ 162,656**	**$ 55,409**	**$ 48,141**
Reconciliation of cash, cash equivalents and restricted cash:			
Cash and cash equivalents	$ 162,636	$ 52,389	$ 48,121
Short term restricted cash	—	3,000	—
Long term restricted cash	20	20	20
Total cash, cash equivalents and restricted cash	**$ 162,656**	**$ 55,409**	**$ 48,141**
Supplemental cash flow disclosure:			
Cash paid for amounts included in the measurement of lease liabilities	$ 174	$ 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.

SESEN BIO, INC.
NOTES TO 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 advancing 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 for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with bacillus Calmette-Guérin ("BCG"). The Company has an ongoing single-arm, multi-center, open-label Phase 3 VISTA clinical trial of Vicineum as a monotherapy in patients with BCG-unresponsive NMIBC (the "VISTA Trial"). The VISTA Trial completed enrollment in April 2018 with a total of 133 patients. On December 18, 2020, the Company submitted its completed Biologics License Application (the "BLA") for Vicineum for the treatment of BCG-unresponsive NMIBC to the United States Food and Drug Administration ("FDA"). On February 12, 2021, the FDA notified the Company that it has accepted for filing the BLA. The FDA also granted Priority Review for the BLA and set a target Prescription Drug User Fee Act ("PDUFA") date for a decision on the BLA of August 18, 2021. On July 13, 2021, the Company participated in a productive Late-Cycle Meeting with the FDA regarding the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. In the meeting, the FDA confirmed that there was no Advisory Committee meeting planned at that time, and that no post-marketing requirements, including a confirmatory trial, had been identified at that time. Also in the meeting, the Company and the FDA discussed remaining questions related to manufacturing facilities inspection, product quality information requests and additional information related to chemistry, manufacturing and controls (“CMC”), and a timeline to submit additional supporting information was agreed upon. On

August 13, 2021, the Company received a complete response letter (“CRL”) from the FDA indicating that the FDA had determined that it could not approve the BLA for Vicineum in its present form and provided recommendations specific to additional clinical/statistical data and analyses in addition to CMC issues pertaining to a recent pre-approval inspection and product quality.

The Company participated in Type A Meetings with the FDA on October 29, 2021 and December 8, 2021 to discuss questions related to CMC and clinical issues raised in the CRL. Both meetings helped the Company determine the appropriate path forward for Vicineum. Any changes in these assumptions and estimates or other information obtained, may have a significant impact on the remeasurement of the contingent consideration liability in the future. The Company believes it has a clear understanding of what additional information regarding CMC is required for resubmission of a BLA. Additionally, although not an issue raised in the CRL, the FDA confirmed that Vicineum manufactured using the proposed commercial process is comparable to Vicineum used in prior clinical trials. The FDA also confirmed that the Company can utilize Vicineum manufactured during process validation for any future clinical trials needed to address issues raised in the CRL, and that these potential trials can proceed while addressing CMC issues.

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. 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, 2021, none of these individuals are active employees or members of the Company's board of directors.

Liquidity and Capital Resources

As of December 31, 2021, the Company had cash and cash equivalents of $162.6 million and an accumulated deficit of $316.3 million. The Company incurred negative cash flows from operating activities of $68.9 million, $30.8 million and $37.5 million for the years ended December 31, 2021, 2020 and 2019, respectively. Since the Company’s inception, it has received no revenue from sales of its products, and the Company anticipates that operating losses will continue for the foreseeable future as it seeks to address the issues raised in the CRL it received for a BLA for Vicineum for the treatment of BCG unresponsive NMIBC and the concerns identified in the EMA Withdrawal Assessment Report, complete the follow-up stage of the ongoing Phase 3 VISTA Trial of Vicineum for the treatment of BCG-unresponsive NMIBC, complete any additional clinical trials for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, and seek marketing approval from the FDA and the European Commission and, if approved, commercialize Vicineum. 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 12. Stockholders’ Equity” below for information regarding the Company’s recently completed equity financings. Management believes that the Company’s cash and cash equivalents as of December 31, 2021 will be sufficient to fund the Company's current operating plan for at least the next twelve months from the date these consolidated financial statements were issued.

Funding Requirements

The Company’s future success is dependent on its ability to develop, and if approved, commercialize its product candidates, including Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, and ultimately upon its ability to attain profitable operations. In order to commercialize its product candidates, including Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, the Company needs to complete clinical development and comply with comprehensive regulatory requirements. The Company is subject to a number of risks similar to other late-stage clinical companies, including, but not limited to, successful discovery and development of its product candidates, raising additional capital, development and commercialization by its competitors of new technological innovations, protection of proprietary technology and market acceptance of its products. The successful discovery, development and, if approved, commercialization of product candidates, including Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, requires substantial working capital, and the Company expects to seek additional funds through equity or debt financings or through additional outside of United States (“OUS”) business development partnerships, collaborations, licensing transactions or other sources. The Company may be unable to obtain equity or debt financings or enter into additional OUS business development partnerships, collaborations or licensing transactions at favorable terms, or at all, and, if necessary, may be required to implement cost reduction strategies.

The Company will incur substantial expenses if and as it:

- addresses the issues identified in the CRL it received from the FDA for its BLA for Vicineum for the treatment of BCG-unresponsive NMIBC and the concerns identified in the European Medicines Agency’s (“EMA”) Withdrawal Assessment Report, which the Company expects will include the completion of an additional Phase 3 clinical trial;
- seeks marketing approvals for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG;
- establishes and implement sales, marketing and distribution capabilities and scale up and validate external manufacturing capabilities to commercialize Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, if approved;
- maintains, expands and protects its intellectual property portfolio;
- hires additional clinical, regulatory, quality control, scientific and management personnel;
- expands its operational, financial and management systems and personnel;

- conducts research and pre-clinical and clinical development of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, and its other product candidates;
- seeks to discover and develop additional product candidates; and
- in-licenses or acquires the rights to other products, product candidates or technologies.

The Company's future capital requirements will depend on many factors, including:

- the scope, initiation, progress, timing, costs and results of laboratory testing and clinical trials for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG and its other product candidates;
- the ongoing COVID-19 pandemic and its impact on the Company’s business;
- the Company’s ability to establish additional OUS business development partnerships, collaborations or licensing arrangements on favorable terms, if at all, particularly manufacturing, marketing and distribution arrangements for its 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, if approved;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing its intellectual property rights and defending any intellectual property-related claims;
- the Company’s obligation to make milestone, royalty and other payments to third-party licensors under its licensing agreements;
- the extent to which the Company in-licenses or acquires rights to other products, product candidates or technologies;
- the outcome, timing and cost of regulatory review by the FDA, EMA and comparable non-US regulatory authorities for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, including the potential for the FDA, EMA or comparable non-US regulatory authorities to require that the Company perform more studies or clinical trials than those that it currently expects to perform;
- the Company’s ability to achieve certain future regulatory, development and commercialization milestones under its out-license and OUS business development 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, if approved.

Until such time, if ever, as the Company can generate substantial product revenues from commercial sales, the Company expects to finance its cash needs through a combination of equity offerings, debt financings, government or other third-party funding, strategic collaborations, OUS business development partnership agreements, partnerships, alliances, and licensing arrangements. The Company does not have any committed external source of funds other than the amounts payable under the license agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (collectively, “Roche”) and the license agreement with Qilu Pharmaceutical, Co., Ltd. (“Qilu”). To the extent 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 OUS business development partnerships, collaborations, alliances or licensing arrangements, the Company 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 to the Company. If the Company is unable to raise additional funds when needed, the Company may be required to delay, limit, reduce or terminate its product development or future commercialization efforts or grant rights to develop and market products or product candidates that the Company would otherwise prefer to develop and market itself.

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 the Company’s 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 the Company’s ability to raise additional capital in the future.

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 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 US 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 and accounts receivable. As of December 31, 2021 and 2020, 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.

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 acquisition of Viventia 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 Vicineum's commercial launch 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 unpredictable and inherently uncertain. Actual future cash flows may differ from the estimates used in impairment testing. The Company recognizes an impairment loss when and to the extent that the estimated fair value of an intangible asset is less than its carrying value. In addition, on a quarterly basis, the Company performs a qualitative review of its business operations to determine whether events or changes in circumstances have occurred which could indicate that the carrying value of its intangible assets was not recoverable. If an impairment indicator is identified, an interim impairment assessment is performed.

In August 2021, the Company received a CRL from the FDA regarding its BLA for Vicineum for the treatment of NMIBC, its lead product candidate. In the CRL, the FDA determined that it could not approve the BLA for Vicineum in its present form and provided recommendations specific to additional clinical/statistical data and analyses in addition to CMC issues pertaining to a recent pre-approval inspection and product quality. Given the inherent uncertainty in the development plans for Vicineum (and Vysyneum in the EMA) as a result of the CRL and the withdrawal of the Company's marketing authorization application ("MAA"), an interim impairment analysis was conducted in the third quarter of 2021, which concluded that the carrying value of the Company's intangible asset of Vicineum US rights was fully impaired as of September 30, 2021. The $31.7 million of impairment charges were due to delays in the expected start of commercialization and lower probabilities of success, combined with higher operating expenses expected to be incurred prior to commercialization, resulting in lower expected future cash flows estimated in the US market. However, while similar delays in timelines and reduced probabilities of success also affected the estimated fair value of the Company's intangible asset of Vicineum EU rights, this asset was not impaired as of September 30, 2021. At that time, management assessed that the carrying value of the Vicineum EU rights is not at significant risk of impairment in the future within the current range of commercialization timelines and probability of clinical and regulatory success ("POS") assumptions. This is primarily due to the fact that the Company expects the Vicineum sales outside of the US to be two to three times the expected sales volume in the US, based on management's reassessment of the total addressable global market for high-risk NMIBC during the quarter ended June 30, 2019, wherein management determined that both the global market size and the estimated potential Vicineum commercial sales within the global market were likely higher than the Company's previous estimate. In addition, the EU asset is burdened with significantly less expense than the US asset, as the Company's strategic operating plan is to sublicense Vicineum to business development partners in all regions outside the US, including the EU, with it earning a potential combination of upfront, milestone, and royalty payments, and the business development partner bearing the majority of regulatory and commercialization costs. The Company participated in Type A Meetings with the FDA on October 29, 2021 and December 8, 2021 to discuss questions related to CMC and clinical issues raised in the CRL. Both meetings helped the Company determine the appropriate path forward for Vicineum. Based upon the outcome of these meetings, the Company plans to conduct an additional Phase 3 clinical trial. Also, during the Clinical Type A Meeting, the Company aligned with FDA to include patients with less than adequate BCG into its new clinical trial. The Company performed the annual impairment test, which incorporated the impact of the CRL and the subsequent Type A Meetings in the fourth quarter of 2021 and concluded that the carrying value of the Company's intangible asset of Vicineum EU rights was not impaired as of December 31, 2021.

The Company did not recognize any impairment charges during the year ended December 31, 2020.

Goodwill

Goodwill on the Company's consolidated balance sheets is the result of the Company's acquisition of Viventia in September 2016 and represents the difference between the purchase price and the fair value of the identifiable tangible and intangible net assets acquired under the acquisition method of accounting. Goodwill is not amortized; rather than recording periodic amortization, goodwill is quantitatively tested for impairment at least annually during the fourth quarter of the fiscal year, or more often if indicators of impairment are present. Impairment testing of goodwill requires management to estimate the future discounted cash flows of a reporting unit using assumptions believed to be reasonable, but which are unpredictable and inherently uncertain. Actual future cash flows may differ from the estimates used in impairment testing. If the fair value of the equity of a reporting unit exceeds the reporting unit's carrying value, including goodwill, then goodwill is considered not to be impaired. The Company recognizes a goodwill impairment when and to the extent that the fair value of the equity of a reporting unit is less than the reporting unit's carrying value, including goodwill. The Company has only one reporting unit. In addition, on a quarterly basis, the Company performs a qualitative review of its business operations to determine whether events or changes in circumstances have occurred which could have a material adverse effect on the estimated fair value of each reporting unit and thus indicate a potential impairment of the goodwill carrying value. If an impairment indicator is identified, an interim impairment assessment is performed. Given the inherent uncertainty in the development plans for Vicineum as a result of the CRL and the Company's withdrawal of its MAA, an impairment analysis was conducted in the third quarter of 2021. While an impairment was recognized in one of the Company's intangible assets, Vicineum US Rights, the Company concluded that the carrying value of its goodwill of $13.1 million was not impaired as of September 30, 2021.

In October and December 2021, we participated in a CMC Type A Meeting and a Clinical Type A Meeting, respectively, with the FDA to discuss issues raised in the CRL and to discuss design elements of an additional Phase 3 clinical trial for Vicineum, which the FDA confirmed will be required for a potential resubmission of a BLA. Following these Type A Meetings, we believe we have greater clarity of the requirements for potential resubmission of a BLA. We have a Type C Meeting scheduled with the FDA for March 28, 2022, in which we expect to discuss the study protocol for the additional Phase 3 clinical trial that we plan to conduct for potential resubmission of our a BLA for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. The Company performed the annual impairment test, which incorporated the impact of the CRL and the subsequent Type A Meetings in the fourth quarter of 2021 and concluded that there was no goodwill impairment as of December 31, 2021. Management believes the Company has sufficient future cash flows from additional geographic regions outside the US to support the value of its goodwill. The

Company projects future cash flows based on various timeline assumptions and applies a probability to each outcome based on management's best estimate. In addition, probabilities of success in achieving certain clinical and regulatory success can also have a material effect on the estimated fair value of the equity of its reporting unit as of the impairment assessment date. The Company will continue to evaluate timelines for commercialization and probability of success of development of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG.

Based on the annual testing and quarterly reviews performed, the Company concluded that there was no goodwill impairment during the year ended December 31, 2020.

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.

In October and December 2021, we participated in a CMC Type A Meeting and a Clinical Type A Meeting, respectively, with the FDA to discuss issues raised in the CRL and to discuss design elements of an additional Phase 3 clinical trial for Vicineum, which the FDA confirmed will be required for a potential resubmission of a BLA. Following these Type A Meetings, we believe we have greater clarity of the requirements for potential resubmission of a BLA. We have a Type C Meeting scheduled with the FDA for March 28, 2022, in which we expect to discuss the study protocol for the additional Phase 3 clinical trial that we plan to conduct for potential resubmission of our a BLA for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. The Company reassessed the underlying assumptions used to develop the revenue projections upon which the fair value of its contingent consideration is based. The most significant and impactful assumptions in the Company's revenue projection models are timing of product launch and probabilities of clinical and regulatory success ("POS"); the Company expects delays in the start of commercialization and estimates lower POS as a direct result of the CRL. The Company plans to conduct an additional clinical trial, which will lead to delays in the start of commercialization globally. The Company has assessed a range of commercialization timeline assumptions and applied a probability to each outcome based on management's best estimate. In addition, the Company now assumes a lower POS in achieving certain clinical and regulatory milestones in the range of approximately 45% to 55% globally. Any changes in these assumptions and estimates, or other information obtained, may have a significant impact on the remeasurement of the contingent consideration liability in the future. The fair value of the Company's contingent consideration is determined based on the present value of projected future cash flows associated with sales-based milestones and earnouts on net sales and is heavily dependent on discount rates to estimate the fair value at each reporting period. Earnouts are determined using an 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 8.8% as of December 31, 2020, to 7.8% as of March 31, 2021, 6.8% as of June 30, 2021, 8.6% as of September 30, 2021, and 9.3% as of December 31, 2021. 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 8.4% as of December 31, 2020, to 7.4% as of March 31, 2021, 6.6% as of June 30, 2021, 7.5% as of September 30, 2021, and 8.0% as of December 31, 2021.

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, 2021, 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, 2021 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, 2021, 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 are specific to the Company's corporate goals, including certain clinical development objectives related to the new clinical 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, 2021, 2020 and 2019 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, 2021 and 2020, the Company did not have any uncertain tax positions.

Revenue Recognition

The Company records revenue from out-license agreements and OUS business development partnership agreements, including the License Agreement with Roche and its OUS partnerships. Under each of these agreements, the Company 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.

The Company determines whether the out-license agreements and OUS business development partnership agreements are in scope of ASC 606, which it adopted as of January 1, 2018. Under ASC 606, in determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under these agreements, management performs 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; and

5) Recognition of revenue when or as the Company satisfies each performance obligation.

Development and Regulatory Milestones and Other Payments

At the inception of an arrangement that includes development milestone payments, management evaluates 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 the Company's 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, the Company will not recognize revenue until the subsequent sale of a licensed product occurs. For arrangements with one than one performance obligations, the 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.

In December 2021, a $20 million milestone was achieved due to Roche initiating a Phase II clinical trial. The Company invoiced Roche $20 million with payment terms of 30 days following the achievement of the corresponding milestone event, pursuant to the Roche License Agreement. Management evaluated the transaction under ASC 606 and determined it is probable that a significant revenue reversal will not occur in future periods, which was not the case in the previous quarter. Accordingly, the Company recorded $20 million as license revenue and accounts receivables in the fourth quarter of 2021. In January 2022, the payment of $20 million was received.

The Company recognized $26.5 million of license revenue related to the Roche, Qilu and MENA License Agreements during the year ended December 31, 2021 and $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 2021

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 adopted this guidance effective January 1, 2021, and it did not have a material impact on its 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, 2021 and 2020 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, 2021 and 2020 (in thousands):

	December 31, 2021				
			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)	$ 16,382	$ 16,382	$ 16,382	$ —	$ —
Liabilities:					
Contingent consideration - short term	—	$ —	$ —	$ —	$ —
Contingent consideration - long term	$ 52,000	$ 52,000	$ —	$ —	$ 52,000

	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

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, 2021.

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 2025 to 2033, the level of commercial sales of Vicineum forecasted for the US, Europe, Japan, China and other potential markets and discount rates ranging from 8.0% to 9.3% as of December 31, 2021 and 8.4% to 8.8% as of December 31, 2020. There have been no changes to the valuation methods utilized during the year ended December 31, 2021.

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, 2021 (in thousands):

Balance at December 31, 2020	$	108,840
Change in fair value included in loss		48,160
Balance at March 31, 2021		157,000
Change in fair value included in loss		13,600
Balance at June 30, 2021		170,600
Change in fair value included in loss		(114,000)
Balance at September 30, 2021		56,600
Change in fair value included in loss		(4,600)
Balance at December 31, 2021	**$**	**52,000**

Balance at December 31, 2021, current portion	$	—
Balance at December 31, 2021, net of current portion	$	52,000

The following table sets forth a summary of the change in the fair value of the Company's total contingent consideration liability, measured on a recurring basis at each reporting period, for the year ended December 31, 2021.

Balance at December 31, 2020	$108,840
Change in fair value of contingent consideration - short term	(8,985)
Change in fair value of contingent consideration - long term	(47,855)
Balance at December 31, 2021	**$ 52,000**

The fair value of the Company’s contingent consideration is determined based on the present value of projected future cash flows associated with sales-based milestones and earnouts on net sales and is heavily dependent on discount rates to estimate the fair value at each reporting period. Earnouts are determined using an 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 WACC, which has fluctuated from 8.8% as of December 31, 2020, to 7.8% as of March 31, 2021, 6.8% as of June 30, 2021, 8.6% as of September 30, 2021, and 9.3% as of December 31, 2021. 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 8.4% as of December 31, 2020, to 7.4% as of March 31, 2021, 6.6% as of June 30, 2021, 7.5% as of September 30, 2021, and 8.0% as of December 31, 2021. The decrease in the fair value of contingent consideration of $56.8 million for the year ended December 31, 2021 was driven by the receipt of the CRL from the FDA, in which the FDA determined that it could not approve the BLA for Vicineum in its present form, and the Company’s withdrawal of its MAA with EMA. In October and December 2021, we participated in a CMC Type A Meeting and a Clinical Type A Meeting, respectively, with the FDA to discuss issues raised in the CRL and to discuss design elements of an additional Phase 3 clinical trial for Vicineum, which the FDA confirmed will be required for a potential resubmission of a BLA. Following these Type A Meetings, we believe we have greater clarity of the requirements for potential resubmission of a BLA. We have a Type C Meeting scheduled with the FDA for March 28, 2022, in which we expect to discuss the study protocol for the additional Phase 3 clinical trial that we plan to conduct for potential resubmission of our a BLA for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. Incorporating the impact of the CRL and the subsequent Type A Meetings in the fourth quarter of 2021, the Company reassessed the underlying assumptions used to develop the revenue projections upon which the fair value of its contingent consideration is based. The most significant and impactful assumptions in the Company’s revenue projection models are timing of commercial product launch and probabilities of clinical and regulatory success; the Company expects delays in the start of commercialization and estimates lower POS as a direct result of the CRL and the Company’s withdrawal of its MAA. The Company plans to conduct an additional Phase 3 clinical trial in order to resubmit a BLA for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, which will lead to delays in the start of commercialization globally. The Company has assessed a commercialization timeline assumption and applied a probability to each outcome based on management’s best estimate. In addition, the Company now assumes a lower POS in achieving certain clinical and regulatory milestones in the range of approximately 45% to 55% globally. Any changes in these assumptions and estimates as a result of these meetings, or other information obtained, may have a significant impact on the remeasurement of the contingent consideration liability in the future.

6. RECEIVABLES

The accounts receivable balance as of December 31, 2021 is $21.0 million, comprised primarily of a $20 million milestone achieved in December 2021 due to Roche initiating a Phase II clinical trial. The Company invoiced Roche $20 million with payment terms of 30 days following the achievement of the corresponding milestone event, pursuant to the Roche License Agreement. In January 2022 the payment of $20 million was received. Additionally, in June 2021, the Qilu License Agreement was recognized by Shandong Province, Bureau of Science and Technology as a "Technology Transfer". As such, the Company recorded $0.9 million of revenue and accounts receivable for the additional purchase price resulting from Qilu's obligation to pay Sesen an amount equal to its recovery of VAT. The Company will not be subject to VAT on future potential milestone payments from Qilu.

The other receivable balance as of December 31, 2021 is $3.5 million. The Company recorded $3.4 million to other receivables in the fourth quarter of 2021 for German VAT recovery related to drug substance sent to Baxter. The Company received a payment for $1.8 million in January 2022 and expects to collect the remaining balance.

The accounts receivable and other receivable balances as of December 31, 2020 were de minims.

7. PROPERTY AND EQUIPMENT

The following table sets forth the composition of property and equipment, net as of December 31, 2021 and 2020 (in thousands):

	December 31,	
	2021	**2020**
Lab equipment	$ 569	$ 570
Furniture and fixtures	16	16
Computer equipment	99	97
Software	32	28
Leasehold improvements	293	293
Property and equipment, gross	1,009	1,004
Less: accumulated depreciation	(966)	(881)
Total Property and Equipment, Net	**$ 43**	**$ 123**

Depreciation expense was $0.1 million, $0.1 million and $0.2 million for the years ended December 31, 2021, 2020 and 2019, respectively.

8. INTANGIBLES AND GOODWILL

Intangibles

Intangible assets on the Company's consolidated balance sheet are the result of the Viventia Acquisition in September 2016. The following table sets forth the composition of intangible assets as of December 31, 2021 and 2020 (in thousands):

	December 31,	
	2021	**2020**
IPR&D intangible assets:		
Vicineum United States rights	$ —	$ 31,700
Vicineum European Union rights	14,700	14,700
Total Intangibles	**$ 14,700**	**$ 46,400**

The fair value of the acquired intangible assets for the US and EU rights of Vicineum is determined using a risk-adjusted discounted cash flow approach, which includes probability adjustments for projected revenues and operating expenses based on the success rates assigned to each stage of development for each geographical region; as well as discount rates applied to the projected cash flows. In August 2021, the Company received a CRL from the FDA regarding its BLA for Vicineum for the

treatment of NMIBC, the Company’s lead product candidate. In the CRL, the FDA determined that it could not approve the BLA for Vicineum in its present form and provided recommendations specific to additional clinical/statistical data and analyses in addition to CMC issues pertaining to a recent pre-approval inspection and product quality. Given the inherent uncertainty in the development plans for Vicineum as a result of the CRL and the Company’s withdrawal of its MAA, an impairment analysis was conducted in the third quarter of 2021, which concluded that the carrying value of the Company’s intangible asset of Vicineum United States rights was fully impaired as of September 30, 2021. The $31.7 million of impairment charges as of September 30, 2021 are due to delays in the expected start of commercialization and lower probabilities of success, combined with higher operating expenses expected to be incurred prior to commercialization, resulting in lower expected future cash flows estimated in the US market. At this time, management has assessed that the carrying value of the Vicineum EU rights is not at significant risk of impairment in the future within the current range of commercialization timelines and POS assumptions. This is primarily due to the fact that the Company expects the Vicineum sales outside of the US to be two to three times the expected sales volume in the US, based on management’s reassessment of the total addressable global market for high-risk NMIBC during the quarter ended June 30, 2019, wherein management determined that both the global market size and the estimated potential Vicineum commercial sales within the global market were likely higher than the Company's previous estimate. In addition, the EU asset is burdened with significantly less expense than the US asset, as the Company’s strategic operating plan is to sublicense Vicineum to business development partners in all regions outside the US, including the EU, with it earning a potential combination of upfront, milestone, and royalty payments, and the business development partner bearing the majority of regulatory and commercialization costs.

In October and December 2021, we participated in a CMC Type A Meeting and a Clinical Type A Meeting, respectively, with the FDA to discuss issues raised in the CRL and to discuss design elements of an additional Phase 3 clinical trial for Vicineum, which the FDA confirmed will be required for a potential resubmission of a BLA. Following these Type A Meetings, we believe we have greater clarity of the requirements for potential resubmission of a BLA. We have a Type C Meeting scheduled with the FDA for March 28, 2022, in which we expect to discuss the study protocol for the additional Phase 3 clinical trial that we plan to conduct for potential resubmission of our a BLA for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG.

The Company performed the annual impairment test, which incorporated the impact of the CRL and the subsequent Type A Meetings in the fourth quarter of 2021 and concluded that the carrying value of the Company's intangible asset of Vicineum EU rights was not impaired as of December 31, 2021.

The Company did not recognize any impairment charges during the year ended December 31, 2020.

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, 2021 and 2020. Given the inherent uncertainty in the development plans for Vicineum as a result of the CRL and the Company's withdrawal of its MAA, a quantitative impairment analysis was conducted during the third quarter of 2021, in advance of the Company's typical annual assessment date of October 1. While an impairment was recognized in one of its intangible assets, Vicineum US Rights, the Company concluded that the carrying value of its goodwill of $13.1 million was not impaired as of September 30, 2021, with the fair value of equity of the reporting unit exceeding the estimated carrying value of the reporting unit by approximately 45%.

In October and December 2021, we participated in a CMC Type A Meeting and a Clinical Type A Meeting, respectively, with the FDA to discuss issues raised in the CRL and to discuss design elements of an additional Phase 3 clinical trial for Vicineum, which the FDA confirmed will be required for a potential resubmission of a BLA. Following these Type A Meetings, we believe we have greater clarity of the requirements for potential resubmission of a BLA. We have a Type C Meeting scheduled with the FDA for March 28, 2022, in which we expect to discuss the study protocol for the additional Phase 3 clinical trial that we plan to conduct for potential resubmission of our a BLA for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. The Company performed the annual impairment test, which incorporated the impact of the CRL and the subsequent Type A Meetings in the fourth quarter of 2021 and concluded that there was no goodwill impairment as of December 31, 2021. The Company believes it has sufficient future cash flows from additional geographic regions outside the US to support the value of its goodwill. The Company projects future cash flows based on various timeline assumptions and applies a probability to each outcome based on management’s best estimate. In addition, probabilities of success in achieving certain clinical and regulatory success in the Company's current development profile (ranging from 45% to 55% globally) also have a material effect on the estimated fair value of its reporting unit as of the impairment assessment date. The Company will continue to evaluate its timelines for commercialization and probability of success of development of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG.

Based on the annual testing and quarterly reviews performed, the Company concluded that there was no goodwill impairment during the year ended December 31, 2020.

9. ACCRUED EXPENSES

The following table sets forth the composition of accrued expenses as of December 31, 2021 and 2020 (in thousands):

	December 31,	
	2021	2020
Research and development	$ 1,841	$ 1,372
Payroll-related expenses	2,967	1,892
Restructuring charge related	1,497	—
Professional fees	1,941	684
Other	9	25
Total Accrued Expenses	**$ 8,255**	**$ 3,973**

10. COMMITMENTS AND CONTINGENCIES

Legal Proceedings

From time to time, the Company may become subject to legal proceedings, claims, and litigation arising in the ordinary course of business. When the Company becomes aware of a claim or potential claim, it assesses the likelihood of any loss or exposure. In accordance with authoritative guidance, the Company records loss contingencies in its financial statements only for matters in which losses are probable and can be reasonably estimated. Where a range of loss can be reasonably estimated with no best estimate in the range, the Company records the minimum estimated liability. If the loss is not probable or the amount of the loss cannot be reasonably estimated, the Company discloses the nature of the specific claim if the likelihood of a potential loss is reasonably possible, and the amount involved is material. The Company continuously assesses the potential liability related to the Company's pending litigation and revises its estimates when additional information becomes available. The Company is not currently a party to any material legal proceedings, other than as described below.

On August 19, 2021, August 31, 2021, and October 7, 2021, three substantially identical securities class action lawsuits captioned Bibb v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-07025, Cizek v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-07309, and Markman v. Sesen Bio, Inc. et al., Case No. 1:21-cv-08308 were filed against the Company and certain of its officers in the US District Court for the Southern District of New York. The three complaints allege violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder based on statements made by the Company concerning its BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. The three complaints seek compensatory damages and costs and expenses, including attorneys' fees. On October 29, 2021, the court consolidated the three cases under the caption In re Sesen Bio, Inc. Securities Litigation, Master File No. 1:21-cv-07025-AKH (the "Securities Litigation"), and appointed Ryan Bibb, Rodney Samaan, Lionel Dreshaj and Benjamin Dreshaj ("Lead Plaintiffs") collectively as the lead plaintiffs under the Private Securities Litigation Reform Act. On November 1, 2021, two stockholders filed motions to reconsider asking the court to appoint a different lead plaintiff. The court has not ruled on those motions at this time. On November 24, 2021, defendants filed a motion to transfer venue to the US District Court for the District of Massachusetts. That motion was fully briefed as of December 13, 2021, but the court has not yet ruled on that motion. On December 6, 2021, the Lead Plaintiffs filed an amended class action complaint (the "Amended Complaint"). The Amended Complaint alleges the same violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder on the same theory as the prior complaints. Defendants' response to the Amended Complaint is due to be filed on March 7, 2022.

On September 20, 2021 and September 24, 2021, two substantially similar derivative lawsuits captioned Myers v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-11538 and D'Arcy v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-11577 were filed against the Company's board of directors and certain of its officers in the US District Court for the District of Massachusetts, with the Company named as a nominal defendant. On January 12, 2022, a third derivative complaint captioned Tang v. Sesen Bio, Inc., et al., was filed in Superior Court in Massachusetts against the Company's board of directors and certain of its officers in the US District Court for the District of Massachusetts, with the Company named as nominal defendant, but no defendant has yet been served. The three derivative complaints allege breach of fiduciary duties, waste of corporate assets, and violations of federal securities laws based on statements made by the Company concerning its BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. The D'Arcy complaint further alleges unjust enrichment, abuse of control, gross mismanagement and aiding and abetting thereof. The three derivative complaints seek unspecified damages, restitution and disgorgement of profits, benefits and compensation obtained by the defendants and costs and expenses, including attorneys' fees. On October 18, 2021, the court consolidated the two federal cases under the caption In re Sesen Bio, Inc. Derivative Litigation, Lead Case No. 1:21-cv-11538 (the "Federal Derivative Litigation"). On December 22, 2021, the court entered a joint stipulation among the parties

to stay the Federal Derivative Litigation until after a ruling on any motion to dismiss filed by defendants in the Securities Litigation. Defendants intend to seek a similar stay of the state court derivative litigation in the event any defendant is served.

The Company believes that these lawsuits are without merit and intends to vigorously defend against them. The lawsuits are in the early stages and, at this time, no assessment can be made as to the likely outcome or whether the outcome will be material to the Company.

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.

11. LEASES

The Company accounts for operating leases under ASC Topic 842, *Leases*. The Company's lease portfolio includes an operating lease for its 31,100 square foot facility in Winnipeg, Manitoba which consists of manufacturing, laboratory, warehouse and office space. In September 2020, the Company entered into an extension of this lease for an additional two years, through September 2022, with a right to extend the lease for one subsequent three-year term. The minimum monthly rent under this lease is CAD $18,100 (approximately $14,300 at exchange rates in effect on December 31, 2021). In addition to rent expense, the Company expects to incur CAD $18,200 per month related to operating expenses (approximately $14,300 at exchange rates in effect on December 31, 2021). Operating lease cost under this lease, including the related operating costs, were $0.3 million and $0.3 million for the year ended December 31, 2021 and $0.3 million and $0.3 million for the year ended December 31, 2020, respectively.

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 term of the lease.

In addition, the Company has short-term property leases for modular office space for 1) its corporate headquarters in Cambridge, MA and 2) office space in Philadelphia, PA. The short-term leases renew every three months to six months and currently extend through June 2022 and May 2022, respectively. The minimum monthly rent for these office spaces is $2,100 and $18,400, respectively, which is subject to change if and as the Company adds space to or deducts space from the leases.

The components of lease cost for the years ended December 31, 2021 and 2020 is as follows (in thousands):

	Year Ended December 31, 2021	Year Ended December 31, 2020
Lease Cost:		
Operating lease (including related operating costs)	$ 327	$ 301
Short term property leases	262	261
Total lease costs	**$ 589**	**$ 562**

Supplemental Information:	Year Ended December 31, 2021	Year Ended December 31, 2020
Weighted-average remaining lease term (years)	0.75	1.75
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, 2021 (in thousands):

Minimum Lease Payments:	Year Ended December 31, 2021
Total future minimum lease payments (2022)	$ 129
Less: Amounts representing present value adjustment	(5)
Operating lease liabilities, net of current portion	**$ 124**

12. STOCKHOLDERS' EQUITY DEFICIT

Equity Financings

ATM Offering

In November 2019, the Company entered into an Open Market Sale Agreement SM (the "Sale Agreement") with Jefferies LLC ("Jefferies"), under which the Company may issue and sell shares of its common stock, par value $0.001 per share, from time to time (the “ATM Offering”) for an aggregate sales price of up to $35 million through Jefferies. In October 2020 and February 2021, the Company entered into Amendments No. 1 and No. 2 to the Sale Agreement, respectively. Amendments No. 1 and No. 2 modified the Sale Agreement to reflect that the Company may issue and sell shares of its common stock from time to time for an aggregate sales price of up to an additional $50.0 million and $34.5 million, respectively. In June 2021, the Company entered into Amendment No. 3 to the Sale Agreement, which modified the Sale Agreement to remove the maximum dollar amount of shares of common stock that may be sold pursuant to the Sale Agreement. In June and July 2021, the Company filed prospectus supplements with the SEC in connection with the offer and sale of up to an aggregate of $200 million of common stock pursuant to the Sale Agreement. Sales 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 Company's common stock. The Company may sell shares of its common stock efficiently from time to time but has no obligation to sell any of its common stock and may at any time suspend offers under the Sale Agreement or terminate the Sale Agreement. Subject to the terms and conditions of the Sale 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 minimum price set by the Company from time to time. 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 under the Sale Agreement. The Company raised $175.0 million of net proceeds from the sale of 56.9 million shares of common stock at a weighted-average price of $3.17 per share during the year ended December 31, 2021, compared to $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 during the year ended December 31, 2020. Share issuance costs, including sales agent commissions, related to the ATM Offering totaled $5.4 million and $1.2 million during the year ended December 31, 2021 and 2020, respectively.

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.

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, 2021 and 2020.

Common Stock

Following approval by the Company’s stockholders on May 3, 2021, an amendment became effective to the Certificate of Incorporation that increased the number of authorized shares of common stock from 200 million to 400 million, of which 199 million and 140 million shares were issued and outstanding as of December 31, 2021 and 2020, 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, 2021 and 2020 (in thousands):

	December 31,	
	2021	2020
Shares of common stock issued	199,464	140,450
Shares of common stock reserved for issuance for:		
Warrants	199	2,247
Stock options	15,703	10,147
RSUs	3,041	—
Shares available for grant under 2014 Stock Incentive Plan	8,933	4,863
Shares available for sale under 2014 Employee Stock Purchase Plan	2,300	—
Total shares of common stock issued and reserved for issuance	**229,640**	**157,707**

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, 2021 (in thousands):

Issued	Exercise Price	Expiration	December 31, 2020	Issued	(Exercised)	(Cancelled)	December 31, 2021
Jun-2019	$1.47	Jun-2020	—	—	—	—	—
Mar-2018	$0.55*	Mar-2023	1,705	—	(1,573)	—	132
Nov-2017	$0.55*	Nov-2022	487	—	(475)	—	12
May-2015	$11.83	Nov-2024	28	—	—	—	28
Nov-2014	$11.04	Nov-2024	27	—	—	—	27
			2,247	**—**	**(2,048)**	**—**	**199**

** 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, 2021, the Company received proceeds of $1.1 million from the exercises of 1.6 million 2018 Warrants and 0.5 million 2017 Warrants.

Warrant Modifications

In October 2019, the Company entered into transactions with holders of its outstanding 2018 Warrants and 2017 Warrants to purchase the Company's common stock. At such time, the 2018 Warrants and 2017 Warrants utilized the same form of warrant, which contained 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

In October 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 to lower the exercise price of the warrants to $0.55; 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

In October 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, 2021, there has been no adjustment to the exercise price of these warrants.

13. EARNINGS (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, 2021, 2020 and 2019 as the Company's participating securities do not have any obligation to absorb net losses.

For purposes of the diluted net loss per share calculation, common stock equivalents are excluded from the calculation if their effect would be anti-dilutive.

The following potentially dilutive securities outstanding as of December 31, 2021, 2020 and 2019 have been excluded from the denominator of the diluted loss per share of common stock outstanding calculation (in thousands):

	December 31,		
	2021	**2020**	**2019**
Warrants	199	2,247	22,895
Stock options	15,703	10,147	6,236
Total	**15,902**	**12,394**	**29,131**

14. 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 and Comprehensive Loss for the years ended December 31, 2021, 2020 and 2019 (in thousands):

	Year ended December 31,		
	2021	**2020**	**2019**
Research and development	$ 973	$ 350	$ 188
General and administrative	4,170	1,407	1,049
Total Share Based Compensation	**$ 5,143**	**$ 1,757**	**$ 1,237**

2014 Stock Incentive Plan

The Company's 2014 Stock Incentive Plan, as amended (the "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 restricted stock 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.

At the Annual Meeting of the Company's 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. At the Annual Meeting of the Company's stockholders in May 2021, the Company's stockholders approved an amendment to the 2014 Plan that increased by 12 million the number of shares of common stock reserved for issuance under the 2014 Plan. There were approximately 8.9 million shares of common stock available for issuance under the 2014 Plan as of December 31, 2021.

Stock options outstanding under the 2014 Plan 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 approximately 12.8 million stock options outstanding under the 2014 Plan as of December 31, 2021.

On September 9, 2021, the Board of Directors and the Compensation Committee of the Company approved a retention program for all current employees, except for the Chief Executive Officer, pursuant to which the Company will provide certain incentives designed to retain such employees (the “Retention Program”). Pursuant to the Retention Program and effective as of October 1, 2021, the Company’s non-executive employees received a combination of a cash bonus award and a one-time restricted stock unit (“RSU”) award which vests in full on September 30, 2022, subject to continued employment through September 30, 2022. Each RSU represents a contingent right to receive one share of the Company’s common stock. The Company recorded an expense of $0.5 million for retention-related RSUs for the year ended December 31, 2021. Additionally, the Company expensed $0.6 million in relation to the cash bonus portion of the retention program.

Also pursuant to the Retention Program and effective as of October 1, 2021, the Company’s executive officers, except for the Chief Executive Officer, were granted a one-time performance-based restricted stock unit (“PSU”) award equal to the value of approximately fifty percent of current base salary. Each PSU represents a contingent right to receive one share of the Company’s common stock upon the satisfaction of pre-determined performance criteria. Subject to continued employment, such awards vest on September 30, 2023 upon the determination by the Compensation Committee of the level of achievement of certain key milestones consisting of a clinical trial milestone, an employee retention milestone and cash management milestones. As none of the retention milestones were met in the year ended December 31, 2021 and achievement was deemed not probable, the Company did not record expenses for retention-related PSUs. As of December 31, 2021, the unrecognized compensation expense for the retention-related PSUs, granted on October 1, 2021, was $0.4 million.

A summary of the status of restricted stock units is presented below:

	Restricted Stock Units (in thousands)
Unvested at December 31, 2020	—
Granted RSU	2,482
Granted PSU	559
Unvested at December 31, 2021	**3,041**

The weighted average remaining contractual life of unvested RSUs and PSUs as of December 31, 2021 is 9.75 years. The Company did not grant restricted stock units during the years ended December 31, 2020 and 2019.

2009 Stock Incentive Plan

The Company maintains a 2009 Stock Incentive Plan, as amended and restated (the "2009 Plan"), which provided for the grant of incentive and non-qualified stock options and restricted stock awards and restricted stock 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 approximately 0.1 million fully vested stock options outstanding under the 2009 Plan as of December 31, 2021.

Out-of-Plan Inducement Grants

From time to time, the Company has granted equity awards to its newly hired employees, including executives, 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. There were approximately 2.8 million stock options outstanding which were granted as employment inducement awards outside of the 2014 Plan as of December 31, 2021.

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, 2021, 2020 and 2019:

	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, 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
Granted	8,273	$3.32		
Exercised	(34)	$1.23		
Canceled or forfeited	(2,683)	$3.70		
Outstanding at December 31, 2021	15,703	$1.93	8.03	$ 82
Exercisable at December 31, 2021	7,562	$1.65	7.41	$ 59

The Company recognized share-based compensation expense of $5.1 million for the year ended 2021. The stock option related expenses were $4.6 million, $1.8 million and $1.2 million for the years ended December 31, 2021, 2020 and 2019, respectively. The RSU related expense was $0.5 million for the year ended December 31, 2021. The Company did not record RSU related expenses for the years ended December 31, 2020 and 2019. As of December 31, 2021, there was $10.4 million of total unrecognized compensation cost related to non-vested stock options which the Company expects to recognize over a weighted-average period of 2.7 years. The weighted-average grant-date fair value of stock options granted during the year ended December 31, 2021, 2020 and 2019 were $2.16, $0.56 and $1.02, respectively. The total intrinsic value of stock options exercised for the years ended December 31, 2021, 2020 and 2019 was de minimis.

For the years ended December 31, 2021, 2020 and 2019, 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,		
	2021	2020	2019
Fair market value	$3.32	$0.87	$1.02
Grant exercise price	$3.32	$0.87	$1.02
Expected term (in years)	6.0	6.1	6.0
Risk-free interest rate	0.9%	1.3%	2.1%
Expected volatility	74.6%	71.5%	78.1%
Dividend yield	—%	—%	—%

15. 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. At the Annual Meeting of the Company's stockholders in May 2021, the Company's stockholders approved an amendment to the 2014 ESPP that increased by 2.3 million the number of shares of

common stock reserved for issuance under the 2014 ESPP. 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 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 common stock issued and sold pursuant to the 2014 ESPP are shown on the consolidated statements of changes in stockholders' equity (deficit). As of December 31, 2021, there were 2.3 million shares of common stock available for sale under the 2014 ESPP. The Company sold a de minimis number of shares under the ESPP for the years ended December 31, 2021, 2020 and 2019, respectively.

Defined Contribution Plans

United States - 401(k) Plan

The Company maintains a 401(k) defined contribution retirement plan which covers all of its US 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, 2021, 2020 and 2019, 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, 2021, 2020 and 2019, respectively.

16. 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,		
	2021	**2020**	**2019**
Country			
United States	$ (32,757)	$ (35,529)	$ (27,468)
Canada	24,148	14,577	(80,032)
Total Loss Before Income Taxes	**$ (8,609)**	**$ (20,952)**	**$ (107,500)**

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

	Year Ended December 31,		
	2021	2020	2019
Current Tax Provision			
Federal	$ —	$ —	$ —
State	—	—	—
Foreign	(286)	(1,445)	—
Total current (provision)	$ (286)	$ (1,445)	$ —
Deferred tax provision			
Federal	$ —	$ —	$ —
State	—	—	—
Foreign	8,559	—	—
Total deferred benefit (provision)	$ 8,559	$ —	$ —
Total Tax Benefit (Provision)	**$ 8,273**	**$ (1,445)**	**$ —**

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

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,		
	2021	2020	2019
United States federal statutory income tax rate	21.0 %	21.0 %	21.0 %
Impact of foreign rate differential	(15.9)	(4.2)	4.4
State taxes, net of federal benefit	2.3	2.0	0.6
Stock option cancellations	(1.1)	(0.2)	—
Contingent consideration	178.2	14.4	(18.0)
General business credits and other credits	2.4	6.6	0.4
Permanent differences	(1.4)	0.2	—
Other	(13.8)	(2.1)	(0.5)
Foreign taxes	(3.3)	(6.9)	—
Change in valuation allowance	(72.3)	(37.7)	(7.9)
Effective Income Tax Rate	**96.1 %**	**(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,		
	2021	2020	2019
Deferred tax assets:			
NOL carryforwards	$ 63,381	$ 57,935	$ 50,727
R&D credit carryforwards	4,316	3,787	4,385
Accruals and other	4,058	3,811	2,464
Capitalized start-up costs	53	70	91
Other	41	28	57
Gross deferred tax assets	71,849	65,631	57,724
Deferred tax liabilities:			
IPR&D	(3,969)	(12,528)	(12,528)
Gross deferred tax liabilities	(3,969)	(12,528)	(12,528)
Valuation allowance	(71,849)	(65,631)	(57,724)
Net Deferred Tax Liability	**$ (3,969)**	**$ (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 $71.8 million, $65.6 million and $57.7 million have been established as of December 31, 2021, 2020 and 2019, respectively. The $6.2 million increase in the valuation allowance was attributable to the NOL for the year ended December 31, 2021.

The net deferred tax liability of $4.0 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, 2021 (in millions):

	Amount	Expiration Beginning in	Through
United States:			
Federal NOL carryforwards - indefinite	$ 101.1	None	None
Federal NOL carryforwards	$ 118.9	2030	2038
State NOL carryforwards	$ 138.4	2030	2040
Federal R&D credit carryforwards	$ 2.5	2027	2040
State R&D credit carryforwards	$ 0.8	2027	2040
Canada:			
Federal non-capital loss carryforwards	$ 31.2	2035	2040
Federal scientific research and experimental development expense carryforwards	$ 5.1	2032	2040
Federal and provincial investment tax credit carryforwards	$ 1.2	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 non-US 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.

We assess the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where we have operations to determine the potential effect on our business and any assumptions we have made about our future taxable income. We cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on our business if they were to be enacted. Beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminates the currently available option to deduct research and development expenditures and requires taxpayers to amortize them over five years. The U.S. Congress is considering legislation that would defer the amortization requirement to future periods, however, we have no assurance that the provision will be repealed or otherwise modified.

As of December 31, 2021, 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 2020 remain subject to examination by the taxing jurisdictions. There are currently no audits in process in any of the Company's tax filing jurisdictions.

17. LICENSE AGREEMENTS

In-License Agreements

License Agreement with Zurich

The Company has a license agreement with the University of Zurich ("Zurich") which grants the Company exclusive license rights, with the right to sublicense, to make, have made, use and sell under certain patents primarily directed to the Company's targeting agent, including an EpCAM chimera and related immunoconjugates and methods of use and manufacture of the same (the “Zurich License Agreement”). These patents cover some key aspects of Vicineum. Upon the Company's receipt of the CRL regarding the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC, the Company became obligated to pay $0.5 million in a milestone payment to Zurich. 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 $0.5 million and $0.3 million related to achievement of a development milestone, (the submission of the Company’s BLA with the FDA in December 2020), in the year ended December 31, 2021 and 2020, respectively, and a regulatory milestone, (the Company’s receipt of the CRL from the FDA in August 2021), in the twelve months ended December 31, 2021, respectively.

License Agreement with Micromet

The Company has a License Agreement with Micromet AG ("Micromet"), now part of Amgen, Inc., which grants it nonexclusive rights, with certain sublicense rights, for know-how and patents allowing exploitation of certain single chain antibody products (the “Micromet License Agreement”). These patents cover some key aspects of Vicineum. Under the terms of the Micromet License Agreement, as of December 31, 2021, the Company may be obligated to pay up to €2.4 million in milestone payments for the first product candidate that achieves applicable regulatory and sales-based development milestones (approximately $2.7 million at exchange rates in effect on December 31, 2021). 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 (approximately $56,625 at exchange rates in effect as of December 31, 2021), which can be credited towards any royalty payment the Company owes to Micromet. The Company recorded an expense of €0.7 million ($0.9 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 for Vicineum with the FDA in December 2020. The Company recorded an expense of €0.5 million ($0.6 million) related to the submission of the MAA to the EMA for Vysyneum™ in the first quarter of 2021. Vysyneum is the proprietary brand name that was conditionally approved by the EMA for oportuzumab monatox in the European Union.

License Agreement with XOMA

The Company has a license agreement with XOMA Ireland Limited ("XOMA") which grants it non-exclusive rights to certain XOMA patent rights and know-how related to certain expression technology, including plasmids, expression strains, plasmid maps and production systems (the “XOMA License Agreement”). 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 Vicineum’s clinical development pathway. The Company is also required to pay a 2.5% royalty on the net sales for products incorporating XOMA’s technology, which includes 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 Agreements

Roche License Agreement

In June 2016, the Company entered into the license agreement with Roche (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 "Roche 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 Roche Licensed Intellectual Property that contains an IL-6 antagonist anti-IL monoclonal antibody (“Roche 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 next of which is $30 million for initiation of the first Phase III clinical trial, (ii) $50 million in regulatory milestones and (iii) $75 million in commercialization milestones. Additional amounts of up to $65 million are payable upon the achievement of specified development and regulatory milestones in a second indication.

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. In December 2021, a $20 million milestone was achieved due to Roche initiating a Phase II clinical trial. Management evaluated the milestone under ASC 606 and determined it is probable that a significant revenue reversal will not occur in future periods, which was not the case in the previous quarter. Accordingly, the Company invoiced Roche $20 million with payment terms of 30 days following the achievement of the corresponding milestone event, pursuant to the Roche License Agreement and $20 million was recorded as license revenue and accounts receivables in the fourth quarter of 2021. In January 2022, the payment of $20 million was received.

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 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 Roche Licensed Product until the day before Initiation of the first Phase 3 study for a Roche Licensed Product, in which case Roche is required to pay the Company $135 million within 30 days after Roche's exercise of such buy-out option and receipt of an invoice from the Company, or (ii) Roche may exercise a buy-out option following the day after Initiation of the first Phase 3 study for a Roche 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 Roche Licensed Product in either the United States or in the EU, in which case Roche is required to pay the Company, within 30 days after Roche’s exercise of such buy-out option and receipt of an invoice from the Company, $265 million, which amount would be reduced to $220 million if none of the Company’s patent rights containing a composition of matter claim covering any compound or Roche Licensed Product has issued in the EU.

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 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 Roche Licensed Product, there is a period of twelve months where Roche is not conducting sufficient development activities with respect to the products made from the Roche Licensed Intellectual Property.

OUS Business Development Partnership Agreements

Qilu License Agreement

On July 30, 2020, the Company and its a wholly-owned subsidiary, Viventia Bio, Inc., entered into an exclusive license agreement with Qilu (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 “Qilu 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 Qilu Licensed Product in Greater China. The Company retains (i) development, and commercialization rights in the rest of the world excluding Greater China, the Middle East and North Africa region ("MENA”) and Turkey 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 a one-time upfront cash payment of $12 million, and milestone payments totaling up to $23 million upon the achievement of certain technology transfer, development and regulatory milestones. All payments were to be inclusive of value-added tax ("VAT"), which can be withheld by Qilu upon payment, and for which future recovery of such taxes may be available.

Qilu also agreed to pay the Company a 12% royalty based upon annual net sales of Qilu Licensed Products in Greater China. The royalties are payable on a Qilu 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 Qilu 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 Qilu Licensed Product in such region, and (iii) the expiration of regulatory or data exclusivity for such Qilu Licensed Product in such region (collectively, the “Royalty Terms”). The royalty rate is subject to reduction under certain circumstances, including when there is no valid claim of a licensed patent that covers a Qilu Licensed Product in a particular region or no data or regulatory exclusivity of a Qilu Licensed Product in a particular region.

Qilu is responsible for all costs related to developing, obtaining regulatory approval of and commercializing the Qilu 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 Qilu 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 Qilu 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 Qilu Licensed Product necessary for Qilu to develop and

commercialize the Qilu 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 ("NMPA") for the Qilu Licensed Product has been obtained.

The Qilu License Agreement will expire on a Qilu 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. In 2020, 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 agreements 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 Investigational New Drug application for Vicineum submitted by Qilu to the Center for Drug Evaluation of the NMPA was accepted for review in January 2021 and approved in March 2021, resulting in a $3 million milestone payment from Qilu, the first milestone payment out of the $23 million in potential milestone payments. The Company recorded $2.8 million (net of VAT) as license revenue during the three-month period ended March 31, 2021. The Company received the payment in 2021.

In June 2021, the Qilu License Agreement was recognized by Shandong Province, Bureau of Science and Technology as a "Technology Transfer". An agreement that is designated as a Technology Transfer shall be entitled to a tax incentive of VAT recovery. As such, the Company recorded $0.9 million of revenue during the three months ended June 30, 2021 for additional purchase price resulting from Qilu's obligation to pay Sesen an amount equal to its recovery of VAT. The Company will not be subject to VAT on future potential milestone payments from Qilu.

MENA License Agreement

On November 30, 2020, the Company entered into a license agreement with a third party 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 MENA region, ("MENA License Agreement"). The Company retains development and commercialization rights in the rest of the world excluding Greater China, Turkey and MENA. In consideration for the rights granted by the Company, the counterparty to the MENA License Agreement 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 to the Company milestone payments upon the achievement of certain sales-based milestones as well as a royalty based upon annual net sales in the MENA region for the term of the MENA License Agreement.

The MENA License Agreement is 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 remaining upfront payment ($1.5 million) is subject to a refund if certain regulatory approvals in MENA are not obtained and recorded as long-term deferred revenue as of December 31, 2021. The Company also concluded that its agreements 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. The first performance obligation (delivery of the license, associated know-how and certain documentation) was achieved during the quarter ended March 31, 2021; as such, revenue of $1.5 million has been recognized. 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, 2021, none of these additional amounts were reasonably certain to be achieved due to the nature and timing of the underlying activities.

EIP License Agreement

On August 5, 2021, the Company entered into an exclusive license agreement with EİP Eczacıbaşı İlaç Pazarlama A.Ş., ("EIP") pursuant to which it granted EIP an exclusive license to register and commercialize Vicineum for the treatment of BCG-unresponsive NMIBC in Turkey and Northern Cyprus (the "EIP License Agreement). Under the terms of the License Agreement, the Company is entitled to receive an upfront payment of $1.5 million. The Company is in the process of amending the license agreement to defer payment of the upfront payment to coincide with the potential FDA approval of Vicineum. The

Company is eligible to receive additional regulatory and commercial milestone payments of $2.0 million and is also entitled to receive a 30% royalty on net sales in Turkey and Northern Cyprus. The EIP License Agreement is subject to the provisions of ASC 606 and as of December 31, 2021, none of these amounts have been received by the Company. No initial transaction price was estimated by management as of December 31, 2021, as the upfront payment is subject to a refund if certain regulatory approvals in the US are not obtained. The Company also concluded that its promises under the EIP License Agreement represented two distinct performance obligations, the first of which is a bundled performance obligation related to the delivery of the license and associated know-how. The second performance obligation relates to the delivery of manufactured product. Additional variable consideration, determined to be allocated entirely to the bundled license performance obligation, to be paid to the Company based upon future regulatory milestones will be recognized as achievement of those milestones. 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, 2021, none of these additional amounts were reasonably certain to be achieved due to the nature and timing of the underlying activities.

18. 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, 2021, 2020 and 2019, 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, 2021, 2020 and 2019, the Company paid $0.1 million under this license agreement.

Due to his retirement in July 2019, Mr. Dan was not deemed a related party during the twelve-month period ended December 31, 2020 and 2021; as such, only payments made through the nine month period ended September 30, 2019 are considered payments to a related party.

19. RESTRUCTURING AND RELATED ACTIVITIES

On August 30, 2021, the Company approved a restructuring plan to reduce operating expenses and better align its workforce with the needs of its business following receipt of the CRL from the FDA regarding the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC (the “Restructuring Plan”).

The Restructuring Plan included a reduction in the Company’s workforce by 18 positions (or approximately 35% of the Company’s workforce as of the date of the Restructuring Plan), as well as additional cost-saving initiatives intended to preserve capital while the Company continues development of Vicineum. The following is a summary of accrued restructuring costs related to the Restructuring Plan:

	December 31, 2021
	(in thousands)
Severance and benefits costs	$ 2,792
Contract termination costs	2,736
Other restructuring costs	—
Total restructuring costs	$ 5,528
Cash payments	(4,031)
Balance at December 31, 2021	$ 1,497

Restructuring costs related to the Restructuring Plan were recorded in operating expenses in the Company’s Consolidated Statements of Operations and Comprehensive Loss in the year ended December 31, 2021. The Company expects that substantially all of the accrued restructuring costs as of December 31, 2021 will be paid in cash by the end of September 2022.

20. SUBSEQUENT EVENTS

On January 7, 2022, the FDA granted the Company's request for a Type C Meeting ("Type C Meeting") to discuss the study protocol for an additional Phase 3 clinical trial that the Company plans to conduct for potential resubmission of a BLA for Vicineum™ for the treatment of BCG-unresponsive NMIBC. The Type C Meeting has been scheduled for March 28, 2022.

On January 24, 2022, the Company received written notice (the "Notice") from Nasdaq indicating that the Company is not in compliance with the $1.00 minimum bid price requirement for continued listing on The Nasdaq Global Market, as set forth in Nasdaq Listing Rule 5450(a)(1). The Notice has no effect at this time on the listing of the Company's common stock (the "Common Stock"), which continues to trade on The Nasdaq Global Market under the symbol "SESN". In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has a period of 180 calendar days, or until July 25, 2022, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of the Company's Common Stock must meet or exceed $1.00 per share for a minimum of ten consecutive business days during this 180-day period.

If the Company is not in compliance by July 25, 2022, the Company may qualify for a second 180 calendar day compliance period. If the Company does not qualify for, or fail to regain, compliance during the second compliance period, then Nasdaq will notify the Company of its determination to delist the Company's common stock, at which point the Company would have an opportunity to appeal the delisting determination to a Nasdaq hearings panel.

The Company intends to actively monitor the closing bid price of the Company's common stock and may, if appropriate, consider implementing available options to regain compliance with the minimum bid price requirement under the Nasdaq Listing Rules.

As previously announced, the Company's Board of Directors (the "Board") initiated an independent internal review conducted by outside counsel with the assistance of subject matter experts focusing on the conduct of, and data generated from, the clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC, and the overall safety of Vicineum (the "Review"). The Review took place over the course of five months, involved full cooperation from the Company's management team, a review of more than 600,000 documents, and 39 interviews of current and former employees and consultants. It is now complete. As a result of the Review, the Board continues to fully support the Company's current management team and believes no changes or amendments relating to the Company's prior disclosures to the SEC or the FDA relating to Vicineum, the Phase 3 VISTA trial for Vicineum for the treatment of BCG-unresponsive NMIBC, or the BLA for Vicineum are warranted. The Company intends to work cooperatively with the FDA in preparing for an additional Phase 3 clinical trial for Vicineum.

Exhibit 4.1

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 400,000,000 shares of common stock with a par value of $0.001 per share. As of February 21, 2022, there were 199,463,645 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.

Anti-Takeover Effects of Our Certificate of Incorporation and By-laws and Delaware Law

Staggered Board; Removal of Directors. Our certificate of incorporation and our bylaws divide our board of directors into three classes with staggered three-year terms. In addition, our certificate of incorporation and our bylaws provide that directors may be removed only for cause and only by the affirmative vote of the holders of 75% of our shares of common stock present in person or by proxy and entitled to vote. Under our certificate of incorporation and bylaws, any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office. Furthermore, our certificate of incorporation provides that the authorized number of directors may be changed only by the resolution of our board of directors. The classification of our board of directors and the limitations on the ability of our stockholders to remove directors, change the authorized number of directors and fill vacancies

could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our company.

Stockholder Action; Special Meeting of Stockholders; Advance Notice Requirements for Stockholder Proposals and Director Nominations. Our certificate of incorporation and our bylaws provide that any action required or permitted to be taken by our stockholders at an annual meeting or special meeting of stockholders may only be taken if it is properly brought before such meeting and may not be taken by written action in lieu of a meeting. Our certificate of incorporation and our bylaws also provide that, except as otherwise required by law, special meetings of the stockholders can only be called by the chairman of our board of directors, our chief executive officer or our board of directors. In addition, our bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of candidates for election to our board of directors. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors, or by a stockholder of record on the record date for the meeting who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities. These provisions also could discourage a third party from making a tender offer for our common stock because even if the third party acquired a majority of our outstanding voting stock, it would be able to take action as a stockholder, such as electing new directors or approving a merger, only at a duly called stockholders meeting and not by written consent.

Super-Majority Voting. The Delaware General Corporation Law provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws unless a corporation's certificate of incorporation or bylaws, as the case may be, requires a greater percentage. Our bylaws may be amended or repealed by a majority vote of our board of directors or the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in any annual election of directors. In addition, the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in any election of directors is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of our certificate of incorporation described above.

Delaware Law. We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding upon consummation of the transaction, excluding for purposes of determining the number of shares outstanding (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the consummation of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;

- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, Inc.

Stock Market Listing

Our common stock is listed for trading on the Nasdaq Global Market under the symbol “SESN.”

Exhibit 10.8

INDEMNIFICATION AGREEMENT

This Indemnification Agreement ("Agreement") is made as of [ ], 20[ ] by and between Sesen Bio, Inc., a Delaware corporation (the "Company"), and [ ] (the "Indemnitee"). This Agreement supersedes and replaces any and all previous Agreements between the Company and Indemnitee covering the subject matter of this Agreement.

RECITALS

WHEREAS, highly competent persons have become more reluctant to serve publicly-held corporations as directors, officers or in other capacities unless they are provided with adequate protection through insurance or adequate indemnification against inordinate risks of claims and actions against them arising out of their service to and activities on behalf of the corporation;

WHEREAS, the Board of Directors of the Company (the "Board") has determined that, in order to attract and retain qualified individuals, the Company will attempt to maintain on an ongoing basis, at its sole expense, liability insurance to protect persons serving the Company and its subsidiaries from certain liabilities. Although the furnishing of such insurance has been a customary and widespread practice among United States-based corporations and other business enterprises, the Company believes that, given current market conditions and trends, such insurance may be available to it in the future only at higher premiums and with more exclusions. At the same time, directors, officers, and other persons in service to corporations or business enterprises are being increasingly subjected to expensive and time-consuming litigation relating to, among other things, matters that traditionally would have been brought only against the Company or business enterprise itself. The Certificate of Incorporation of the Company (as the same may be amended from time to time, the "Certificate of Incorporation") requires indemnification of the officers and directors of the Company. Indemnitee may also be entitled to indemnification pursuant to the General Corporation Law of the State of Delaware (the "DGCL"). The Certificate of Incorporation and the DGCL expressly provide that the indemnification provisions set forth therein are not exclusive, and thereby contemplate that contracts may be entered into between the Company and members of the board of directors, officers and other persons with respect to indemnification;

WHEREAS, the uncertainties relating to such insurance and to indemnification have increased the difficulty of attracting and retaining such persons;

WHEREAS, the Board has determined that the increased difficulty in attracting and retaining such persons is detrimental to the best interests of the Company and its stockholders and that the Company should act to assure such persons that there will be increased certainty of such protection in the future;

WHEREAS, it is reasonable, prudent and necessary for the Company contractually to obligate itself to indemnify, and to advance expenses on behalf of, such persons to the fullest extent permitted by applicable law so that they will serve or continue to serve the Company free from undue concern that they will not be so indemnified;

WHEREAS, this Agreement is a supplement to and in furtherance of the Certificate of Incorporation and any resolutions adopted pursuant thereto, and shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder;

WHEREAS, Indemnitee does not regard the protection available under the Certificate of Incorporation and insurance as adequate in the present circumstances, and may not be willing to serve as an officer or director without adequate protection, and the Company desires Indemnitee to serve in such capacity. Indemnitee is willing to serve, continue to serve and to take on additional service for or on behalf of the Company on the condition that he be so indemnified; and

[WHEREAS, Indemnitee is a representative of [ ] [and its affiliated investment funds] (the "Fund"), and has certain rights to indemnification and/or insurance provided by the Fund which Indemnitee and the Fund intend to be secondary to the primary obligation of the Company to indemnify Indemnitee as provided herein, with the Company's acknowledgement and agreement to the foregoing being a material condition to Indemnitee's willingness to serve on the Board;]

NOW, THEREFORE, in consideration of the premises and the covenants contained herein, the Company and Indemnitee do hereby covenant and agree as follows:

Section 1. Services to the Company. Indemnitee agrees to serve a[n] [director] [officer] of the Company. Indemnitee may at any time and for any reason resign from such position (subject to any other contractual obligation or any obligation imposed by operation of law), in which event the Company shall have no obligation under this Agreement to continue Indemnitee in such position. This Agreement shall not be deemed an employment contract between the Company (or of its subsidiaries or any Enterprise) and Indemnitee. Indemnitee specifically acknowledges that Indemnitee's employment with the Company (or of its subsidiaries or any Enterprise), if any, is at will, and the Indemnitee may be discharged at any time for any reason, with or without cause, except as may be otherwise provided in any written employment contract between Indemnitee and the Company (or of its subsidiaries or any Enterprise), other applicable formal severance policies duly adopted by the Board, or, with respect to service as a director or officer of the Company, by the Certificate of Incorporation, the Company's Bylaws, and the DGCL. The foregoing notwithstanding, this Agreement shall continue in force after Indemnitee has ceased to serve as a[n] [director] [officer] of the Company, as provided in Section 16 hereof.

Section 2. Definitions. As used in this Agreement:

(a) References to "agent" shall mean any person who is or was a director, officer, or employee of the Company or a subsidiary of the Company or other person authorized by the Company to act for the Company, to include such person serving in such capacity as a director, officer, employee, fiduciary or other official of another corporation, partnership, limited liability company, joint venture, trust or other enterprise at the request of, for the convenience of, or to represent the interests of the Company or a subsidiary of the Company.

(b) A "Change in Control" shall be deemed to occur upon the earliest to occur after the date of this Agreement of any of the following events:

i. Acquisition of Stock by Third Party. Any Person (as defined below) is or becomes the Beneficial Owner (as defined below), directly or indirectly, of securities of the Company representing forty percent (40%) or more of the combined voting power of the Company's then outstanding securities unless the change in relative Beneficial Ownership of the Company's securities by any Person results solely from a reduction in the aggregate number of outstanding shares of securities entitled to vote generally in the election of directors;

ii. Change in Board of Directors. During any period of two (2) consecutive years (not including any period prior to the execution of this Agreement), individuals who at the beginning of such period constitute the Board, and any new director (other than a director designated by a person who has entered into an agreement with the Company to effect a transaction described in Sections 2(b)(i), 2(b)(iii) or 2(b)(iv)) whose election by the Board or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the period or whose election or nomination for election was previously so approved, cease for any reason to constitute at least a majority of the members of the Board;

iii. Corporate Transactions. The effective date of a merger or consolidation of the Company with any other entity, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or its ultimate parent, as applicable) more than 51% of the combined voting power of the voting securities of the surviving entity or its ultimate parent, as applicable, outstanding immediately after such merger or consolidation and with the power to elect at least a majority of the board of directors or other governing body of such surviving entity or its ultimate parent, as applicable;

iv. Liquidation or Sale of Assets. The approval by the stockholders of the Company of a complete liquidation of the Company or an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets; and

v. Other Events. There occurs any other event of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A (or a response to any similar item on any similar schedule or form) promulgated under the Exchange Act (as defined below), whether or not the Company is then subject to such reporting requirement.

For purposes of this Section 2(b), the following terms shall have the following meanings:

(A) "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended from time to time.

(B) "Person" shall have the meaning as set forth in Sections 13(d) and 14(d) of the Exchange Act; provided, however, that Person shall exclude (i) the Company, (ii) any trustee or other fiduciary holding securities under an employee benefit plan of the Company, and (iii) any corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company.

(C) "Beneficial Owner" shall have the meaning given to such term in Rule 13d-3 under the Exchange Act; provided, however, that Beneficial Owner shall exclude any Person otherwise becoming a Beneficial Owner by reason of the stockholders of the Company approving a merger of the Company with another entity.

(D) "Corporate Status" describes the status of a person as a current or former director or officer of the Company or as a current or former director, manager, partner, officer, employee, agent, or trustee of any other entity or enterprise that such person is or was serving at the request of the Company.

(E) "Disinterested Director" shall mean a director of the Company who is not and was not a party to the Proceeding in respect of which indemnification is sought by Indemnitee.

(F) "Enterprise" shall mean the Company and any other corporation, limited liability company, partnership, joint venture, trust or other enterprise of which Indemnitee is or was serving at the request of the Company as a director, officer, trustee, partner, managing member, employee, agent or fiduciary.

(G) "Expenses" shall include all reasonable attorneys' fees, retainers, court costs, transcript costs, fees of experts and other professionals, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees, any federal, state, local or foreign taxes imposed on Indemnitee as a result of the actual or deemed receipt of any payments under this Agreement, ERISA excise taxes and penalties, and all other disbursements or expenses of the types customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, being or preparing to be a witness in, or otherwise participating in, a Proceeding. Expenses also shall include (i) Expenses incurred in connection with any appeal resulting from any Proceeding, including without limitation the premium, security for, and other costs relating to any cost bond, supersedeas bond, or other appeal bond or its equivalent, and (ii) for purposes of Section 14(d) only, Expenses incurred by Indemnitee in connection with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement, by litigation or otherwise. The parties agree that for the purposes of any advancement of Expenses for which Indemnitee has made written demand to the Company in accordance with this Agreement, all Expenses included in such demand that are certified by affidavit of Indemnitee's counsel as being reasonable shall be presumed conclusively to be reasonable. Expenses, however, shall not include amounts paid in settlement by Indemnitee or the amount of judgments or fines against Indemnitee.

(H) "Independent Counsel" shall mean a law firm, or a member of a law firm, that is experienced in matters of corporation law and neither presently is, nor in the past five years has been, retained to represent: (i) the Company or Indemnitee in any matter material to either such party (other than with respect to matters concerning the Indemnitee under this Agreement, or of other indemnitees under similar indemnification agreements), or (ii) any other party to the Proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term "Independent Counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company or Indemnitee in an action to determine Indemnitee's rights under this Agreement. The Company agrees to pay the reasonable fees and expenses of the Independent Counsel referred to above and to fully indemnify such counsel against any and all Expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.

(I) The term "Proceeding" shall include any threatened, pending or completed action, suit, claim, counterclaim, cross claim, arbitration, mediation, alternate dispute resolution mechanism, investigation, inquiry, administrative hearing or any other actual, threatened or completed proceeding, whether brought in the right of the Company or otherwise and whether of a civil, criminal, administrative, legislative, or investigative (formal or informal) nature, including any appeal therefrom, in which Indemnitee was, is or will be involved as a party, potential party, non-party witness or otherwise by reason of the fact that Indemnitee is or was a director or officer of the Company, by reason of any action taken by him (or a failure to take action by him) or of any action (or failure to act) on his part while acting pursuant to his Corporate Status, in each case whether or not serving in such capacity at the time any liability or Expense is incurred for which indemnification, reimbursement, or advancement of Expenses can

be provided under this Agreement. If the Indemnitee believes in good faith that a given situation may lead to or culminate in the institution of a Proceeding, this shall be considered a Proceeding under this paragraph.

(J) Reference to "other enterprise" shall include employee benefit plans; references to "fines" shall include any excise tax assessed with respect to any employee benefit plan; references to "serving at the request of the Company" shall include any service as a director, officer, employee or agent of the Company which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner he reasonably believed to be in the best interests of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in manner "not opposed to the best interests of the Company" as referred to in this Agreement.

Section 3. Indemnity in Third-Party Proceedings. The Company shall indemnify Indemnitee in accordance with the provisions of this Section 3 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding, other than a Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 3, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses, judgments, fines and amounts paid in settlement (including all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses, judgments, fines and amounts paid in settlement) actually and reasonably incurred by Indemnitee or on his behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the Company and, in the case of a criminal Proceeding had no reasonable cause to believe that his conduct was unlawful. The parties hereto intend that this Agreement shall provide to the fullest extent permitted by law for indemnification in excess of that expressly permitted by statute, including, without limitation, any indemnification provided by the Certificate of Incorporation, the Bylaws, vote of its stockholders or disinterested directors or applicable law.

Section 4. Indemnity in Proceedings by or in the Right of the Company. The Company shall indemnify Indemnitee in accordance with the provisions of this Section 4 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 4, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses actually and reasonably incurred by him or on his behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the Company. No indemnification for Expenses shall be made under this Section 4 in respect of any claim, issue or matter as to which Indemnitee shall have been finally adjudged by a court to be liable to the Company, unless and only to the extent that the Delaware Court of Chancery (the "Delaware Court") or any court in which the Proceeding was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnification for such expenses as the Delaware Court shall deem proper.

Section 5. Indemnification for Expenses of a Party Who is Wholly or Partly Successful. Notwithstanding any other provisions of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is a party to (or a participant in) and is successful, on the merits or otherwise, in any Proceeding or in defense of any claim, issue or matter therein, in whole or in part, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by him in connection therewith. If Indemnitee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, as to one or

more but less than all claims, issues or matters in such Proceeding, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by him or on his behalf in connection with or related to each successfully resolved claim, issue or matter to the fullest extent permitted by law. For purposes of this Section and without limitation, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, shall be deemed to be a successful result as to such claim, issue or matter.

Section 6. Indemnification For Expenses of a Witness. Notwithstanding any other provision of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is, by reason of his Corporate Status, a witness or otherwise asked to participate in any Proceeding to which Indemnitee is not a party, he shall be indemnified against all Expenses actually and reasonably incurred by him or on his behalf in connection therewith.

Section 7. Partial Indemnification. If Indemnitee is entitled under any provision of this Agreement to indemnification by the Company for some or a portion of Expenses, but not, however, for the total amount thereof, the Company shall nevertheless indemnify Indemnitee for the portion thereof to which Indemnitee is entitled.

Section 8. Additional Indemnification.

(a) Notwithstanding any limitation in Sections 3, 4, or 5, the Company shall indemnify Indemnitee to the fullest extent permitted by applicable law if Indemnitee is a party to or threatened to be made a party to any Proceeding (including a Proceeding by or in the right of the Company to procure a judgment in its favor) against all Expenses, judgments, fines and amounts paid in settlement (including all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses, judgments, fines and amounts paid in settlement) actually and reasonably incurred by Indemnitee in connection with the Proceeding.

(b) For purposes of Section 8(a), the meaning of the phrase “to the fullest extent permitted by applicable law” shall include, but not be limited to:

i. to the fullest extent permitted by the provision of the DGCL that authorizes or contemplates additional indemnification by agreement, or the corresponding provision of any amendment to or replacement of the DGCL, and

ii. to the fullest extent authorized or permitted by any amendments to or replacements of the DGCL adopted after the date of this Agreement that increase the extent to which a corporation may indemnify its officers and directors.

Section 9. Exclusions. Notwithstanding any provision in this Agreement [but subject to Section 15(e), however], the Company shall not be obligated under this Agreement to make any indemnification payment in connection with any claim made against Indemnitee:

(a) for which payment has actually been made to or on behalf of Indemnitee under any insurance policy or other indemnity provision, except with respect to any excess beyond the amount paid under any insurance policy or other indemnity provision; or

(b) for (i) an accounting of profits made from the purchase and sale (or sale and purchase) by Indemnitee of securities of the Company within the meaning of Section 16(b) of the Exchange Act (as defined in Section 2(b) hereof) or similar provisions of state statutory law or common law, or (ii) any reimbursement of the Company by the Indemnitee of any bonus or other incentive-based or equity-based compensation or of any profits realized by the Indemnitee from the sale of securities of the Company, as required in each case under the

Exchange Act (including any such reimbursements that arise from an accounting restatement of the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), or the payment to the Company of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 306 of the Sarbanes-Oxley Act); or

(c) except as provided in Section 14(d) of this Agreement, in connection with any Proceeding (or any part of any Proceeding) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against the Company or its directors, officers, employees or other indemnitees, unless (i) the Board authorized the Proceeding (or any part of any Proceeding) prior to its initiation or (ii) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law.

Section 10. Advances of Expenses. Notwithstanding any provision of this Agreement to the contrary (other than Section 14(d)), the Company shall advance, to the extent not prohibited by law, the Expenses incurred by Indemnitee in connection with any Proceeding (or any part of any Proceeding) not initiated by Indemnitee, and such advancement shall be made within thirty (30) days after the receipt by the Company of a statement or statements requesting such advances from time to time, whether prior to or after final disposition of any Proceeding. Advances shall be unsecured and interest free. Advances shall be made without regard to Indemnitee's ability to repay the Expenses and without regard to Indemnitee's ultimate entitlement to indemnification under the other provisions of this Agreement. In accordance with Section 14(d), advances shall include any and all reasonable Expenses incurred pursuing an action to enforce this right of advancement, including Expenses incurred preparing and forwarding statements to the Company to support the advances claimed. The Indemnitee shall qualify for advances upon the execution and delivery to the Company of this Agreement, which shall constitute an undertaking providing that the Indemnitee undertakes to repay the amounts advanced (without interest) to the extent that it is ultimately determined that Indemnitee is not entitled to be indemnified by the Company. No other form of undertaking shall be required other than the execution of this Agreement. This Section 10 shall not apply to any claim made by Indemnitee for which indemnity is excluded pursuant to Section 9.

Section 11. Procedure for Notification and Defense of Claim.

(a) Indemnitee shall notify the Company in writing of any matter with respect to which Indemnitee intends to seek indemnification or advancement of Expenses hereunder as soon as reasonably practicable following the receipt by Indemnitee of written notice thereof. The written notification to the Company shall include a description of the nature of the Proceeding and the facts underlying the Proceeding. To obtain indemnification under this Agreement, Indemnitee shall submit to the Company a written request, including therein or therewith such documentation and information as is reasonably available to Indemnitee and is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification following the final disposition of such Proceeding. The omission by Indemnitee to notify the Company hereunder will not relieve the Company from any liability which it may have to Indemnitee hereunder or otherwise than under this Agreement, and any delay in so notifying the Company shall not constitute a waiver by Indemnitee of any rights under this Agreement. The Secretary of the Company shall, promptly upon receipt of such a request for indemnification, advise the Board in writing that Indemnitee has requested indemnification.

(b) The Company will be entitled to participate in the Proceeding at its own expense.

Section 12. Procedure Upon Application for Indemnification.

(a) Upon written request by Indemnitee for indemnification pursuant to Section 11(a), a determination, if required by applicable law, with respect to Indemnitee's entitlement thereto shall be made in the specific case: (i) if a Change in Control shall have occurred, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to Indemnitee; or (ii) if a Change in Control shall not have occurred, (A) by a majority vote of the Disinterested Directors, even though less than a quorum of the Board, (B) by a committee of Disinterested Directors designated by a majority vote of the Disinterested Directors, even though less than a quorum of the Board, (C) if there are no such Disinterested Directors or, if such Disinterested Directors so direct, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to Indemnitee or (D) if so directed by the Board, by the stockholders of the Company; and, if it is so determined that Indemnitee is entitled to indemnification, payment to Indemnitee shall be made within ten (10) days after such determination. Indemnitee shall cooperate with the person, persons or entity making such determination with respect to Indemnitee's entitlement to indemnification, including providing to such person, persons or entity upon reasonable advance request any documentation or information which is not privileged or otherwise protected from disclosure and which is reasonably available to Indemnitee and reasonably necessary to such determination. Any costs or Expenses (including attorneys' fees and disbursements) incurred by Indemnitee in so cooperating with the person, persons or entity making such determination shall be borne by the Company (irrespective of the determination as to Indemnitee's entitlement to indemnification) and the Company hereby indemnifies and agrees to hold Indemnitee harmless therefrom. The Company promptly will advise Indemnitee in writing with respect to any determination that Indemnitee is or is not entitled to indemnification, including a description of any reason or basis for which indemnification has been denied.

(b) In the event the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 12(a) hereof, the Independent Counsel shall be selected as provided in this Section 12(b). If a Change in Control shall not have occurred, the Independent Counsel shall be selected by the Board, and the Company shall give written notice to Indemnitee advising him of the identity of the Independent Counsel so selected. If a Change in Control shall have occurred, the Independent Counsel shall be selected by Indemnitee (unless Indemnitee shall request that such selection be made by the Board, in which event the preceding sentence shall apply), and Indemnitee shall give written notice to the Company advising it of the identity of the Independent Counsel so selected. In either event, Indemnitee or the Company, as the case may be, may, within ten (10) days after such written notice of selection shall have been given, deliver to the Company or to Indemnitee, as the case may be, a written objection to such selection; provided, however, that such objection may be asserted only on the ground that the Independent Counsel so selected does not meet the requirements of "Independent Counsel" as defined in Section 2 of this Agreement, and the objection shall set forth with particularity the factual basis of such assertion. Absent a proper and timely objection, the person so selected shall act as Independent Counsel. If such written objection is so made and substantiated, the Independent Counsel so selected may not serve as Independent Counsel unless and until such objection is withdrawn or the Delaware Court has determined that such objection is without merit. If, within twenty (20) days after the later of submission by Indemnitee of a written request for indemnification pursuant to Section 11(a) hereof and the final disposition of the Proceeding, no Independent Counsel shall have been selected and not objected to, either the Company or Indemnitee may petition the Delaware Court for resolution of any objection which shall have been made by the Company or Indemnitee to the other's selection of Independent Counsel and/or for the appointment as Independent Counsel of a person selected by such court or by such other person as such court shall designate, and the person with respect to whom all objections are so resolved or the person so appointed shall act as Independent Counsel under Section 12(a) hereof. Upon the due commencement of any judicial proceeding or arbitration pursuant to Section 14(a) of this Agreement, Independent Counsel shall be discharged and relieved of any further

responsibility in such capacity (subject to the applicable standards of professional conduct then prevailing).

Section 13. Presumptions and Effect of Certain Proceedings.

(a) In making a determination with respect to entitlement to indemnification hereunder, the person or persons or entity making such determination shall, to the fullest extent not prohibited by law, presume that Indemnitee is entitled to indemnification under this Agreement if Indemnitee has submitted a request for indemnification in accordance with Section 11(a) of this Agreement, and the Company shall, to the fullest extent not prohibited by law, have the burden of proof to overcome that presumption in connection with the making by any person, persons or entity of any determination contrary to that presumption. Neither the failure of the Company (including by its directors or Independent Counsel) to have made a determination prior to the commencement of any action pursuant to this Agreement that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Company (including by its directors or Independent Counsel) that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct.

(b) Subject to Section 14(e), if the person, persons or entity empowered or selected under Section 12 of this Agreement to determine whether Indemnitee is entitled to indemnification shall not have made a determination within sixty (60) days after receipt by the Company of the request therefor, the requisite determination of entitlement to indemnification shall, to the fullest extent not prohibited by law, be deemed to have been made and Indemnitee shall be entitled to such indemnification, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law; provided, however, that such 60-day period may be extended for a reasonable time, not to exceed an additional thirty (30) days, if the person, persons or entity making the determination with respect to entitlement to indemnification in good faith requires such additional time for the obtaining or evaluating of documentation and/or information relating thereto; and provided, further, that the foregoing provisions of this Section 13(b) shall not apply (i) if the determination of entitlement to indemnification is to be made by the stockholders pursuant to Section 12(a) of this Agreement and if (A) within fifteen (15) days after receipt by the Company of the request for such determination the Board has resolved to submit such determination to the stockholders for their consideration at an annual meeting thereof to be held within seventy-five (75) days after such receipt and such determination is made thereat, or (B) a special meeting of stockholders is called within fifteen (15) days after such receipt for the purpose of making such determination, such meeting is held for such purpose within sixty (60) days after having been so called and such determination is made thereat, or (ii) if the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 12(a) of this Agreement.

(c) The termination of any Proceeding or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or upon a plea of nolo contendere or its equivalent, shall not (except as otherwise expressly provided in this Agreement) of itself adversely affect the right of Indemnitee to indemnification or create a presumption that Indemnitee did not act in good faith and in a manner which he reasonably believed to be in or not opposed to the best interests of the Company or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that his conduct was unlawful.

(d) For purposes of any determination of good faith, Indemnitee shall be deemed to have acted in good faith if Indemnitee's action is based on the records or books of

account of the Enterprise, including financial statements, or on information supplied to Indemnitee by the directors or officers of the Enterprise in the course of their duties, or on the advice of legal counsel for the Enterprise or on information or records given or reports made to the Enterprise by an independent certified public accountant or by an appraiser or other expert selected with the reasonable care by the Enterprise. The provisions of this Section 13(d) shall not be deemed to be exclusive or to limit in any way the other circumstances in which the Indemnitee may be deemed to have met the applicable standard of conduct set forth in this Agreement.

(e) The knowledge and/or actions, or failure to act, of any director, officer, trustee, partner, managing member, fiduciary, agent or employee of the Enterprise shall not be imputed to Indemnitee for purposes of determining the right to indemnification under this Agreement.

Section 14. Remedies of Indemnitee.

(a) Subject to Section 14(e), in the event that (i) a determination is made pursuant to Section 12 of this Agreement that Indemnitee is not entitled to indemnification under this Agreement, (ii) advancement of Expenses is not timely made pursuant to Section 10 of this Agreement, (iii) no determination of entitlement to indemnification shall have been made pursuant to Section 12(a) of this Agreement within ninety (90) days after receipt by the Company of the request for indemnification, (iv) payment of indemnification is not made pursuant to Section 5, 6 or 7 or the last sentence of Section 12(a) of this Agreement within ten (10) days after receipt by the Company of a written request therefor, (v) payment of indemnification pursuant to Section 3, 4 or 8 of this Agreement is not made within ten (10) days after a determination has been made that Indemnitee is entitled to indemnification, or (vi) in the event that the Company or any other person takes or threatens to take any action to declare this Agreement void or unenforceable, or institutes any litigation or other action or Proceeding designed to deny, or to recover from, the Indemnitee the benefits provided or intended to be provided to the Indemnitee hereunder, Indemnitee shall be entitled to an adjudication by a court of his entitlement to such indemnification or advancement of Expenses. Alternatively, Indemnitee, at his option, may seek an award in arbitration to be conducted by a single arbitrator pursuant to the Commercial Arbitration Rules of the American Arbitration Association. Indemnitee shall commence such proceeding seeking an adjudication or an award in arbitration within 180 days following the date on which Indemnitee first has the right to commence such proceeding pursuant to this Section 14(a); provided, however, that the foregoing clause shall not apply in respect of a proceeding brought by Indemnitee to enforce his rights under Section 5 of this Agreement. The Company shall not oppose Indemnitee's right to seek any such adjudication or award in arbitration.

(b) In the event that a determination shall have been made pursuant to Section 12(a) of this Agreement that Indemnitee is not entitled to indemnification, any judicial proceeding or arbitration commenced pursuant to this Section 14 shall be conducted in all respects as a de novo trial, or arbitration, on the merits and Indemnitee shall not be prejudiced by reason of that adverse determination. In any judicial proceeding or arbitration commenced pursuant to this Section 14, the Company shall have the burden of proving Indemnitee is not entitled to indemnification or advancement of Expenses, as the case may be.

(c) If a determination shall have been made pursuant to Section 12(a) of this Agreement that Indemnitee is entitled to indemnification, the Company shall be bound by such determination in any judicial proceeding or arbitration commenced pursuant to this Section 14, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law.

(d) The Company shall, to the fullest extent not prohibited by law, be precluded from asserting in any judicial proceeding or arbitration commenced pursuant to this Section 14 that the procedures and presumptions of this Agreement are not valid, binding and enforceable and shall stipulate in any such court or before any such arbitrator that the Company is bound by all the provisions of this Agreement. It is the intent of the Company that, to the fullest extent permitted by law, the Indemnitee not be required to incur legal fees or other Expenses associated with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement by litigation or otherwise because the cost and expense thereof would substantially detract from the benefits intended to be extended to the Indemnitee hereunder. The Company shall, to the fullest extent permitted by law, indemnify Indemnitee against any and all Expenses and, if requested by Indemnitee, shall (within ten (10) days after receipt by the Company of a written request therefor) advance, to the extent not prohibited by law, such Expenses to Indemnitee, which are incurred by Indemnitee in connection with any action brought by Indemnitee for indemnification or advance of Expenses from the Company under this Agreement or under any directors' and officers' liability insurance policies maintained by the Company if, in the case of indemnification, Indemnitee is wholly successful on the underlying claims; if Indemnitee is not wholly successful on the underlying claims, then such indemnification shall be only to the extent Indemnitee is successful on such underlying claims or otherwise as permitted by law, whichever is greater.

(e) Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement of Indemnitee to indemnification under this Agreement shall be required to be made prior to the final disposition of the Proceeding.

Section 15. Non-exclusivity; Survival of Rights; Insurance; Subrogation.

(a) The rights of indemnification and to receive advancement of Expenses as provided by this Agreement shall not be deemed exclusive of any other rights to which Indemnitee may at any time be entitled under applicable law, the Certificate of Incorporation, the Bylaws, any agreement, a vote of stockholders or a resolution of directors, or otherwise. No amendment, alteration or repeal of this Agreement or of any provision hereof shall limit or restrict any right of Indemnitee under this Agreement in respect of any action taken or omitted by such Indemnitee in his Corporate Status prior to such amendment, alteration or repeal. To the extent that a change in Delaware law, whether by statute or judicial decision, permits greater indemnification or advancement of Expenses than would be afforded currently under the Certificate of Incorporation and this Agreement, it is the intent of the parties hereto that Indemnitee shall enjoy by this Agreement the greater benefits so afforded by such change. No right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. The assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other right or remedy.

(b) To the extent that the Company maintains an insurance policy or policies providing liability insurance for directors, officers, employees, or agents of the Enterprise, Indemnitee shall be covered by such policy or policies in accordance with its or their terms to the maximum extent of the coverage available for any such director, officer, employee or agent under such policy or policies. If, at the time of the receipt of a notice of a claim pursuant to the terms hereof, the Company has director and officer liability insurance in effect, the Company shall give prompt notice of such claim or of the commencement of a Proceeding, as the case may be, to the insurers in accordance with the procedures set forth in the respective policies. The Company shall thereafter take all necessary or desirable action to cause such insurers to pay, on

behalf of the Indemnitee, all amounts payable as a result of such Proceeding in accordance with the terms of such policies.

(c) In the event of any payment under this Agreement, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee [(other than any rights of recovery of Indemnitee from a Fund Indemnitor or under any insurance provided by the Fund or its affiliates)], who shall execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Company to bring suit to enforce such rights.

(d) [Except as provided for under Section 15(e) of this Agreement, the] The Company shall not be liable under this Agreement to make any payment of amounts otherwise indemnifiable (or for which advancement is provided hereunder) hereunder if and to the extent that Indemnitee has otherwise actually received such payment under any insurance policy, contract, agreement or otherwise.

(e) [The Company hereby acknowledges that Indemnitee has certain rights to indemnification, advancement of expenses and/or insurance provided by the Fund and certain of its affiliates (collectively, the "Fund Indemnitors"). The Company hereby agrees (i) that it is the indemnitor of first resort (i.e., its obligations to Indemnitee are primary and any obligation of the Fund Indemnitors to advance expenses or to provide indemnification for the same expenses or liabilities incurred by Indemnitee are secondary), (ii) that it shall be required to advance the full amount of Expenses incurred by Indemnitee and shall be liable for the full amount of all Expenses, judgments, penalties, fines and amounts paid in settlement to the extent legally permitted and as required by the Certificate of Incorporation or Bylaws (or any agreement between the Company and Indemnitee), without regard to any rights Indemnitee may have against the Fund Indemnitors, and, (iii) that it irrevocably waives, relinquishes and releases the Fund Indemnitors from any and all claims against the Fund Indemnitors for contribution, subrogation or any other recovery of any kind in respect thereof. The Company further agrees that no advancement or payment by the Fund Indemnitors on behalf of Indemnitee with respect to any claim for which Indemnitee has sought indemnification from the Company shall affect the foregoing and the Fund Indemnitors shall have a right of contribution and/or be subrogated to the extent of such advancement or payment to all of the rights of recovery of Indemnitee against the Company. The Company and Indemnitee agree that the Fund Indemnitors are express third party beneficiaries of the terms hereof.]

Section 16. Duration of Agreement. This Agreement shall continue until and terminate upon the later of: (a) ten (10) years after the date that Indemnitee shall have ceased to serve as a [director] [officer] of the Company or (b) one (1) year after the final termination of any Proceeding then pending in respect of which Indemnitee is granted rights of indemnification or advancement of Expenses hereunder and of any proceeding commenced by Indemnitee pursuant to Section 14 of this Agreement [or by a Fund Indemnitor pursuant to Section 15(e) of this Agreement, in either case,] relating thereto. The indemnification and advancement of expenses rights provided by or granted pursuant to this Agreement shall be binding upon and be enforceable by the parties hereto and their respective successors and assigns (including any direct or indirect successor by purchase, merger, consolidation or otherwise to all or substantially all of the business or assets of the Company), shall continue as to an Indemnitee who has ceased to be a director, officer, employee or agent of the Company or of any other Enterprise, and shall inure to the benefit of Indemnitee and his or her spouse, assigns, heirs, devisees, executors and administrators and other legal representatives.

Section 17. Severability. If any provision or provisions of this Agreement shall be held to be invalid, illegal or unenforceable for any reason whatsoever: (a) the validity, legality and

enforceability of the remaining provisions of this Agreement (including without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and shall remain enforceable to the fullest extent permitted by law; (b) such provision or provisions shall be deemed reformed to the extent necessary to conform to applicable law and to give the maximum effect to the intent of the parties hereto; and (c) to the fullest extent possible, the provisions of this Agreement (including, without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested thereby.

Section 18. Enforcement.

(a) The Company expressly confirms and agrees that it has entered into this Agreement and assumed the obligations imposed on it hereby in order to induce Indemnitee to serve as a director or officer of the Company, and the Company acknowledges that Indemnitee is relying upon this Agreement in serving as a director or officer of the Company.

(b) This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral, written and implied, between the parties hereto with respect to the subject matter hereof; provided, however, that this Agreement is a supplement to and in furtherance of the Certificate of Incorporation, the Bylaws and applicable law, and shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder.

Section 19. Modification and Waiver. No supplement, modification or amendment of this Agreement shall be binding unless executed in writing by the parties hereto. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions of this Agreement nor shall any waiver constitute a continuing waiver.

Section 20. Notice by Indemnitee. Indemnitee agrees promptly to notify the Company in writing upon being served with any summons, citation, subpoena, complaint, indictment, information or other document relating to any Proceeding or matter which may be subject to indemnification or advancement of Expenses covered hereunder. The failure of Indemnitee to so notify the Company shall not relieve the Company of any obligation which it may have to the Indemnitee under this Agreement or otherwise.

Section 21. Notices. All notices, requests, demands and other communications under this Agreement shall be in writing and shall be deemed to have been duly given if (a) delivered by hand and receipted for by the party to whom said notice or other communication shall have been directed, (b) mailed by certified or registered mail with postage prepaid, on the third business day after the date on which it is so mailed, (c) mailed by reputable overnight courier and receipted for by the party to whom said notice or other communication shall have been directed or (d) sent by facsimile transmission, with receipt of oral confirmation that such transmission has been received:

(a) If to Indemnitee, at the address indicated on the signature page of this Agreement, or such other address as Indemnitee shall provide to the Company.

(b) If to the Company to:

Sesen Bio, Inc.
245 First Street, Suite 1800

Cambridge, MA 02142
Attention: Chief Financial Officer

or to any other address as may have been furnished to Indemnitee by the Company.

Section 22. Contribution. To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to Indemnitee for any reason whatsoever, the Company, in lieu of indemnifying Indemnitee, shall contribute to the amount incurred by Indemnitee, whether for judgments, fines, penalties, excise taxes, amounts paid or to be paid in settlement and/or for Expenses, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in light of all of the circumstances of such Proceeding in order to reflect (i) the relative benefits received by the Company, on the one hand, and Indemnitee, on the other hand, as a result of the event(s) and/or transaction(s) giving cause to such Proceeding; and/or (ii) the relative fault of the Company (and its other directors, officers, employees and agents), on the one hand, and Indemnitee, on the other hand, in connection with such event(s) and/or transaction(s).

Section 23. Applicable Law and Consent to Jurisdiction. This Agreement and the legal relations among the parties shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, without regard to its conflict of laws rules. Except with respect to any arbitration commenced by Indemnitee pursuant to Section 14(a) of this Agreement, the Company and Indemnitee hereby irrevocably and unconditionally (i) agree that any action or proceeding arising out of or in connection with this Agreement shall be brought only in the Delaware Court, and not in any other state or federal court in the United States of America or any court in any other country, (ii) consent to submit to the exclusive jurisdiction of the Delaware Court for purposes of any action or proceeding arising out of or in connection with this Agreement, (iii) appoint, to the extent such party is not otherwise subject to service of process in the State of Delaware, irrevocably the Corporation Trust Center as its agent in the State of Delaware as such party's agent for acceptance of legal process in connection with any such action or proceeding against such party with the same legal force and validity as if served upon such party personally within the State of Delaware, (iv) waive any objection to the laying of venue of any such action or proceeding in the Delaware Court, and (v) waive, and agree not to plead or to make, any claim that any such action or proceeding brought in the Delaware Court has been brought in an improper or inconvenient forum.

Section 24. Identical Counterparts. This Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement. Only one such counterpart signed by the party against whom enforceability is sought needs to be produced to evidence the existence of this Agreement.

Section 25. Miscellaneous. Use of the masculine pronoun shall be deemed to include usage of the feminine pronoun where appropriate. The headings of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.

[*The remainder of this page is intentionally left blank.*]

The parties executed this Agreement as of the day and year first set forth above.

SESEN BIO, INC.

By: _____
Name: _____
Office: _____

INDEMNITEE

_____
Name: _____

Address:_____
_____
_____

Schedule of Material Differences to Exhibit 10.2

The following directors and executive officers are parties to an Indemnification Agreement with the Company, each of which are substantially identical in all material respects to the representative Indemnification Agreement filed herewith as Exhibit 10.2 except as to the name of the signatory and the effective date of each signatory's Indemnification Agreement and the fund affiliation of each signatory, which are listed below. The actual Indemnification Agreements are omitted pursuant to Instruction 2 to Item 601 of Regulation S-K.

Indemnitee	**Effective Date**	**Fund Affiliation**
Wendy L. Dixon, Ph.D.	October 22, 2014	
Daniel S. Lynch	February 11, 2014	
Jane V. Henderson	February 11, 2014	
Jay S. Duker	January 20, 2015	
Leslie L. Dan	September 20, 2016	
Stephen A. Hurly	September 20, 2016	
Richard F. Fitzgerald	January 23, 2018	
Thomas R. Cannell, D.V.M.	August 7, 2018	
Dennis Kim, M.D., MPH	December 3, 2018	
Glen MacDonald, Ph.D.	August 26, 2019	
Mark R. Sullivan	August 26, 2019	
Monica Forbes	August 26, 2019	
Carrie L. Bourdow	February 24, 2020	
Jason A. Keyes	February 24, 2020	
Elly Ryu	July 20, 2021	
Patricia M. Drake	July 20, 2021	
Peter K Honig, M.D.	July 20, 2021	
Michael A.S. Jewett, M.D.	July 20, 2021	
Minori Koshiji Rosales, M.D., Ph.D.	January 5, 2022	

Sesen Bio, Inc.

Restricted Stock Unit and Cash Retention Award Agreement
Granted Under 2014 Stock Incentive Plan

NOTICE OF GRANT

This Restricted Stock Unit and Cash Retention Award Agreement (this "Agreement") is made as of the Agreement Date between Sesen Bio, Inc. (the "Company"), a Delaware corporation, and the Participant.

I. Agreement Date

Date:	October 1, 2021

II. Participant Information

Participant:	[_____]
Participant Address:	

III. Grant Information

Grant Date:	October 1, 2021
Number of Restricted Stock Units:	[_____]
Amount of Cash Retention Award:	An amount equal 50% of Participant's base salary as of September 30, 2022

IV. Vesting Table

Vesting Date	Number of Restricted Stock Units that Vest	Amount of Cash Retention Award that Vests
September 30, 2022	[_____]	An amount equal 50% of Participant's base salary as of September 30, 2022

This Agreement includes this Notice of Grant and the following Exhibit, which is expressly incorporated by reference in its entirety herein:

Exhibit A – General Terms and Conditions

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the Agreement Date.

SESEN BIO, INC.

_____
Name: Thomas R. Cannell
Title: President & CEO

PARTICIPANT

_____
Name: [_____]

Restricted Stock Unit and Cash Retention Award Agreement
2014 Stock Incentive Plan

EXHIBIT A

GENERAL TERMS AND CONDITIONS

For valuable consideration, receipt of which is acknowledged, the parties hereto agree as follows:

1. Award of Restricted Stock Units.

In consideration of services rendered and to be rendered to the Company by the Participant, the Company has granted to the Participant, subject to the terms and conditions set forth in this Agreement and in the Company's 2014 Stock Incentive Plan, as amended (the "Plan"), an award with respect to the number of Restricted Stock Units (the "RSUs") set forth in the Notice of Grant that forms part of this Agreement (the "Notice of Grant"). Each RSU represents the right to receive one share of common stock, $0.001 par value per share, of the Company (the "Common Stock") upon vesting of the RSU, subject to the terms and conditions set forth herein.

2. Grant of Cash Retention Award.

In consideration of services rendered and to be rendered to the Company by the Participant, the Company has granted to the Participant a cash retention award (the "Cash Retention Award"), which represents the right to receive a cash amount equal to the amount set forth in the Notice of Grant upon vesting of the Cash Retention Award, subject to the terms and conditions set forth herein.

3. Vesting.

The RSUs and the Cash Retention Award shall vest in accordance with the Vesting Table set forth in the Notice of Grant (the "Vesting Table"). Upon the vesting of the RSUs, the Company will deliver to the Participant, for each RSU that becomes vested, one share of Common Stock, subject to the payment of any taxes pursuant to Section 8. The Common Stock will be delivered to the Participant as soon as practicable following a vesting date, but in any event within fourteen (14) days following such vesting date. Upon the vesting of the Cash Retention Award, the Company will pay to the Participant an amount in cash equal to the amount set forth in the Notice of Grant, subject to the payment of any taxes pursuant to Section 8, which amount will be payable to the Participant in a single lump sum on the next regular payroll date following the vesting date.

4. Forfeiture of Unvested RSUs and Cash Retention Award Upon Cessation of Service.

(a) Except as otherwise provided in Sections 4(b) or (c), as applicable, in the event that the Participant ceases to perform services to the Company for any reason or no reason, with or without cause, all of the RSUs that are unvested as of the time of such cessation, and the Cash Retention Award, to the extent unvested, shall be forfeited immediately and automatically to the Company, without the payment of any consideration to the Participant, effective as of such cessation. The Participant shall have no further rights with respect to (i) the unvested RSUs or any Common Stock that may have been issuable with respect thereto, or (ii) the Cash Retention Award, to the extent unvested. If the Participant provides services to a subsidiary of the

Company, any references in this Agreement to provision of services to the Company shall instead be deemed to refer to service with such subsidiary.

(b) If the Participant's employment with the Company and its subsidiaries is terminated by the Company or one of its subsidiaries without Cause (as defined below), then all of the RSUs that are unvested as of the time of such termination of employment shall become immediately and automatically vested as of the date of the Participant's termination of employment, and the shares of Common Stock underlying such RSUs will be delivered to the Participant within fourteen (14) days following the date of the Participant's termination of employment

(c) If, on or prior to March 31, 2022, the Participant's employment with the Company and its subsidiaries is terminated by the Company or one of its subsidiaries without Cause, then the Pro-Rated Cash Retention Award (as defined below) shall become immediately and automatically vested as of the date of the Participant's termination of employment. For purposes of this Agreement, the term "Pro-Rated Cash Retention Award" shall mean the product of (i) the amount equal to 50% of Participant's base salary on the date of Participant's termination of employment, multiplied by (ii) a fraction, the numerator of which is the number of days during the period commencing on the Grant Date and ending on (and including) the date of the Participant's termination of employment, and the denominator of which is the number of days during the period commencing on the Grant Date and ending on (and including) the Vesting Date set forth on the Notice of Grant. If, on or following April 1, 2022 and prior to the Vesting Date set forth on the Notice of Grant, the Participant's employment with the Company and its subsidiaries is terminated by the Company or one of its subsidiaries without Cause, then the amount equal to 50% of Participant's base salary on the date of Participant's termination of employment shall become immediately and automatically vested as of the date of the Participant's termination of employment. If all or a portion of the Cash Retention Award becomes vested pursuant to this Section 4(c), the Company shall pay to the Participant the amount that becomes vested (rounded to the nearest whole cent), subject to the payment of any taxes pursuant to Section 8, in a single lump sum within 30 days following the date of the Participant's termination of employment.

(d) For purposes of this Agreement, the term "Cause" shall have the meaning specified in the Participant's employment agreement with the Company or, if the Participant does not have an employment agreement with the Company, the term "Cause" shall mean the Participant's commission of one or more of the following: (i) an act of material dishonesty involving the Company, embezzlement, or misappropriation of assets or property of the Company; (ii) gross negligence or willful misconduct in connection with the performance of Participant's duties, theft, fraud or breach of fiduciary duty to the Company; (iii) Participant's willful, sustained, or repeated failure to substantially perform the duties or obligations of your position (other than due to illness or injury); (iv) a violation of federal or state securities law; (v) the conviction of a felony or any crime involving moral turpitude, including a plea of nolo contendere; or (vi) a material breach of any of the Company's written policies related to conduct, ethics, equal employment or harassment.

5. Restrictions on Transfer.

The Participant shall not sell, assign, transfer, pledge, hypothecate or otherwise dispose of, by operation of law or otherwise (collectively "transfer") any RSUs or the Cash Retention Award, or any interest therein. The Company shall not be required to treat as the owner of any RSUs, issue any Common Stock to, or pay any cash amounts to, any transferee to whom such RSUs or Cash Retention Award have been transferred in violation of any of the provisions of this Agreement.

6. Rights as a Shareholder.

The Participant shall have no rights as a stockholder of the Company with respect to any shares of Common Stock that may be issuable with respect to the RSUs until the issuance of the shares of Common Stock to the Participant following the vesting of the RSUs.

7. Provisions of the Plan.

This Agreement is subject to the provisions of the Plan, a copy of which is furnished to the Participant with this Agreement.

8. Tax Matters.

(a) Acknowledgments; No Section 83(b) Election. The Participant acknowledges that he or she is responsible for obtaining the advice of the Participant's own tax advisors with respect to the award of RSUs and the Cash Retention Award, and the Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents with respect to the tax consequences relating to the RSUs and the Cash Retention Award. The Participant understands that the Participant (and not the Company) shall be responsible for the Participant's tax liability that may arise in connection with the acquisition, vesting, disposition and/or payment of the RSUs and the Cash Retention Award. The Participant acknowledges that no election under Section 83(b) of the Internal Revenue Code, as amended, is available with respect to RSUs or the Cash Retention Award.

(b) Withholding. The Participant acknowledges and agrees that the Company has the right to deduct from payments of any kind otherwise due to the Participant any federal, state, local or other taxes of any kind required by law to be withheld with respect to the vesting and/or payment of the RSUs and the Cash Retention Award. At such time as the Participant is not aware of any material nonpublic information about the Company or the Common Stock, the Participant shall execute the instructions set forth in Schedule A attached hereto (the "Automatic Sale Instructions") as the means of satisfying such tax obligation with respect to the RSUs. If the Participant does not execute the Automatic Sale Instructions prior to an applicable vesting date of the RSUs, then the Participant agrees that if under applicable law the Participant will owe taxes at such vesting date on the portion of the RSUs then vested the Company shall be entitled to immediate payment from the Participant of the amount of any tax required to be withheld by the Company. The Company shall not deliver any shares of Common Stock in respect of vested RSUs to the Participant until it is satisfied that all required withholdings have been made.

9. Miscellaneous.

(a) Authority of Compensation Committee. In making any decisions or taking any actions with respect to the matters covered by this Agreement, the Compensation Committee shall have all of the authority and discretion, and shall be subject to all of the protections, provided for in the Plan. All decisions and actions by the Compensation Committee with respect to this Agreement shall be made in the Compensation Committee's discretion and shall be final and binding on the Participant.

(b) No Right to Continued Service. The Participant acknowledges and agrees that, notwithstanding the fact that the vesting of the RSUs and the Cash Retention Award is contingent upon his or her continued service to the Company, this Agreement does not constitute an express or implied promise of continued service relationship with the Participant or confer upon the Participant any rights with respect to a continued service relationship with the Company.

(c) Section 409A. The RSUs and the Cash Retention Award awarded pursuant to this Agreement are intended to be exempt from or comply with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended, and the Treasury Regulations issued thereunder

("Section 409A"). The delivery of shares of Common Stock on the vesting of the RSUs, and the payment of cash on the vesting of the Cash Retention Award, may not be accelerated or deferred unless permitted or required by Section 409A.

(d) Participant's Acknowledgements. The Participant acknowledges that he or she: (i) has read this Agreement; (ii) has been represented in the preparation, negotiation and execution of this Agreement by legal counsel of the Participant's own choice or has voluntarily declined to seek such counsel; (iii) understands the terms and consequences of this Agreement; and (iv) is fully aware of the legal and binding effect of this Agreement.

(e) Governing Law. This Agreement shall be construed, interpreted and enforced in accordance with the internal laws of the State of Delaware without regard to any applicable conflicts of laws provisions.

I hereby acknowledge that I have read this Agreement, have received and read the Plan, and understand and agree to comply with the terms and conditions of this Agreement and the Plan.

PARTICIPANT ACCEPTANCE

_____

Name: [_____]

Schedule A

Automatic Sale Instructions

The undersigned hereby consents and agrees that any taxes due on a vesting date as a result of the vesting of RSUs on such date shall be paid through an automatic sale of shares as follows:

(a) Upon any vesting of RSUs pursuant to Sections 3 or 4 hereof, as applicable, the Company shall sell, or arrange for the sale of, such number of shares of Common Stock issuable with respect to the RSUs that vest pursuant to Section 3 or Section 4, as applicable, as is sufficient to generate net proceeds sufficient to satisfy the Company's minimum statutory withholding obligations with respect to the income recognized by the Participant upon the vesting of the RSUs (based on minimum statutory withholding rates for all tax purposes, including payroll and social security taxes, that are applicable to such income), and the Company shall retain such net proceeds in satisfaction of such tax withholding obligations.

(b) The Participant hereby appoints the President and Chief Executive Officer and Secretary of the Company, and either of them acting alone and with full power of substitution, to serve as his or her attorneys in fact to sell the Participant's Common Stock in accordance with this Schedule A. The Participant agrees to execute and deliver such documents, instruments and certificates as may reasonably be required in connection with the sale of the Shares pursuant to this Schedule A.

(c) The Participant represents to the Company that, as of the date hereof, he or she is not aware of any material nonpublic information about the Company or the Common Stock. The Participant and the Company have structured this Agreement, including this Schedule A, to constitute a "binding contract" relating to the sale of Common Stock, consistent with the affirmative defense to liability under Section 10(b) of the Securities Exchange Act of 1934 under Rule 10b5-1(c) promulgated under such Act.

The Company shall not deliver any shares of Common Stock to the Participant until it is satisfied that all required withholdings have been made.

_____

Participant Name: _____

Date: _____

Sesen Bio, Inc.

Performance-Based Restricted Stock Unit Agreement
Granted Under 2014 Stock Incentive Plan

NOTICE OF GRANT

This Performance-Based Restricted Stock Unit Agreement (this "Agreement") is made as of the Agreement Date between Sesen Bio, Inc. (the "Company"), a Delaware corporation, and the Participant.

I. Agreement Date

Date:	October 1, 2021

II. Participant Information

Participant:	[_____]
Participant Address:	

III. Grant Information

Grant Date:	October 1, 2021
Number of Restricted Stock Units:	[_____]

This Agreement includes this Notice of Grant and the following Exhibit, which is expressly incorporated by reference in its entirety herein:

Exhibit A – General Terms and Conditions

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the Agreement Date.

SESEN BIO, INC.

_____
Name: Thomas R. Cannell
Title: President & CEO

PARTICIPANT

_____
Name: [_____]

Performance-Based Restricted Stock Unit Agreement
2014 Stock Incentive Plan

EXHIBIT A

GENERAL TERMS AND CONDITIONS

For valuable consideration, receipt of which is acknowledged, the parties hereto agree as follows:

1. Award of Restricted Stock Units.

In consideration of services rendered and to be rendered to the Company by the Participant, the Company has granted to the Participant, subject to the terms and conditions set forth in this Agreement and in the Company's 2014 Stock Incentive Plan, as amended (the "Plan"), an award with respect to the number of performance-based Restricted Stock Units (the "PSUs") set forth in the Notice of Grant that forms part of this Agreement (the "Notice of Grant"). Each PSU represents the right to receive one share of common stock, $0.001 par value per share, of the Company (the "Common Stock") upon vesting of the PSU, subject to the terms and conditions set forth herein.

2. Vesting.

The PSUs may be earned based on the achievement of one or more of the performance milestones (each, a "Performance Milestone") set forth in the table below. The number of PSUs that may be earned based on the achievement of each Performance Milestone is set forth in the table below. The determination of whether, and to what extent, each Performance Milestone has been achieved shall be made by the Compensation Committee in its sole discretion. Any PSUs that are earned based on the achievement of the Performance Milestones shall vest on September 30, 2023 (the "End Date"). Upon the vesting of the PSUs, the Company will deliver to the Participant, for each PSU that becomes vested, one share of Common Stock, subject to the payment of any taxes pursuant to Section 7. The Common Stock will be delivered to the Participant within fourteen (14) days of the End Date.

Performance Milestones	**Weightings**	**Number of PSUs that will be Earned Upon Achievement of Performance Milestone**
Clinical Performance Milestone[1]	50%	[●]
Employee Retention Performance Milestone[2]	30%	[●]
Financial Performance Milestone[3]	20%	[●]

1 The Clinical Performance Milestone shall be achieved if the timing for completing full patient enrollment for the new study to be determined based on regulatory feedback and as endorsed by the Board of Directors of the Company (the "Board"), is achieved.

2 The Employee Retention Performance Milestone shall be achieved if 80% of the thirty-two (32) employees that are employed by the Company and its subsidiaries on the Grant Date remain employed by the Company and its subsidiaries on the End Date.

3 The Financial Performance Milestone shall be achieved if the Company's cash balance is no lower than 90% of the Board approved budget/forecast as of both December 31, 2022 and June 30, 2023.

3. Forfeiture of Unvested PSUs Upon Cessation of Service.

(a) Except as otherwise provided in Section 3(b), in the event that the Participant ceases to perform services to the Company for any reason or no reason, with or without cause, all of the PSUs that are unvested as of the time of such cessation shall be forfeited immediately and automatically to the Company, without the payment of any consideration to the Participant, effective as of such cessation. The Participant shall have no further rights with respect to the unvested PSUs or any Common Stock that may have been issuable with respect thereto. If the Participant provides services to a subsidiary of the Company, any references in this Agreement to provision of services to the Company shall instead be deemed to refer to service with such subsidiary.

(b) If, prior to the End Date, the Participant's employment with the Company and its subsidiaries is terminated by the Company or one of its subsidiaries without Cause (as defined below), then each PSU that has become earned as of the time of such termination of employment based on the achievement of the applicable Performance Milestone, as determined by the Compensation Committee in its sole discretion, shall become immediately and automatically vested as of the date of the Participant's termination of employment, and the shares of Common Stock underlying such PSU will be delivered to the Participant as soon as practicable following the date of the Participant's termination of employment, but in any event within fourteen (14) of such date. For purposes of this Agreement, the term "Cause" shall have the meaning specified in the Participant's employment agreement with the Company.

4. Restrictions on Transfer.

The Participant shall not sell, assign, transfer, pledge, hypothecate or otherwise dispose of, by operation of law or otherwise (collectively "transfer") any PSUs, or any interest therein. The Company shall not be required to treat as the owner of any PSUs or issue any Common Stock to any transferee to whom such PSUs have been transferred in violation of any of the provisions of this Agreement.

5. Rights as a Shareholder.

The Participant shall have no rights as a stockholder of the Company with respect to any shares of Common Stock that may be issuable with respect to the PSUs until the issuance of the shares of Common Stock to the Participant following the vesting of the PSUs.

6. Provisions of the Plan.

This Agreement is subject to the provisions of the Plan, a copy of which is furnished to the Participant with this Agreement.

7. Tax Matters.

(a) Acknowledgments; No Section 83(b) Election. The Participant acknowledges that he or she is responsible for obtaining the advice of the Participant's own tax advisors with respect to the award of PSUs and the Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents with respect to the tax consequences relating to the PSUs. The Participant understands that the Participant (and not the Company) shall be responsible for the Participant's tax liability that may arise in connection with

the acquisition, vesting and/or disposition of the PSUs. The Participant acknowledges that no election under Section 83(b) of the Internal Revenue Code, as amended, is available with respect to PSUs.

(b) Withholding. The Participant acknowledges and agrees that the Company has the right to deduct from payments of any kind otherwise due to the Participant any federal, state, local or other taxes of any kind required by law to be withheld with respect to the vesting of the PSUs. At such time as the Participant is not aware of any material nonpublic information about the Company or the Common Stock, the Participant shall execute the instructions set forth in Schedule A attached hereto (the "Automatic Sale Instructions") as the means of satisfying such tax obligation. If the Participant does not execute the Automatic Sale Instructions prior to an applicable vesting date, then the Participant agrees that if under applicable law the Participant will owe taxes at such vesting date on the portion of the PSUs then vested the Company shall be entitled to immediate payment from the Participant of the amount of any tax required to be withheld by the Company. The Company shall not deliver any shares of Common Stock to the Participant until it is satisfied that all required withholdings have been made.

8. Miscellaneous.

(a) Authority of Compensation Committee. In making any decisions or taking any actions with respect to the matters covered by this Agreement, the Compensation Committee shall have all of the authority and discretion, and shall be subject to all of the protections, provided for in the Plan. All decisions and actions by the Compensation Committee with respect to this Agreement shall be made in the Compensation Committee's discretion and shall be final and binding on the Participant.

(b) No Right to Continued Service. The Participant acknowledges and agrees that, notwithstanding the fact that the vesting of the PSUs is contingent upon his or her continued service to the Company, this Agreement does not constitute an express or implied promise of continued service relationship with the Participant or confer upon the Participant any rights with respect to a continued service relationship with the Company.

(c) Section 409A. The PSUs awarded pursuant to this Agreement are intended to be exempt from or comply with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended, and the Treasury Regulations issued thereunder ("Section 409A"). The delivery of shares of Common Stock on the vesting of the PSUs may not be accelerated or deferred unless permitted or required by Section 409A.

(d) Participant's Acknowledgements. The Participant acknowledges that he or she: (i) has read this Agreement; (ii) has been represented in the preparation, negotiation and execution of this Agreement by legal counsel of the Participant's own choice or has voluntarily declined to seek such counsel; (iii) understands the terms and consequences of this Agreement; and (iv) is fully aware of the legal and binding effect of this Agreement.

(e) Governing Law. This Agreement shall be construed, interpreted and enforced in accordance with the internal laws of the State of Delaware without regard to any applicable conflicts of laws provisions.

I hereby acknowledge that I have read this Agreement, have received and read the Plan, and understand and agree to comply with the terms and conditions of this Agreement and the Plan.

_____

PARTICIPANT ACCEPTANCE

_____

Name: [_____]

Schedule A

Automatic Sale Instructions

The undersigned hereby consents and agrees that any taxes due on a vesting date as a result of the vesting of PSUs on such date shall be paid through an automatic sale of shares as follows:

(a) Upon any vesting of PSUs pursuant to Sections 2 or 3 hereof, as applicable, the Company shall sell, or arrange for the sale of, such number of shares of Common Stock issuable with respect to the PSUs that vest pursuant to Section 2 or Section 3, as applicable, as is sufficient to generate net proceeds sufficient to satisfy the Company's minimum statutory withholding obligations with respect to the income recognized by the Participant upon the vesting of the PSUs (based on minimum statutory withholding rates for all tax purposes, including payroll and social security taxes, that are applicable to such income), and the Company shall retain such net proceeds in satisfaction of such tax withholding obligations.

(b) The Participant hereby appoints the President and Chief Executive Officer and Secretary of the Company, and either of them acting alone and with full power of substitution, to serve as his or her attorneys in fact to sell the Participant's Common Stock in accordance with this Schedule A. The Participant agrees to execute and deliver such documents, instruments and certificates as may reasonably be required in connection with the sale of the Shares pursuant to this Schedule A.

(c) The Participant represents to the Company that, as of the date hereof, he or she is not aware of any material nonpublic information about the Company or the Common Stock. The Participant and the Company have structured this Agreement, including this Schedule A, to constitute a "binding contract" relating to the sale of Common Stock, consistent with the affirmative defense to liability under Section 10(b) of the Securities Exchange Act of 1934 under Rule 10b5-1(c) promulgated under such Act.

The Company shall not deliver any shares of Common Stock to the Participant until it is satisfied that all required withholdings have been made.

_____

Participant Name: _____

Date: _____

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
(13) Registration Statement (Form S-8 No. 333-254264) pertaining to the Sesen Bio, Inc. Inducement Stock Option Awards
(14) Registration Statement (Form S-8 No. 333-255941) pertaining to the Sesen Bio, Inc. 2014 Stock Incentive Plan (as amended effective May 3, 2021) and the Sesen Bio, Inc. 2014 Employee Stock Purchase Plan (as amended effective May 3, 2021)
(15) Registration Statement (Form S-3 No. 333-255943) of Sesen Bio, Inc.

of our reports dated February 28, 2022, with respect to the consolidated financial statements of Sesen Bio, Inc. and the effectiveness of internal control over financial reporting of Sesen Bio, Inc. included in this Annual Report (Form 10-K) of Sesen Bio, Inc. for the year ended December 31, 2021.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 28, 2022

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, 2021 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: February 28, 2022

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

Exhibit 31.2

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Monica Forbes, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2021 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: February 28, 2022

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

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Sesen Bio, Inc. (the "Company") for the fiscal year ended December 31, 2021 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: February 28, 2022

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

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Sesen Bio, Inc. (the "Company") for the fiscal year ended December 31, 2021 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: February 28, 2022

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