



carisma  
THERAPEUTICS

**2022 ANNUAL REPORT**

**3675 Market Street, Suite 200  
Philadelphia, Pennsylvania 19104  
(267) 491-6422**

Dear Carisma Therapeutics Inc. Stockholders:

2022 was a transformational year for our company, and I want to thank each patient, employee, partner, collaborator and stockholder for their contributions to and support of our mission to develop transformative macrophage targeted therapies for patients with devastating diseases. We were founded in 2016 with the belief that we could be a pioneer in next-generation cell therapies. Now, with our lead product candidate from our proprietary cell therapy platform focused on engineered macrophages in the clinic, we see that vision coming to life, with opportunity for effective gene delivery, tunable phenotypes, multiple payloads and applications in oncology and beyond.

On March 7, 2023, we closed our merger with Sesen Bio, Inc. and our common stock commenced trading on the Nasdaq Global Market under the symbol “CARM” on March 8. The successful close of the merger and concurrent financing from a syndicate of our investors has further strengthened our foundation, providing a cash runway through the end of 2024, which enables us to continue to advance our pipeline of important therapies through several key milestones.

Since the closing of the merger was subsequent to year end, our 2022 Annual Report includes Sesen Bio’s Annual Report on Form 10-K for the year ended December 31, 2022. To review (i) the audited consolidated financial statements of Carisma as of and for the years ended December 31, 2022 and 2021, (ii) Carisma’s Management’s Discussion and Analysis of Financial Condition and Results of Operations for the years ended December 31, 2022 and 2021, and (iii) the unaudited pro forma condensed combined financial information of Sesen Bio and Carisma as of and for the year ended December 31, 2022, please see Amendment No. 1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on April 4, 2023.

In 2022, we made meaningful progress across all areas of our business, including entering a development collaboration with Moderna, advancing our lead program CT-0508 in HER2+ solid tumors, and announcing our merger with Sesen Bio. We look forward to the multiple potential value inflection points over the next 18 months, including the completion of our Phase 1 study of CT-0508, data from clinical trial sub-study of CT-0508 in combination with pembrolizumab and the filing of our IND for a Phase 1 study of CT-0525.

These are exciting times for Carisma. On behalf of myself, our Board of Directors, management and the entire Carisma team, I want to thank you again for your continued support. We believe we are well positioned for continued growth, with groundbreaking science and a driven team, and we look forward to engaging with you as we continue our journey.

Very truly yours,

Steven Kelly  
*President and Chief Executive Officer*



**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, 2022  
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**

(State or other jurisdiction of  
incorporation or organization)

**26-2025616**

(I.R.S. Employer  
Identification No.)

**245 First Street, Suite 1800  
Cambridge, MA**

(Address of principal executive offices)

**02142**

(Zip Code)

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

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 Stock Market LLC               |

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 | <input type="checkbox"/>            | Smaller reporting company | <input checked="" type="checkbox"/> |
| Accelerated filer       | <input type="checkbox"/>            | Emerging growth company   | <input type="checkbox"/>            |
| Non-accelerated filer   | <input checked="" type="checkbox"/> |                           |                                     |

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.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b).

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 Capital Market on June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$161.6 million.

There were 203,492,202 shares of the registrant's common stock outstanding as of February 21, 2023.

### **Documents Incorporated by Reference**

Portions of the registrant's Definitive Proxy Statement relating to the 2023 Annual Meeting of Stockholders ("2023 Proxy Statement") or an amendment to this Annual Report on Form 10-K are incorporated by reference into Part III of this Annual Report on Form 10-K. The registrant will file the 2023 Proxy Statement or an amendment to this Annual Report on Form 10-K with the Securities and Exchange Commission within 120 days of December 31, 2022.

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# SESEN BIO, INC.

## Annual Report on Form 10-K for the Fiscal Year Ended December 31, 2022

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### SIGNATURES

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. We refer to the surviving corporation following the merger (as discussed below) as the "combined company".



## 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, including statements regarding our future results of operations and financial position, the proposed merger with CARISMA Therapeutics Inc. (“Carisma”), the impact of the COVID-19 pandemic, business strategy, current and prospective products, product approvals, research and development costs, current and prospective collaborations, timing and likelihood of success, plans and objectives of management for future operations and future results of current and anticipated products, 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 ability to complete, on a timely basis or at all, the proposed merger with Carisma announced on September 21, 2022, pursuant to the terms and conditions of the Merger Agreement (as defined below);
- the receipt of any potential future payments to our stockholders under the CVR Agreement (as defined below);
- the strategy or future operations of the combined company following the closing of the proposed merger with Carisma,
- advancement of the combined company’s product candidates and product pipeline, clinical development of the combined company’s product candidates, including expectations regarding timing of initiation and results of clinical trials of the combined company;
- our ability to seek a partner for the further development of Vicineum, and the potential challenges involved;
- the expected timing of implementing and completing our 2022 Restructuring Plan (as defined below) following the decision to voluntarily pause further development of Vicineum in the United States;
- the expected timing for incurring costs associated with the 2022 Restructuring Plan;
- our ability to preserve capital during the pendency of the proposed merger with Carisma and while we seek a potential partner for the further development of Vicineum;
- the potential impact of the COVID-19 pandemic on our ability to consummate the proposed merger with Carisma and seek a partner for the further development of Vicineum;
- our projected financial position;
- our ability to maintain intellectual property protection for our product candidates and our proprietary technology;
- our beliefs regarding key advantages of our targeted fusion protein therapeutics platform; and
- our expectations regarding the amount of future milestone payments pursuant to our Asset Purchase Agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc.

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:

- the risk that the conditions to the closing of the proposed merger with Carisma are not satisfied, including the failure to obtain stockholder approval of matters related to the proposed merger in a timely manner or at all;
- uncertainties as to the timing of the consummation of the proposed merger with Carisma and the ability of each of us and Carisma to consummate the proposed merger, including Carisma’s completion of the Carisma Pre-Closing Financing (as defined below);
- risks related to our ability to correctly estimate our expected net cash at the closing of the proposed merger and our ability to correctly estimate and manage our respective operating expenses and expenses associated with the proposed merger;
- risks related to our continued listing on The Nasdaq Stock Market LLC;
- the risk that as a result of adjustments to the Exchange Ratio (as defined below) our stockholders could own less of the combined company than is currently anticipated;

- the risk that the conditions to payment under the CVR Agreement will not be met and may never deliver any value to our stockholders;
- risks associated with the possible failure to realize certain anticipated benefits of the proposed merger, including with respect to future financial and operating results;
- uncertainties regarding the impact any delay in the closing of the proposed merger would have on the anticipated cash resources of the combined company upon closing of the proposed merger and other events and unanticipated spending and costs that could reduce the combined company's cash resources;
- the effect of uncertainties related to the actions of activist stockholders, which could make it more difficult to obtain the approval of our stockholders with respect to the proposed merger related proposals and result in us incurring significant fees and other expenses, including for third-party advisors;
- the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the Merger Agreement;
- the effect of the announcement, pendency or completion of the proposed merger on our or Carisma's business relationships, operating results and business generally;
- costs related to the proposed merger;
- the outcome of any legal proceedings that have been and may be instituted against us or any of our directors or officers related to the Merger Agreement or the transactions contemplated thereby;
- the ability of us or Carisma to protect our and their intellectual property rights, as applicable;
- competitive responses to the proposed merger and changes in expected or existing competition;
- risks related to the inability of the combined company to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs;
- legislative, regulatory, political and economic developments, among other risks and uncertainties;
- the risk that we may not be successful in identifying a partner for the further development of Vicineum;
- the risk that we may not be able to implement the 2022 Restructuring Plan as currently anticipated or within the timing currently anticipated;
- the risk that we may incur unanticipated charges as a result of the 2022 Restructuring Plan;
- the risk that we may be unable to defend and enforce patent claims and other intellectual property rights;
- the risk that we may be unable to defend against pending or threatened litigation, which may be costly and time-consuming; and
- such other factors described in "Item 1A. Risk Factors" and "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Annual Report on Form 10-K.

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 the Merger with CARISMA Therapeutics Inc.**

- The Exchange Ratio will not change or otherwise be adjusted based on the market price of our common stock as the exchange ratio depends on our net cash at the closing of the Merger and not the market price of our common stock, so the merger consideration at the closing of the Merger may have a greater or lesser value than at the time the Merger Agreement was signed.
- Our stockholders and Carisma’s stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger and the Carisma Pre-Closing Financing and the conversion of the Carisma convertible note.
- Failure to complete the Merger may result in either us or Carisma paying a termination fee to the other party and could significantly harm the market price of our common stock and negatively affect the future business and operations of each company.
- The issuance of our common stock to Carisma’s stockholders pursuant to the Merger Agreement and the resulting change in control from the Merger must be approved by our stockholders, and the Merger Agreement and transactions contemplated thereby must be approved by Carisma’s stockholders. Failure to obtain these approvals would prevent the closing of the Merger.
- Some of our executive officers and directors have interests in the Merger that are different from our stockholders and that may influence them to support or approve the Merger without regard to the interests of our stockholders.
- Our stockholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the closing of the Merger as compared to their current ownership and voting interest in our company.
- During the pendency of the Merger, we may not be able to enter into a business combination with another party on more favorable terms because of restrictions in the Merger Agreement, which could adversely affect our business prospects.
- Certain provisions of the Merger Agreement may discourage third parties from submitting alternative takeover proposals, including proposals that may be superior to the transactions contemplated by the Merger Agreement.
- Because the lack of a public market for Carisma common stock makes it difficult to evaluate the value of Carisma common stock, the Carisma stockholders may receive shares of our common stock in the Merger that have a value that is less than, or greater than, the fair market value of Carisma common stock.
- If the conditions to the Merger are not satisfied or waived, the Merger will not occur.
- Lawsuits have been filed, and additional lawsuits may be filed in the future, against us and the members of our board of directors arising out of the proposed Merger, which may delay or prevent the proposed Merger.
- If the Merger is not completed, our board of directors may decide to pursue a dissolution of our company. In a dissolution, there can be no assurances as to the amount or timing of available cash, if any, to distribute to our stockholders after paying our debts and other obligations and setting aside funds for reserves.
- Our stockholders may not receive any payment on the CVRs (as defined below) from the proceeds related to either the Roche Asset Purchase Agreement (as defined below) or any sale of our non-cash assets and therefore the CVR may expire valueless or result in lower returns than anticipated or none at all.
- The United States federal income tax treatment of the CVRs is unclear and there can be no assurance that the Internal Revenue Service would not assert, or that a court would not sustain, a position that could result in adverse United States federal income tax consequences to holders of the CVRs.
- We have never paid and, other than in connection with the Merger with Carisma, do not intend to pay any cash dividends in the foreseeable future.
- We are substantially dependent on our remaining employees to facilitate the consummation of the Merger.

### **Risks Related to Our Intellectual Property**

- We may not be able to protect our intellectual property rights throughout the world.
- If we cannot meet the requirements under our license agreements with Zurich, Micromet and XOMA, we could lose important rights to Vicineum, which could have material adverse effect on our ability to sell Vicineum.

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

#### **Risks Related to our Business and Operations**

- We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.
- Our restructuring plans and the associated headcount reductions may not result in anticipated savings, could result in total costs and expenses that are greater than expected.
- We may not be able to enter into a transaction with a suitable acquiror or licensee for Vicineum or any transaction entered into may not be on terms that are favorable to us.
- In connection with our strategic decision to voluntarily pause further development of Vicineum in the United States, we may become involved in disagreements or disputes with our licensees, licensors and other counterparties relating to the development and/or commercialization of Vicineum, which may be time consuming, costly and could divert our efforts and attention from consummating the proposed Merger with Carisma and harm our efforts to seek a partner to continue development of Vicineum.
- We and certain of our officers have been, and may in the future be, named as defendants in lawsuits. 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. Any other lawsuits to which we are subject may be costly to defend and are uncertain in their outcome.

#### **Risks Related to Ownership of Our Common Stock**

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

## PART I

### Item 1. Business.

#### Overview

We are a late-stage clinical company that previously focused on advancing targeted fusion protein therapeutics ("TFPTs") for the treatment of patients with cancer.

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 bladder cancer ("NMIBC").

On July 15, 2022, we made the strategic decision to voluntarily pause further development of Vicineum in the United States. The decision was based on a thorough reassessment of Vicineum following discussions with the United States Food and Drug Administration ("FDA"), which had implications on the size, timeline, and costs of an additional Phase 3 clinical trial, which the FDA previously confirmed would be required for a potential resubmission of a biologics license application ("BLA") for Vicineum for the treatment of NMIBC. As a result of this decision, we turned our primary focus to consummating a strategic transaction with the goal of maximizing stockholder value.

Following an extensive process of evaluating strategic alternatives, including identifying and reviewing potential candidates for a strategic transaction, on September 20, 2022, we, Seahawk Merger Sub, Inc., a Delaware corporation and our wholly-owned subsidiary ("Merger Sub"), and CARISMA Therapeutics Inc. ("Carisma"), entered into the Agreement and Plan of Merger and Reorganization dated as of September 20, 2022, as amended by the First Amendment thereto dated as of December 29, 2022 and the Second Amendment thereto dated as of February 13, 2023 (the "Merger Agreement"), pursuant to which, among other things, and subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement, Merger Sub will merge with and into Carisma, with Carisma continuing as our wholly-owned subsidiary and the surviving corporation of the merger (the "Merger"). Our board of directors unanimously approved the Merger Agreement and resolved to recommend that our stockholders approve the proposals described in the Merger Agreement. If the Merger is completed, the business of Carisma will continue as the business of the combined company.

We continue to believe that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with a larger infrastructure, and as such, we are seeking a partner that can execute further development to realize the full potential of Vicineum. As a result of such decision and our subsequent decision to enter into the proposed Merger with Carisma, we no longer plan to pursue regulatory approval of Vicineum for NMIBC in the European Union (the "E.U.") and have started to wind down certain of our manufacturing operations and business development partnerships. Additionally, we are seeking a partner for the further development of Vicineum and have initiated a formal process and engaged a financial advisor for the potential sale of Vicineum. If the proposed Merger is consummated, the combined company does not expect to pursue further development of Vicineum.

#### Current Strategy

##### *Anticipated Merger with CARISMA Therapeutics Inc.*

The Merger is expected to be completed during the first quarter of 2023. In connection with the Merger, we are seeking the approval of our stockholders to, among other things, (a) issue the shares of our common stock issuable in connection with the Merger pursuant to the rules of The Nasdaq Stock Market LLC ("Nasdaq"), and (b) amend our amended and restated Certificate of Incorporation to effect a reverse stock split of the outstanding shares of our common stock at a ratio of 1-for-20 (clauses (a) and (b), collectively, the "Sesen Bio Voting Proposals"). The special meeting of stockholders in which our stockholders will be asked to vote on the Sesen Bio Voting Proposals (the "Special Meeting") will be held on March 2, 2023 at 10:00 a.m. Eastern Time.

Consummation of the Merger is subject to certain closing conditions, including, among other things, (a) approval by our stockholders of the Sesen Bio Voting Proposals as described in the Merger Agreement, (b) approval by Carisma's stockholders of, among other things, the adoption of the Merger Agreement, (c) Nasdaq's approval of the listing of the shares of our common stock to be issued in connection with the Merger, (d) the effectiveness of a registration statement on Form S-4 to register the shares of our common stock to be issued in connection with the Merger, and (e) our having net cash as of closing of the Merger greater than or equal to \$70.0 million.

The Merger Agreement contains certain termination rights of each of us and Carisma. Upon termination of the Merger Agreement under specified circumstances, we may be required to pay Carisma a termination fee of \$7.6 million and/or reimburse Carisma's expenses up to a maximum of \$1.75 million, and Carisma may be required to pay us a termination fee of \$5.49 million and/or reimburse our expenses up to a maximum of \$1.75 million.

Subject to the terms and conditions of the Merger Agreement, at the completion of the Merger, (a) each then outstanding share of Carisma common stock and Carisma preferred stock (including shares of Carisma’s common stock issued in connection with the pre-closing financing described below) will be converted into the right to receive a number of the shares of our common stock calculated in accordance with the Merger Agreement (the “Exchange Ratio”), and (b) each then outstanding Carisma stock option to purchase Carisma’s common stock will be assumed by us, subject to adjustment as set forth in the Merger Agreement.

Concurrently with the execution and delivery of the Merger Agreement, Carisma entered into a subscription agreement with certain investors named therein, pursuant to which such investors have agreed, subject to the terms and conditions of such subscription agreement, to purchase prior to the consummation of the Merger shares of Carisma’s common stock for an aggregate purchase price of approximately \$30.6 million (the “Carisma Pre-Closing Financing”). The consummation of the Carisma Pre-Closing Financing is conditioned on the satisfaction or waiver of the conditions set forth in the Merger Agreement. Shares of Carisma’s common stock issued pursuant to the Carisma Pre-Closing Financing will be converted into shares of our common stock in the Merger in accordance with the Exchange Ratio.

At or prior to the effective time of the Merger, we will enter into a Contingent Value Rights Agreement (the “CVR Agreement”) with a rights agent (the “Rights Agent”) pursuant to which we intend to declare a dividend payable to our stockholders of record as of a date agreed to by us and Carisma prior to the effective time of the Merger with respect to the receipt of one contingent value right (each, a “CVR”), for each outstanding share of our common stock held by such stockholders on such date. Each CVR will represent the contractual right to receive (i) contingent cash payments upon the receipt by us of certain proceeds payable by Roche, if any, pursuant to the asset purchase agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (collectively, “Roche”) (the “Roche Asset Purchase Agreement”), upon the achievement by Roche of a specified milestone set forth in the Roche Asset Purchase Agreement as well as (ii) proceeds from any sale of our legacy assets, including Vicineum, subject to certain customary deductions, including for expenses and taxes, in the event any sale occurs prior to March 31, 2027. The contingent payments under the CVR Agreement, if they become due, will be payable to the Rights Agent for subsequent distribution to the holders of the CVRs. In the event that no such proceeds are received, holders of the CVRs will not receive any payment pursuant to the CVR Agreement. There can be no assurance that any cash payment will be made or that any holders of CVRs will receive any amounts with respect thereto.

Also in connection with the Merger, we intend to declare a one-time \$75.0 million cash dividend payable to our stockholders of record as of a date prior to the effective time of the Merger, subject to the terms and condition set forth in the Merger Agreement.

On February 13, 2023, a group of our significant stockholders (the “Investor Group”) entered into a voting and support agreement with us and Carisma (the “Support Agreement”) pursuant to which the Investor Group agreed to vote, at the Special Meeting, any and all of their shares of our common stock in favor of the Merger and related matters, subject to the terms and conditions set forth in the Support Agreement.

Our future operations are highly dependent on the success of the Merger and there can be no assurances that the Merger will be successfully consummated. In the event that we do not complete the Merger with Carisma, we may decide to pursue a dissolution under Delaware law. In a dissolution, there can be no assurances as to the amount or timing of available cash, if any, to distribute to our stockholders after paying our debts and other obligations and setting aside funds for reserves.

### ***Other Recent Events***

#### ***2022 Restructuring Plan***

On July 15, 2022, we approved a restructuring plan to reduce operating expenses and better align our workforce with the needs of our business following the decision to voluntarily pause further development of Vicineum in the United States (the “2022 Restructuring Plan”). Execution of the 2022 Restructuring Plan is expected to be substantially completed in connection with the closing of the Merger, which is expected to occur in the first quarter of 2023. The 2022 Restructuring Plan includes an incremental reduction in our workforce as well as additional cost-saving initiatives intended to preserve capital during the pendency of the Merger and while we seek a potential partner for the further development of Vicineum. We also incurred one-time cash costs associated with the termination of certain contracts and all other activities under the 2022 Restructuring Plan.

#### ***2022 Retention Program***

On August 28, 2022, our board of directors and the compensation committee of the board of directors approved a retention program for certain employees pursuant to which we will provide a cash incentive designed to retain such employees (the “2022 Retention Program”). Pursuant to the 2022 Retention Program, certain of our employees, including certain executive officers other than our Chief Executive Officer, were to have received a cash bonus award, vesting in full upon the earlier of (a) the completion of a strategic transaction and (b) the termination of such employee without cause, subject to the employee’s continued employment through that time. On February 7, 2023, the compensation committee of the board of directors approved a modification to the 2022 Retention Program, such that the vesting of the retention bonus awards for employees, other than

executive officers, will occur upon the earlier of (a) 5:00 pm Eastern Time on the second business day following the date of the Special Meeting regardless of the results of the Special Meeting and (b) the termination of the Merger Agreement in accordance with its terms. The terms of the 2022 Retention Program for those executive officers participating in the 2022 Retention Program were not modified.

#### *Nasdaq Delisting Notice*

On January 25, 2023, we were notified by the Listing Qualifications Department (the “Staff”) of Nasdaq that, based upon our non-compliance with the \$1.00 bid price requirement for continued listing on The Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550(a)(2) (the “Bid Price Rule”), our common stock will be delisted from Nasdaq unless we timely request a hearing before a Nasdaq Hearings Panel (the “Panel”).

We requested a hearing before the Panel, which stayed any delisting action by the Staff and ensured our common stock remains listed and eligible for trading on Nasdaq pending a determination by the Panel. The hearing had been scheduled for March 16, 2023. On February 24, 2023, we received a determination from the Nasdaq Office of General Counsel that the Panel granted us an exception from our non-compliance with the Bid Price Rule to complete the Merger by March 10, 2023. Pursuant to Nasdaq Listing Rule 5110(a), we must demonstrate compliance with all initial listing requirements of Nasdaq upon the closing of the Merger. We are seeking approval for the Merger and the implementation of a reverse stock split of our common stock at the Special Meeting. In the event we fail to establish compliance with the initial listing standards by March 10, 2023, our common stock will be delisted from Nasdaq, unless granted an additional exception by the Panel.

As previously disclosed, on January 24, 2022, we received written notice from the Staff indicating that, based upon the closing bid price for our common stock for the previous 30 consecutive business days, we no longer satisfied the Bid Price Rule and, in accordance with the Nasdaq Listing Rules, were afforded an initial grace period of 180 calendar days, through July 25, 2022, and a second 180-calendar day period, through January 23, 2023, to regain compliance with the Bid Price Rule. We did not regain compliance with the Bid Price Rule by January 23, 2023, which resulted in the Staff’s January 25, 2023, determination.

#### ***Sale of EBI-031 Legacy Technology to Roche***

In June 2016, we entered into a license agreement with Roche (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 “Roche Licensed Intellectual Property”). Under the Roche License Agreement, Roche was 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 and pursue ongoing patent prosecution, at its cost. At the time of entering into 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.

On July 15, 2022, we entered into the Roche Asset Purchase Agreement pursuant to which Roche purchased all patent rights and know-how related to the monoclonal antibody EBI-031 and all other IL-6 antagonist monoclonal antibody technology owned by us for up to \$70.0 million. As a result of the Roche Asset Purchase Agreement, the Roche License Agreement was terminated resulting in no further diligence, milestone or royalty payment obligations under the Roche License Agreement. Pursuant to the Roche Asset Purchase Agreement, Roche made a \$40.0 million payment to us upon execution of the Roche Asset Purchase Agreement. The Roche Asset Purchase Agreement also provides that Roche will make an additional \$30.0 million payment to us upon Roche’s initiation of a Phase 3 clinical trial with EBI-031 for a defined indication if initiated prior to December 31, 2026.

Additionally, in connection with the Merger, each CVR will represent the contractual right to receive contingent cash payments upon the receipt by us of certain proceeds payable by Roche, if any, pursuant to the Roche Asset Purchase Agreement, upon the achievement by Roche of a specified milestone set forth in the Roche Asset Purchase Agreement as well as proceeds from any sale of our legacy assets, including Vicineum.

#### **Our Historical TFPT Platform**

Our historical 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 antibody drug conjugates and were 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 antibody fragments, which include Fabs, single chain variable domains (“scFvs”), and non-covalent scFv dimers, derived from the domains of antibodies that confer antigen recognition. We selected antibody fragments for our historical product candidates depending upon the target therapeutic indication. We targeted tumor cell surface antigens showing limited expression on normal cells and once bound, is rapidly internalized into the targeted cancer cell. For local administrations, we utilized an immunogenic cytotoxic protein payload designed to both target cancer cells and promote a heightened local immune response against the

tumor. Our most advanced locally administered TFPT product candidate was Vicineum, in development for the treatment of non-muscle invasive carcinoma in situ (“CIS”) of the bladder in patients previously treated with adequate or less than adequate bacillus Calmette-Guérin (“BCG”). For systemic administrations, we used 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.

*Vicineum for the treatment of NMIBC*

We completed the follow-up stage of our single-arm, multi-center, open-label Phase 3 clinical trial of Vicineum as a monotherapy in patients with BCG-unresponsive NMIBC (the “VISTA Trial”) in May 2022.

The VISTA Trial completed enrollment in April 2018 with a total of 133 patients. 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 Prescription Drug User Fee Act date for a decision on the BLA of August 18, 2021. On August 13, 2021, we 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 chemistry, manufacturing, and controls (“CMC”) issues pertaining to a pre-approval inspection and product quality. On August 20, 2021, we withdrew our marketing authorization application (“MAA”) to the European Medicines Agency (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 E.U. until there was more clarity from the FDA on next steps for Vicineum in the United States. Vysyneum is the proprietary brand name conditionally approved by the EMA for oportuzumab monatox in the E.U. In October 2021, the EMA issued its Withdrawal Assessment Report relating to its MAA for Vysyneum, as is consistent with the EMA’s standard practice when an MAA is withdrawn. The EMA Withdrawal Assessment Report reflected the initial assessment and corresponding questions from the EMA and identified major objections in the areas of quality, good clinical practice, efficacy, and safety. As a result of our decision on July 15, 2022 to pause further development of Vicineum in the United States, we no longer plan to pursue regulatory approval of Vysyneum for NMIBC in the E.U.

In October 2021 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 would be required for a potential resubmission of a BLA. In March 2022, we participated in a Type C meeting with the FDA. During the Type C meeting, the FDA agreed to a majority of our proposed protocol and statistical analysis plan design elements for an additional Phase 3 clinical trial. On July 11, 2022, we participated in a Type B meeting with the FDA to discuss outstanding items related to our proposed protocol and statistical analysis plan design elements for an additional Phase 3 clinical trial. As discussed above, on July 15, 2022, we made the strategic decision to voluntarily pause further development of Vicineum in the United States. If the Merger is consummated, the combined company does not expect to pursue further development of Vicineum.

*Phase 3 Clinical Trial – VISTA Trial*

In the third quarter of 2015, in the United States and Canada, through our subsidiary Viventia Bio, Inc., we commenced the VISTA Trial in patients with BCG-unresponsive NMIBC who had received adequate BCG and whose disease was-then BCG-unresponsive, and for whom the then-current standard of care was radical cystectomy. 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. In May 2022, we completed the follow up phase of the VISTA Trial.

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

|                          |  |
|--------------------------|--|
| <b>Dose</b>              | 30 mg of Vicineum (in 50 mL of saline)   |
| <b>Total enrollment</b>  | 133 patients, including 93 CIS patients whose disease is BCG-unresponsive  |
| <b>Primary endpoints</b> | Complete response rate (“CRR”) at 3 months in patients with CIS (with or without papillary disease) whose disease is BCG-unresponsive                          |
|                          | Kaplan-Meier estimate of duration of response (“DoR”) for BCG-unresponsive CIS patients who experience a complete response (“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.

|                            |  |
|----------------------------|--|
| <b>Secondary endpoints</b> | 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   |
|                            | Progression free survival (PFS) in all patients  |
|                            | Overall survival (OS) in all patients  |
|                            | Safety and tolerability of Vicineum therapy in all patients                                      |

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

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

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

| <b>Time Point</b> | <b>Evaluable Patients*</b> | <b>Complete Response Rate (95% Confidence Interval)</b> |
|-------------------|----------------------------|---|
| 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:**

| <b>Time Point</b> | <b>Evaluable Patients*</b> | <b>Complete Response Rate (95% Confidence Interval)</b> |
|-------------------|----------------------------|---|
| 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) was 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) showed 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 showed 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) was 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.

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

In connection with our decision to voluntarily pause further development of Vicineum, we commenced the process to wind down our OUS business development partnerships in the Middle East and North Africa region ("MENA") and Turkey by providing notice of termination for our exclusive license agreements in these respective regions on July 20, 2022. In connection with the termination of the exclusive license agreement with our partner in MENA, we refunded the \$3.0 million upfront payment previously paid to us.

### 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") (the "Qilu License Agreement") pursuant to which we granted Qilu an exclusive, sublicensable, royalty-bearing license, under certain intellectual property owned or exclusively licensed by us, to develop, manufacture, and commercialize Vicineum for the treatment of BCG-unresponsive NMIBC and other types of cancer in China, Hong Kong, Macau and Taiwan (collectively, "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 retained (i) development and commercialization rights in the rest of the world excluding Greater China, MENA, and Turkey and (ii) manufacturing rights with respect to Vicineum in the rest of the world excluding Greater China.

On December 23, 2022, we terminated the Qilu License Agreement. In connection with the termination of the Qilu License Agreement, we agreed to make an aggregate payment to Qilu of \$1.4 million, which consists of a \$1.2 million termination fee payable upon the termination of the Qilu License Agreement, which was paid in the fourth quarter of 2022, and a \$200,000 payment payable upon our receipt of certain clinical data and chemistry, manufacturing, and controls data from Qilu, which such payment was not made as of December 31, 2022. As a result of the termination of the Qilu License Agreement, all rights to Vicineum in Greater China have reverted to us. We currently retain all global rights to Vicineum.

### MENA

On November 30, 2020, we and our wholly owned subsidiary, Viventia Bio, Inc., entered into an exclusive license agreement with Hikma Pharmaceuticals LLC ("Hikma") (the "Hikma License Agreement"), 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.

On July 20, 2022, we provided notice of termination of the Hikma License Agreement as a result of the Company's strategic decision to voluntarily pause further development of Vicineum in the United States. In connection with such termination and as required under the Hikma License Agreement, we refunded to Hikma the \$3.0 million upfront payment previously paid to us.

## 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 (the “EIP License Agreement”). On July 20, 2022, we provided notice of termination of the EIP License Agreement as a result of our strategic decision to voluntarily pause further development of Vicineum in the United States. The EIP License Agreement was terminated on October 20, 2022.

### **Our Intellectual Property**

We currently own or exclusively license approximately 13 families of patents and applications, which generally relate to our TFPT-based historical product candidates and our platform of targeting agents, cytotoxins (such as deBouganin) and linker technologies.

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 United States 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"), 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 (the "Micromet License Agreement"). 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") 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 (the "XOMA License Agreement"). These patents and related know-how cover some key aspects of Vicineum. See "Our Vicineum License Agreements" below for additional information.

### **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 (the “Zurich License Agreement”). These patents cover some key aspects of Vicineum. Upon receipt of the CRL regarding the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC, we became obligated to pay a \$0.5 million milestone payment to Zurich pursuant to the Zurich License Agreement. 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 the 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. For the year ended December 31, 2022, no related expense was recorded.

##### *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*

The Micromet License Agreement grants us nonexclusive rights, with certain sublicense rights, for know-how and patents allowing exploitation of certain single chain antibody products. These patents (which are now expired) cover some key aspects of Vicineum. Under the terms of the Micromet License Agreement, as of December 31, 2021, even though the patents have expired, 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 \$2.6 million at exchange rates in effect on December 31, 2022). We are also required to pay up to a 3.5% royalty on the net sales for products covered by the Micromet License Agreement, which includes Vicineum. The royalty rate owed to Micromet in a particular country will be reduced to 1.5% if there are no valid claims covering the product in that country. The obligation to pay royalties in a particular country expires upon the later of the expiration date of the last valid claim covering the product and the tenth anniversary of the first commercial sale of the product in such country. Finally, we are required to pay to Micromet an annual license maintenance fee of €50,000, which can be credited towards any royalty payment we owe to Micromet. 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 the 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. For the year ended December 31, 2022, we recorded an expense of €50,000 (\$51,770) related to the annual license maintenance fee.

#### *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 covered by the Micromet License Agreement. Either party has the right to terminate the Micromet License Agreement if the other party fails to comply with any of its material obligations under the Micromet License Agreement and fails to cure such non-compliance within the applicable cure periods.

### ***In-License Agreement with XOMA***

#### *Overview*

The XOMA License Agreement grants us non-exclusive rights, with certain sublicense rights, to certain XOMA patent rights (which are now expired) and know-how related to certain expression technology, including plasmids, expression strains, plasmid maps and production systems. These patents and related know-how cover some key aspects of Vicineum. Under the terms of the XOMA License Agreement, even though the patents have expired, 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. 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**

During the third quarter of 2022, we entered into a Lease Termination Agreement (the "Lease Termination Agreement") pursuant to which we terminated the operating lease agreement for our 31,100 square foot facility in Winnipeg, Manitoba which consisted of manufacturing, laboratory, warehouse, and office space and agreed to end the lease by September 30, 2022. As part of the execution of the Lease Termination Agreement, we paid the landlord the all-inclusive sum of CAD \$1.2 million (USD \$0.9 million).

#### *Fujifilm and Baxter*

In October 2018, we entered into a Master Bioprocessing Services Agreement with FUJIFILM DIOSYNTH Biotechnologies U.S.A., Inc. ("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 Oncology GmbH ("Baxter") (the "Baxter CMSA") 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 was 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 with Fujifilm under the Fujifilm MSA for the manufacturing of commercial batches of Vicineum in 2022 and 2023.

In July 2022, in connection with our decision to voluntarily pause further development of Vicineum, we terminated the Fujifilm MSA and Baxter CMSA and requested that Fujifilm and Baxter cease all work under the respective agreements and refrain from incurring any additional costs or expenses. As a result of the termination, and in accordance with the terms of the Fujifilm MSA and Baxter CMSA, we paid Fujifilm and Baxter for certain non-manufacturing stage services and current Good Manufacturing Practice batches of drug substance of Vicineum.

#### *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 (the "Qilu Global Supply Agreement"). On December 23, 2022, we terminated the Qilu Global Supply Agreement in connection with the termination of the Qilu License Agreement.

## **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 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**

As of December 31, 2022, we had seventeen full-time employees and no part-time employees. We have no collective bargaining agreements with our employees, and none are represented by labor unions. We have not experienced any work stoppages. We believe our relationship with our employees is satisfactory.

## **Corporate Information and Access to SEC Reports**

Our principal executive offices are located at 245 First Street, Suite 1800, Cambridge, Massachusetts 02142, our telephone number is (617)-444-8550 and our website address is [www.sesensbio.com](http://www.sesensbio.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 Securities and Exchange Commission (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.sesensbio.com](http://www.sesensbio.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](http://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 the Merger with CARISMA Therapeutics Inc.**

***The Exchange Ratio will not change or otherwise be adjusted based on the market price of our common stock as the exchange ratio depends on our net cash at the closing of the Merger and not the market price of our common stock, so the merger consideration at the closing of the Merger may have a greater or lesser value than at the time the Merger Agreement was signed.***

On September 20, 2022, we, Seahawk Merger Sub, Inc., a Delaware corporation and our wholly-owned subsidiary (“Merger Sub”), and CARISMA Therapeutics Inc. (“Carisma”), entered into the Agreement and Plan of Merger and Reorganization dated as of September 20, 2022, as amended by the First Amendment thereto dated as of December 29, 2022 and the Second Amendment thereto dated as of February 13, 2023 (the “Merger Agreement”), pursuant to which, among other things, and subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement, Merger Sub will merge with and into Carisma, with Carisma continuing as our wholly-owned subsidiary and the surviving corporation of the merger (the “Merger”). Subject to the terms and conditions of the Merger Agreement, at the closing of the Merger, (a) each then outstanding share of Carisma common stock and Carisma preferred stock (including shares of Carisma’s common stock issued in connection with the pre-closing financing described below) will be converted into the right to receive a number of the shares of our common stock calculated in accordance with the Merger Agreement (the “Exchange Ratio”). Concurrently with the execution and delivery of the Merger Agreement, Carisma entered into a subscription agreement with certain investors named therein, pursuant to which such investors have agreed, subject to the terms and conditions of such subscription agreement, to purchase prior to the consummation of the Merger shares of Carisma’s common stock for an aggregate purchase price of approximately \$30.6 million (the “Carisma Pre-Closing Financing”). The Merger Agreement has set the calculation of the Exchange Ratio for the Carisma capital stock, and the Exchange Ratio is based on the fully-diluted capitalization of Carisma and us, in each case immediately prior to the closing of the Merger (after giving effect to the Carisma Pre-Closing Financing). The Merger Agreement does not include a price-based termination right. Therefore, if before the completion of the Merger the market price of our common stock declines from the market price on the date of the Merger Agreement, then Carisma’s stockholders could receive merger consideration with substantially lower value than the value of such merger consideration on the date of the Merger Agreement. Similarly, if before the completion of the Merger the market price of our common stock increases from the market price of our common stock on the date of the Merger Agreement, then Carisma’s stockholders could receive merger consideration with substantially greater value than the value of such merger consideration on the date of the Merger Agreement. Because the Exchange Ratio does not adjust as a direct result of changes in the market price of our common stock, changes in the market price of our common stock will change the value of the total merger consideration payable to Carisma’s stockholders pursuant to the Merger Agreement.

Stock price changes may result from a variety of factors, including changes in our or Carisma’s respective businesses, operations and prospects, reductions or changes in United States government spending or budgetary policies, market assessments of the likelihood that the Merger will be completed, interest rates, federal, state and local legislation, governmental regulation, legal developments in the industry segments in which we or Carisma operate, the timing of the Merger, and general market, industry and economic conditions, including pandemics and other public health emergencies. Recent events surrounding the global economy, geopolitics and the COVID-19 pandemic continue to evolve and have introduced unusually high levels of volatility into financial and stock markets, and may affect the value of our common stock.

***Our stockholders and Carisma’s stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger and the Carisma Pre-Closing Financing and the conversion of the Carisma convertible note.***

If the combined company is unable to realize the full strategic and financial benefits currently anticipated from the Merger, our stockholders and Carisma’s stockholders will have experienced substantial dilution of their ownership interests in their respective companies, including as a result of the Carisma Pre-Closing Financing and the conversion of Carisma’s \$35.0 million outstanding convertible note, without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined company is able to realize only part of the strategic and financial benefits currently anticipated from the Merger and the Carisma Pre-Closing Financing.

***Failure to complete the Merger may result in either us or Carisma paying a termination fee to the other party and could significantly harm the market price of our common stock and negatively affect the future business and operations of each company.***

If the Merger is not completed and the Merger Agreement is terminated under certain circumstances, we may be required to pay Carisma a termination fee of \$7.6 million and/or reimburse Carisma's expenses up to a maximum of \$1.75 million, and Carisma may be required to pay us a termination fee of \$5.49 million and/or reimburse our expenses up to a maximum of \$1.75 million. Even if a termination fee or reimbursement of expenses of the other party are not payable in connection with a termination of the Merger Agreement, each of us and Carisma will have incurred significant fees and expenses, which must be paid whether or not the Merger is completed.

In addition, if the Merger Agreement is terminated and our board of directors determines to seek another business combination, there can be no assurance that we will be able to find a partner and close an alternative transaction on terms that are as favorable or more favorable than the terms set forth in the Merger Agreement.

***The issuance of our common stock to Carisma's stockholders pursuant to the Merger Agreement and the resulting change in control from the Merger must be approved by our stockholders, and the Merger Agreement and transactions contemplated thereby must be approved by Carisma's stockholders. Failure to obtain these approvals would prevent the closing of the Merger.***

Before the Merger can be completed, our stockholders must approve, among other things, the issuance of our common stock to Carisma's stockholders pursuant to the Merger Agreement and the resulting change in control from the Merger, and Carisma's stockholders must adopt the Merger Agreement and approve the Merger and the related transactions. Failure to obtain the required stockholder approvals may result in a material delay in, or the abandonment of, the Merger. Any delay in completing the Merger may materially adversely affect the timing and benefits that are expected to be achieved from the Merger.

***Some of our executive officers and directors have interests in the Merger that are different from our stockholders and that may influence them to support or approve the Merger without regard to the interests of our stockholders.***

Certain of our executive officers and directors participate in arrangements that provide them with interests in the Merger that are different from the interests of our stockholders, including, among others, severance benefits, the acceleration of equity vesting, continued indemnification and the potential ability to sell an increased number of shares of common stock of the combined company in accordance with Rule 144 under the Securities Act of 1933, as amended. These interests, among others, may influence our executive officers and directors to support or approve the Merger.

***Our stockholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the closing of the Merger as compared to their current ownership and voting interest in our company.***

If the proposed Merger is completed, our current stockholders will own a smaller percentage of the combined company than their ownership in our company prior to the Merger. Immediately after the Merger, after taking into account shares of Carisma common stock purchased in connection with the Carisma Pre-Closing Financing and the conversion of Carisma's \$35.0 million outstanding convertible note, our pre-Merger stockholders and Carisma's pre-Merger stockholders are expected to own approximately 24.2% and 75.8%, respectively, of the outstanding shares of capital stock of the combined company, subject to certain assumptions, including our net cash as of the closing of the Merger being greater than or equal to \$70.0 million.

***During the pendency of the Merger, we may not be able to enter into a business combination with another party on more favorable terms because of restrictions in the Merger Agreement, which could adversely affect our business prospects.***

Covenants in the Merger Agreement impede our ability to make acquisitions during the pendency of the Merger, subject to specified exceptions. As a result, if the Merger is not completed, we may be at a disadvantage to our competitors during such period. In addition, while the Merger Agreement is in effect, we are generally prohibited from soliciting, initiating or knowingly encouraging, inducing or facilitating any inquiries, indications of interest, proposals or offers that constitute or may reasonably be expected to lead to certain transactions involving a third party, including a merger, sale of assets or other business combination, subject to specified exceptions. Any such transactions could be favorable to our stockholders, but we may be unable to pursue them.

***Certain provisions of the Merger Agreement may discourage third parties from submitting alternative takeover proposals, including proposals that may be superior to the transactions contemplated by the Merger Agreement.***

The terms of the Merger Agreement prohibit us from soliciting alternative takeover proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances when our board of directors determines in good faith that an unsolicited alternative takeover proposal is or is reasonably likely to result in a superior takeover proposal and that failure to cooperate with the proponent of the proposal is reasonably likely to be inconsistent with our board's fiduciary duties. Any such transactions could be favorable to our stockholders. In addition, if we terminate the Merger Agreement under certain

circumstances, including terminating because of a decision of ours to enter into a definitive agreement with respect to a superior offer, we would be required to pay a termination fee of \$7.6 million to Carisma and/or reimburse Carisma's expenses up to a maximum of \$1.75 million. This termination fee described above may discourage third parties from submitting alternative takeover proposals to our stockholders, and may cause our board of directors to be less inclined to recommend an alternative takeover proposal.

***Because the lack of a public market for Carisma common stock makes it difficult to evaluate the value of Carisma common stock, the Carisma stockholders may receive shares of our common stock in the Merger that have a value that is less than, or greater than, the fair market value of Carisma common stock.***

The outstanding common stock of Carisma is privately held and is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of Carisma. Because the percentage of our common stock to be issued to Carisma's stockholders was determined based on negotiations between the parties, it is possible that the value of our common stock to be received by Carisma's stockholders will be less than the fair market value of Carisma, or that the value of our common stock to be received by Carisma's stockholders may be more than the aggregate fair market value for Carisma.

***If the conditions to the Merger are not satisfied or waived, the Merger will not occur.***

Even if the transactions contemplated by the Merger Agreement are approved by our stockholders and Carisma's stockholders, certain other specified conditions set forth in the Merger Agreement must be satisfied, to the extent permitted by applicable law, or waived to complete the Merger, including approval from The Nasdaq Stock Market LLC ("Nasdaq") to maintain the listing of our common stock on the Nasdaq Capital Market following the Merger and the listing of the shares of our common stock being issued in the Merger and upon the conversion of the Carisma convertible note. We cannot assure you that all of the conditions will be satisfied or waived. If the conditions are not satisfied or waived, the Merger will not occur or will be delayed, and we may lose some or all of the intended benefits of the Merger.

***Lawsuits have been filed, and additional lawsuits may be filed in the future, against us and the members of our board of directors arising out of the proposed Merger, which may delay or prevent the proposed Merger.***

Putative stockholder complaints, including stockholder class action complaints, and other complaints may be filed against us and our board of directors in connection with the transactions contemplated by the Merger Agreement. For example, we have received several letters from purported stockholders demanding that we amend the Registration Statement on Form S-4 filed pursuant to the Merger Agreement (File No. 333-267891) (the "Registration Statement") with the Securities and Exchange Commission ("SEC") to provide additional disclosures that such stockholders allege were improperly omitted from the Registration Statement, including information regarding the financial projections for Carisma, the financial analyses performed by our financial advisor in support of its fairness opinion, and the background and process leading to the execution of the Merger Agreement. We believe that these demands are without merit and we intend to vigorously defend against them. Additionally, several complaints have been filed asserting claims against us and our board of directors under Section 14(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and Rule 14a-9 promulgated thereunder for allegedly false and misleading statements in the proxy statement/prospectus filed as part of the Registration Statement. The outcome of such demands or any future demands that we may receive or any litigation is uncertain, and we may not be successful in defending against any such claims. Lawsuits that have been and may be filed against us and our board of directors, could delay or prevent the Merger, divert the attention of our management team and employees from our day-to-day business and otherwise adversely affect our business and financial condition.

***If the Merger is not completed, our board of directors may decide to pursue a dissolution of our company. In a dissolution, there can be no assurances as to the amount or timing of available cash, if any, to distribute to our stockholders after paying our debts and other obligations and setting aside funds for reserves.***

While we have entered into the Merger Agreement with Carisma, the closing of the Merger may be delayed or may not occur at all and there can be no assurance that the Merger will deliver the anticipated benefits we expect or enhance stockholder value. If the Merger is not completed and the Merger Agreement is terminated under certain circumstances, we may be required to pay Carisma a termination fee of \$7.6 million and/or reimburse Carisma's expenses up to a maximum of \$1.75 million. Even if a termination fee is not payable in connection with a termination of the Merger Agreement, we will have incurred significant fees and expenses, which must be paid whether or not the Merger is completed.

If, for any reason, the Merger does not close, our board of directors may elect to, among other things, attempt to complete another strategic transaction like the Merger, attempt to sell or otherwise dispose of the various assets of ours or resume our research and development activities and continue to operate our business, and/or pursue a dissolution of our company. Any of these alternatives would be costly and time-consuming and may require that we obtain additional funding. We expect that it would be difficult to secure financing in a timely manner, on favorable terms or at all. We can make no assurances that we would be able to obtain additional financing or find a partner and close an alternative transaction on terms that are as favorable or more favorable than the terms set forth in the Merger Agreement or that any such alternatives are possible or would be

successful, if pursued. To the extent that we seek and are able to 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 their rights as a common stockholder. Debt financing or 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 funds through strategic transactions or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. Even if we are able to pursue such alternatives, the failure to complete the Merger may result in negative publicity and/or a negative impression of us in the investment community, could significantly harm the market price of our common stock and may affect our relationship with employees and other partners in the business community.

If the Merger is not completed, our board of directors may decide that it is in the best interests of our stockholders to dissolve our company under a judicially-supervised process under Delaware law. For example, we may rely on the "safe harbor" procedures under Sections 280 and 281(a) of the Delaware General Corporation Law (the "DGCL") which would require us to, among other things, obtain an order from the Delaware Court of Chancery establishing the amount and form of security for pending claims for which we are a party, contingent or unmatured contract claims for which the holder declined our offer of a security, and unknown claims that, based on facts known to us, are likely to arise or become known within five years filing of a Certificate of Dissolution (or such longer period of time, not to exceed ten years, as the Delaware Court of Chancery may determine).

In that event, the amount of cash available, if any, for distribution to our stockholders would depend heavily on the timing of such decision since the amount of cash available for distribution continues to decrease as we fund our operations and incur fees and expenses related to the Merger. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution of our company, we would be required under the DGCL to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution of our company. If a dissolution were pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, our stockholders could lose all or a significant portion of their investment in the event of a dissolution of our company.

***Our stockholders may not receive any payment on the CVRs from the proceeds related to either the Roche Asset Purchase Agreement or any sale of our non-cash assets and therefore the CVR may expire valueless or result in lower returns than anticipated or none at all.***

At or prior to the effective time of the Merger, we will enter into a Contingent Value Rights Agreement (the "CVR Agreement") with a rights agent (the "Rights Agent") pursuant to which we intend to declare a dividend payable to our stockholders of record as of a date agreed to by us and Carisma prior to the effective time of the Merger with respect to the receipt of one contingent value right (each, a "CVR"), for each outstanding share of our common stock held by such stockholders on such date. Each CVR will represent the contractual right to receive (i) contingent cash payments upon the receipt by us of certain proceeds payable by Roche, if any, pursuant to the asset purchase agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (collectively, "Roche") (the "Roche Asset Purchase Agreement"), upon the achievement by Roche of a specified milestone set forth in the Roche Asset Purchase Agreement as well as (ii) proceeds from any sale of our legacy assets, including Vicineum, subject to certain customary deductions, including for expenses and taxes, in the event any sale occurs prior to March 31, 2027. The right of our stockholders to receive future payment on the CVRs from the proceeds related to the Roche Asset Purchase Agreement will be contingent upon the occurrence of a certain triggering event, entitling CVR holders to a pro rata portion of the \$30.0 million milestone payment to be made by Roche to us upon Roche's initiation of a Phase 3 clinical trial with legacy IL-6 antagonist antibody technology previously owned by us for a certain indication if initiated prior to December 31, 2026, pursuant to the Roche Asset Purchase Agreement, less certain permitted deductions. We may not receive any future payment pursuant to the Roche Asset Purchase Agreement after the closing of the Merger. If this milestone is not achieved for any reason within the time period specified in the CVR Agreement or the consideration received is not greater than the amounts permitted to be retained or deducted by us, no payments will be made under the CVRs from the proceeds related to the Roche Asset Purchase Agreement, resulting in a lower return for our stockholders with respect to the CVRs.

The right of our stockholders to receive future payment on the CVRs from the proceeds from any sale of our non-cash assets (net of customary deductions) existing as of the date of the Merger Agreement is dependent on our finding a partner to which we can sell, transfer, license, assign or otherwise divest such non-cash assets. With the assistance of a financial advisor, we have initiated a formal process for the potential sale of Vicineum. Given ongoing discussion with potential partners, completing a sale may be challenging. Our board of directors may elect not to divest any of our non-cash assets, resulting in a lower return for our stockholders with respect to the CVRs.

Further, if we do not receive any future payment pursuant to the Roche Asset Purchase Agreement and we do not divest any of our non-cash assets, our stockholders will not receive any payments on the CVRs and the CVRs will expire valueless.

Furthermore, the CVRs will be unsecured obligations of the combined company and all payments under the CVRs, all other obligations under the CVR Agreement and the CVRs and any rights or claims relating thereto will be subordinated in right of payment to the prior payment in full of all current or future senior obligations of the combined company.

***The United States federal income tax treatment of the CVRs is unclear and there can be no assurance that the Internal Revenue Service would not assert, or that a court would not sustain, a position that could result in adverse United States federal income tax consequences to holders of the CVRs.***

The United States federal income tax treatment of the CVRs is unclear. There is no legal authority directly addressing the United States federal income tax treatment of the receipt of, and payments on, the CVRs, and there can be no assurance that the Internal Revenue Service (the “IRS”), would not assert, or that a court would not sustain, a position that could result in adverse United States federal income tax consequences to holders of the CVRs.

We intend to treat the issuance of the CVRs as a distribution of property with respect to our stock. However, there is no authority directly addressing whether contingent value rights with characteristics similar to the CVRs should be treated as a distribution of property with respect to the corporation’s stock, a distribution of equity, a “debt instrument” or an “open transaction” for United States federal income tax purposes. Although we will estimate the value of the CVRs for purposes of reporting on Form 1099 to our stockholders, the value of the CVRs is uncertain and the IRS or a court could determine that the value of the CVRs at the time of issuance was higher. In such case, our stockholders could be treated as having additional income or gain upon receipt of the CVRs. Further, notwithstanding our position that the receipt of CVRs, the receipt of any cash distributed pursuant to a special cash dividend and the proposed reverse stock split are appropriately treated as separate transactions, it is possible that the IRS or a court could determine that our stockholders’ receipt of the CVRs, the receipt of any cash distributed pursuant to a special cash dividend and the proposed reverse stock split constitute a single “recapitalization” for United States federal income tax purposes. No assurance can be given that the IRS would not assert, or that a court would not sustain, a position contrary to our position, which could result in adverse United States federal income tax consequences to holders of the CVRs.

***We have never paid and, other than in connection with the Merger with Carisma, do not intend to pay any cash dividends in the foreseeable future.***

We have never paid cash dividends on any of our capital stock. Pursuant to the terms of the Merger Agreement, we will, in addition to the CVRs, declare and pay a special cash dividend to our stockholders of record prior to the Merger which would be contingent upon (i) stockholder approval of (a) the issuance of the shares of our common stock in connection with the Merger pursuant to the rules of Nasdaq, and (b) an amendment our amended and restated Certificate of Incorporation to effect a reverse stock split of the outstanding shares of our common stock at a ratio of 1-for-20 and (ii) the satisfaction or waiver of other customary closing conditions to the Merger. The amount of the special cash dividend will be \$75.0 million, subject to the terms and conditions in the Merger Agreement. Other than such special cash dividend in connection with the closing of the Merger, we do not currently anticipate declaring or paying cash dividends on our capital stock in the foreseeable future.

***We are substantially dependent on our remaining employees to facilitate the consummation of the Merger.***

As of December 31, 2022, we had 17 full-time employees. Our ability to successfully complete the Merger depends in large part on our ability to retain certain remaining personnel. Despite our efforts to retain these employees, one or more may terminate their employment with us on short notice. The loss of the services of certain employees could potentially harm our ability to consummate the Merger, to run our day-to-day business operations, as well as to fulfill our reporting obligations as a public company.

### **Risks Related to Our Intellectual Property**

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

Filing, prosecuting and defending patents on Vicineum and our other legacy assets 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, including 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 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 United States 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 United States Food and Drug Administration ("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 legacy assets are approved by the FDA, the approval of a biologic product biosimilar to or interchangeable with one of our products could have a material impact on our business. In particular, a biosimilar could be significantly less costly to bring to market and priced significantly lower than our products, if approved by the FDA.

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

***If we cannot meet the requirements under our license agreements with Zurich, Micromet and XOMA, we could lose important rights to Vicineum, which could have material adverse effect on our ability to sell Vicineum.***

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 (the "Zurich License Agreement"). 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 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 legacy assets, 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 legacy assets or other of our compounds, it could have a material adverse effect on our ability to sell Vicineum.

We also have a license agreement with Micromet AG ("Micromet"), now part of Amgen, Inc., which grants us non-exclusive rights, with certain sublicense rights, for know-how and patents allowing exploitation of certain single chain antibody products (the "Micromet License Agreement"). 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 legacy assets, 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 legacy assets or other of our compounds, it could have a material adverse effect on our ability to sell Vicineum.

We also have a license agreement with XOMA Ireland Limited ("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 (the "XOMA License Agreement"). 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 legacy assets, 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 legacy assets, it could have a material adverse effect on our ability to sell Vicineum.

***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.

### **Risks Related to our Business and Operations**

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

Over the past few years, we have focused primarily on developing our lead product candidate, Vicineum, which we voluntarily paused development of in July 2022. 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. We had a net loss of \$19.9 million, \$0.3 million and \$22.4 million for the year ended December 31, 2022, 2021 and 2020, respectively. We incurred positive cash flows from operating activities of \$24.9 million for the year ended December 31, 2022. We incurred negative cash flows from operating activities of \$68.9 million and \$30.8 million for the year ended December 31, 2021 and 2020, respectively. As of December 31, 2022, we had cash, cash equivalents, and marketable securities of \$166.9 million, net working capital (current assets less current liabilities) of \$158.2 million and an accumulated deficit of \$336.1 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, our follow-on public offerings, sales effected in at-the-market offerings, our out-licensing and former OUS business development partnership agreements and from the Roche Asset Purchase Agreement. The majority of our revenue to date has been from milestone payments received under our out-licensing and former OUS business development partnership agreements and from the Roche Asset Purchase Agreement. We expect to continue to incur significant expenses and operating losses for the foreseeable future.

***Our restructuring plans and the associated headcount reductions may not result in anticipated savings, could result in total costs and expenses that are greater than expected.***

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 Complete Response Letter from the FDA regarding our biologics license application ("BLA") for Vicineum for the treatment of bacillus Calmette-Guérin ("BCG")-unresponsive non-muscle invasive bladder cancer ("NMIBC") (the "2021 Restructuring Plan"). The 2021 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. Execution of the 2021 Restructuring Plan was substantially completed by the end of 2021. Restructuring expenses for the year ended December 31, 2021 were \$5.5 million.

On July 15, 2022, we approved a restructuring plan to reduce operating expenses and better align our workforce with the needs of our business following our decision to voluntarily pause further development of Vicineum in the United States (the "2022 Restructuring Plan"). The 2022 Restructuring Plan includes an incremental reduction in our workforce as well as additional cost-saving initiatives intended to preserve capital during the pendency of the proposed Merger with Carisma and while we seek a potential partner for the further development of Vicineum.

Execution of the 2022 Restructuring Plan is expected to be substantially completed in connection with the closing of the proposed Merger with Carisma, which is expected to occur in the first quarter of 2023. Restructuring expenses for the year ended December 31, 2022 were approximately \$11.8 million, consisting primarily of severance and other employee-related costs of \$7.0 million and contract termination costs of \$4.8 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, we may incur unanticipated charges not currently contemplated as a result of the restructuring plans. If we are unable to realize the expected operational cost savings from the restructuring, our operating results and financial condition would be adversely affected.

***We may not be able to enter into a transaction with a suitable acquiror or licensee for Vicineum or any transaction entered into may not be on terms that are favorable to us.***

On July 15, 2022, we made the strategic decision to voluntarily pause further development of Vicineum in the United States. As a result of such decision, the primary paths available to derive value from the Vicineum asset are to find a suitable acquiror or licensee for the asset. Supporting diligence activities conducted by potential acquirors or licensees and negotiating the financial and other terms of an agreement or license are typically long and complex processes, and the results of such processes cannot be predicted. There can be no assurance that we will enter into any transaction as a result of this effort or that any transaction entered into will be on terms that are favorable to us.

***In connection with our strategic decision to voluntarily pause further development of Vicineum in the United States, we may become involved in disagreements or disputes with our licensees, licensors and other counterparties relating to the development and/or commercialization of Vicineum, which may be time consuming, costly and could divert our efforts and attention from consummating the proposed Merger with Carisma and harm our efforts to seek a partner to continue development of Vicineum.***

We have entered into various agreements and licenses with licensees, licensors and other counterparties related to the development and/or commercialization of Vicineum. These agreements and licenses impose a variety of obligations on us and the counterparties to such agreements and licenses. On July 15, 2022, we made the strategic decision to voluntarily pause further development of Vicineum in the United States. As a result of such decision and our subsequent decision to enter into the proposed Merger with Carisma, we have begun the process of winding-down our operations relating to Vicineum and are seeking a partner for the further development of Vicineum. With the assistance of a financial advisor, we have initiated a formal process for the potential sale of Vicineum to a partner. Given ongoing discussion with potential partners, completing a sale may be challenging. Disagreements and disputes between us and certain counterparties have arisen related to such wind-down efforts and additional disagreements or disputes may arise in the future between us and our counterparties regarding each parties' obligations under the respective agreement or license relating to Vicineum.

Any such disagreement or dispute could become time consuming, costly and could divert our efforts and attention from consummating the Merger with Carisma and harm our efforts to seek a partner to continue development of Vicineum. Any disagreements or disputes with such parties that lead to litigation, arbitration or similar proceedings will result in us incurring significant legal expenses, as well as potential significant legal liability.

Further, any disagreements or disputes over our obligations or intellectual property that we have licensed or acquired may prevent or impair our ability to maintain our current arrangements on acceptable terms. If we fail to meet our obligations under these agreements or licenses in a material respect, the respective counterparty may have the right to terminate the respective

agreement or license and to re-obtain the related technology as well as aspects of any intellectual property controlled by us and developed during the period the agreement or license was in force that relates to the applicable technology. While we would expect to exercise our rights and remedies available to us in the event we fail to meet our obligations under such agreement or license in any material respect and otherwise seek to preserve our rights under the technology licensed to or acquired by us, we may not be able to do so in a timely manner, at an acceptable cost or at all. Any uncured, material breach under any agreement or license relating to Vicineum could result in our loss of rights and may lead to a complete termination of the respective agreement or license. Termination of one of these agreements or licenses for any reason could prevent us from completing a transaction to sell or license Vicineum.

***We and certain of our officers have been, and may in the future be, named as defendants in lawsuits. 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. Any other lawsuits to which we are subject may 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 United States District Court for the Southern District of New York. The three complaints alleged 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 sought 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 December 6, 2021, the Lead Plaintiffs filed an amended class action complaint (the "Amended Complaint"). The Amended Complaint alleged 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. On July 19, 2022, the parties reached an agreement in principle to settle the Securities Litigation. On September 28, 2022, the court issued an order granting preliminary approval of the proposed settlement of the Securities Litigation. On January 31, 2023, the court issued an order granting final approval of the settlement of the Securities Litigation. Accordingly, this matter is now resolved.

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 United States District Court for the District of Massachusetts, with us 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 (the "State Derivative Litigation"). The three derivative complaints alleged 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 alleged unjust enrichment, abuse of control, gross mismanagement and aiding and abetting thereof. The three derivative complaints sought 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 July 19, 2022, the parties reached an agreement in principle to settle the Federal Derivative Litigation, the State Derivative Litigation and other potential related derivative claims (collectively, the "Derivative Litigation"). On August 22, 2022, the parties entered into a Stipulation of Settlement to settle the Derivative Litigation, which was filed with the court on August 30, 2022. On September 2, 2022, the court issued an order granting preliminary approval of the Stipulation of Settlement related to the Derivative Litigation. On November 8, 2022, the court issued an order granting final approval of the Stipulation of Settlement related to the Derivative Litigation. Accordingly, this matter is now resolved.

On November 28, 2022, a purported stockholder filed a complaint in the United States District Court for the Southern District of New York against us and our board of directors, captioned *Keller v. Sesen Bio, Inc., et al.*, Case No. 1:22-cv-10085 (S.D.N.Y.) (the "Original Keller Complaint"). The Original Keller Complaint asserted claims against us and our board of directors under Section 14(a) of the Exchange Act and Rule 14a-9 promulgated thereunder for allegedly false and misleading statements in the proxy statement/prospectus filed as part of the Registration Statement and under Section 20(a) of the Exchange Act for alleged "control person" liability with respect to such allegedly false and misleading statements and sought, among other relief, an order enjoining the Merger and an award for plaintiffs' fees and costs. On December 20, 2022, the purported stockholder voluntarily dismissed the Original Keller Complaint and on December 21, 2022, filed a new complaint as a putative class action in the Court of Chancery for the State of Delaware, captioned *Keller v. Sesen Bio, Inc., et al.*, Case No. 2022-1186 (Del. Ch. Dec. 21, 2022) (the "New Keller Complaint"). Along with the complaint, the purported stockholder filed motions for expedited proceedings and for a preliminary injunction to enjoin the special meeting of stockholders scheduled for 10:00 a.m. Eastern Time on March 2, 2023 (the "Special Meeting"). The New Keller Complaint and associated filings contain

substantially the same assertions as the Original Keller Complaint, and seek, among other relief, an order enjoining the Merger and an award for plaintiffs' fees and costs.

On February 3, 2023, a purported stockholder filed a complaint in the United States District Court for the District of Delaware against us and our board of directors, captioned *Plumley v. Sesen Bio, Inc., et al.*, Case No. 1:23-cv-00131 (D. Del.) (the "Plumley Complaint"). The Plumley Complaint asserts claims under Section 14(a) of the Exchange Act and Rule 14a-9 promulgated thereunder for allegedly false and misleading statements in the proxy statement/prospectus filed as part of the Registration Statement and under Section 20(a) of the Exchange Act for alleged "control person" liability with respect to such allegedly false and misleading statements and seeks, among other relief, an order enjoining the Merger and an award for plaintiffs' fees and costs. On February 7, 2023, another purported stockholder filed a complaint in the United States District Court for the Southern District of New York against us and our board of directors, captioned *Franchi v. Sesen Bio, Inc., et al.*, 1:23-cv-01041 (S.D.N.Y.) (the "Franchi Complaint"). The Franchi Complaint contains substantially similar allegations and claims and seeks substantially similar relief as the Plumley Complaint. Additionally, on February 9, 2023, another purported stockholder filed a complaint in the United States District Court for the Southern District of New York against us and our board of directors, captioned *Menzer v. Sesen Bio, Inc., et al.*, 23-cv-01119 (S.D.N.Y.) (the "Menzer Complaint"). The Menzer Complaint contains substantially similar allegations and claims and seeks substantially similar relief as the Plumley Complaint and the Franchi Complaint.

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 Capital Market, our common stock may be delisted from the Nasdaq Capital Market which could have a material adverse effect on our business and could make it more difficult for you to sell your shares of our common stock.***

Our common stock is listed on the Nasdaq Capital Market, and we are therefore subject to Nasdaq's 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 Capital Market.

On January 25, 2023, we were notified by the Listing Qualifications Department (the "Staff") of Nasdaq that, based upon our non-compliance with the \$1.00 bid price requirement for continued listing on The Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Rule"), our common stock will be delisted from Nasdaq unless we timely request a hearing before a Nasdaq Hearings Panel (the "Panel").

We requested a hearing before the Panel, which stayed any delisting action by the Staff and ensured our common stock remains listed and eligible for trading on Nasdaq pending a determination by the Panel. The hearing had been scheduled for March 16, 2023. On February 24, 2023, we received a determination from the Nasdaq Office of General Counsel that the Panel granted us an exception from our non-compliance with the Bid Price Rule to complete the Merger by March 10, 2023. Pursuant to Nasdaq Listing Rule 5110(a), we must demonstrate compliance with all initial listing requirements of Nasdaq upon the closing of the Merger. We are seeking approval for the Merger and the implementation of a reverse stock split of our common stock at the Special Meeting. In the event we fail to establish compliance with the initial listing standards by March 10, 2023, our common stock will be delisted from Nasdaq, unless granted an additional exception by the Panel.

As previously disclosed, on January 24, 2022, we received written notice from the Staff indicating that, based upon the closing bid price for our common stock for the previous 30 consecutive business days, we no longer satisfied the Bid Price Rule and, in accordance with the Nasdaq Listing Rules, were afforded an initial grace period of 180 calendar days, through July 25, 2022, and a second 180-calendar day period, through January 23, 2023, to regain compliance with the Bid Price Rule. We did not regain compliance with the Bid Price Rule by January 23, 2023, which resulted in the Staff's January 25, 2023, determination.

Delisting from the Nasdaq Capital Market would adversely affect our ability to consummate the Merger and may adversely affect our ability to raise additional financing through the public or private sale of equity securities, significantly affect the ability of investors to trade our common stock, or 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 common stock;
- 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.

**Item 1B. Unresolved Staff Comments.**

Not applicable.

**Item 2. Properties.**

Our corporate headquarters is located in Cambridge, MA, where we occupy office space under a lease that was executed in October 2016. The lease is currently extended through June 2023.

**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 United States District Court for the Southern District of New York. The three complaints alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended (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 sought 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 (collectively, the "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. On November 24, 2021, defendants filed a motion to transfer venue to the United States District Court for the District of Massachusetts. That motion was fully briefed as of December 13, 2021, but the court has not ruled on that motion. On December 6, 2021, the Lead Plaintiffs filed an amended class action complaint (the "Amended Complaint"). The Amended Complaint alleged 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. The defendants moved to dismiss the Amended Complaint on March 7, 2022, and that motion was fully briefed on May 6, 2022. On June 3, 2022, before the court ruled on the motion to dismiss, the parties requested that the court hold any decision on the motion to dismiss in abeyance to provide the parties with an opportunity to engage in mediation. On June 30, 2022 and July 6, 2022, we and the plaintiffs engaged in mediation sessions in an attempt to resolve the Securities Litigation and continued to discuss a potential settlement over the following weeks. On July 19, 2022, the parties reached an agreement in principle to settle the Securities Litigation. Pursuant to that agreement, we and the individual defendants will pay or cause to be paid to members of the class who submit timely and valid proofs of claims. In exchange, the Lead Plaintiffs will dismiss the action and all class members who do not timely and validly opt-out of the settlement will provide broad customary releases to us and the individual defendants. On August 3, 2022, the parties entered into a Stipulation and Agreement of Settlement to settle the Securities Litigation, which was filed with the court on August 17, 2022. The Stipulation and Agreement of Settlement related to the Securities Litigation provides for a settlement payment of \$21.0 million to the class and the dismissal of all claims against us and the other defendants. On September 1, 2022, the United States District Court for the Southern District of New York issued an order denying the motions to appoint a different lead plaintiff. On September 28, 2022, the court issued an order granting preliminary approval of the proposed settlement of the Securities Litigation. The settlement payment of \$21.0 million, including the insurance carriers coverage, was funded into an escrow account in the fourth quarter of 2022. Accordingly, \$21.0 million remained in restricted cash on our balance sheet as of December 31, 2022. On January 31, 2023, the court issued an order granting final approval of the settlement of the Securities Litigation. Accordingly, this matter is now resolved.

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 United States District Court for the District of Massachusetts, with us 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 (the "State Derivative Litigation"). The three derivative complaints alleged 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 alleged unjust enrichment, abuse of control, gross mismanagement and aiding and abetting thereof. The three derivative complaints sought 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. On May 1, 2022, the plaintiffs filed a verified consolidated shareholder derivative complaint in the Federal Derivative Litigation. On May 18, 2022, the court entered a joint stipulation among the parties to stay the State Derivative Litigation until after a ruling on any motion to dismiss filed by defendants in the Securities Litigation. On July 6, 2022, we and the plaintiffs to the

Federal Derivative Litigation and the State Derivative Litigation engaged in mediation in an attempt to resolve the litigation, with settlement discussions continuing over the following days. On July 19, 2022, the parties reached an agreement in principle to settle the Federal Derivative Litigation, the State Derivative Litigation and other potential related derivative claims (collectively, the “Derivative Litigation”). Pursuant to that agreement, the individual defendants will cause us to adopt certain enhancements to our corporate governance policies and procedures. In exchange, plaintiffs will dismiss the Derivative Litigation and, on behalf of us, provide broad customary releases to the individual defendants. On August 22, 2022, the parties entered into a Stipulation of Settlement to settle the Derivative Litigation, which was filed with the court on August 30, 2022. The Stipulation of Settlement related to the Derivative Litigation confirms that we previously adopted certain corporate governance enhancements in response to, among other things, the filing of the Derivative Litigation, and that, subject to final court approval, we will adopt additional corporate governance enhancements. The Stipulation of Settlement also provides for a \$630,000 payment for plaintiffs’ attorneys’ fees due to the benefits the corporate governance enhancements are intended to provide to us. The payment of plaintiffs’ attorneys’ fees is being funded by us. On September 2, 2022, the court issued an order granting preliminary approval of the Stipulation of Settlement related to the Derivative Litigation. On November 8, 2022, the court issued an order granting final approval of the Stipulation of Settlement related to the Derivative Litigation. Accordingly, this matter is now resolved.

On November 28, 2022, a purported stockholder filed a complaint in the United States District Court for the Southern District of New York against us and our board of directors, captioned *Keller v. Sesen Bio, Inc., et al.*, Case No. 1:22-cv-10085 (S.D.N.Y.) (the “Original Keller Complaint”). The Original Keller Complaint asserted claims against us and our board of directors under Section 14(a) of the Exchange Act and Rule 14a-9 promulgated thereunder for allegedly false and misleading statements in the proxy statement/prospectus filed as part of the Registration Statement on Form S-4 (File No. 333-267891) (the “Registration Statement”) in connection with the proposed merger (the “Merger”) with CARISMA Therapeutics Inc. (“Carisma”) and under Section 20(a) of the Exchange Act for alleged “control person” liability with respect to such allegedly false and misleading statements and sought, among other relief, an order enjoining the Merger and an award for plaintiffs’ fees and costs. On December 20, 2022, the purported stockholder voluntarily dismissed the Original Keller Complaint and on December 21, 2022, filed a new complaint as a putative class action in the Court of Chancery for the State of Delaware, captioned *Keller v. Sesen Bio, Inc., et al.*, Case No. 2022-1186 (Del. Ch. Dec. 21, 2022) (the “New Keller Complaint”). Along with the complaint, the purported stockholder filed motions for expedited proceedings and for a preliminary injunction to enjoin the Special Meeting. The New Keller Complaint and associated filings contain substantially the same assertions as the Original Keller Complaint, and seek, among other relief, an order enjoining the Merger and an award for plaintiffs’ fees and costs.

On February 3, 2023, a purported stockholder filed a complaint in the United States District Court for the District of Delaware against us and our board of directors, captioned *Plumley v. Sesen Bio, Inc., et al.*, Case No. 1:23-cv-00131 (D. Del.) (the “Plumley Complaint”). The Plumley Complaint asserts claims under Section 14(a) of the Exchange Act and Rule 14a-9 promulgated thereunder for allegedly false and misleading statements in the proxy statement/prospectus filed as part of the Registration Statement in connection with the Merger and under Section 20(a) of the Exchange Act for alleged “control person” liability with respect to such allegedly false and misleading statements and seeks, among other relief, an order enjoining the Merger and an award for plaintiffs’ fees and costs. On February 7, 2023, another purported stockholder filed a complaint in the United States District Court for the Southern District of New York against us and our board of directors, captioned *Franchi v. Sesen Bio, Inc., et al.*, 1:23-cv-01041 (S.D.N.Y.) (the “Franchi Complaint”). The Franchi Complaint contains substantially similar allegations and claims and seeks substantially similar relief as the Plumley Complaint. Additionally, on February 9, 2023, another purported stockholder filed a complaint in the United States District Court for the Southern District of New York against us and our board of directors, captioned *Menzer v. Sesen Bio, Inc., et al.*, 23-cv-01119 (S.D.N.Y.) (the “Menzer Complaint”). The Menzer Complaint contains substantially similar allegations and claims and seeks substantially similar relief as the Plumley Complaint and the Franchi Complaint.

On October 21, 2022, November 4, 2022, February 8, 2023, February 13, 2023 (as updated on February 15, 2023) and February 17, 2023, we received letters from purported stockholders (collectively, the “Demand Letters”) demanding that we amend the Registration Statement to provide additional disclosures that such stockholders allege were improperly omitted from the Registration Statement, including information regarding the financial projections for Carisma, the financial analyses performed by our financial advisor in support of its fairness opinion, and the background and process leading to the execution of the Agreement and Plan of Merger and Reorganization dated as of September 20, 2022, as amended by the First Amendment thereto dated as of December 29, 2022 and the Second Amendment thereto dated as of February 13, 2023. In addition, we received a books and records demand, dated November 18, 2022 (the “Section 220 Demand”), on behalf of a purported stockholder of ours seeking access to certain relevant books and records of ours pursuant to Section 220 of the Delaware General Corporation Law in connection with the Merger and the securities and derivative litigations arising out of the CRL that we received from the FDA. The Section 220 Demand states that the purpose of the demand is to, among other things, investigate purported questions of director independence and disinterestedness and the possibility of wrongdoing, mismanagement, and/or material non-disclosure related to our board’s approval of the Merger and the other transactions contemplated thereby and to determine whether suit should be brought in connection therewith.

We believe that the claims asserted in the Demand Letters, the Section 220 Demand, the New Keller Complaint, the Plumley Complaint, the Franchi Complaint and the Menzer Complaint are without merit and we intend to vigorously defend against them. 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 Capital Market.

#### **Holders**

As of February 21, 2023, 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 any cash dividends on our common stock and we do not anticipate paying cash dividends on our common stock for the foreseeable future, other than the special cash dividend that we will pay to our stockholders in connection with the consummation of the merger, subject to our having net cash as of the closing of the merger greater than or equal to \$70.0 million. Notwithstanding the foregoing, any determination to pay cash dividends subsequent to the merger will be at the discretion of the combined company's then-current board of directors and will depend upon a number of factors, including the combined company's results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors the then-current board of directors deems relevant.

#### **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 that previously focused on advancing targeted fusion protein therapeutics ("TFPTs") for the treatment of patients with cancer.

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 bladder cancer ("NMIBC").

On July 15, 2022, we made the strategic decision to voluntarily pause further development of Vicineum in the United States. The decision was based on a thorough reassessment of Vicineum following discussions with the United States Food and Drug Administration ("FDA"), which had implications on the size, timeline and costs of an additional Phase 3 clinical trial, which the FDA previously confirmed would be required for a potential resubmission of a biologics license application ("BLA") for Vicineum for the treatment of NMIBC. As a result of this decision, we turned our primary focus to consummating a strategic transaction with the goal of maximizing stockholder value.

Following an extensive process of evaluating strategic alternatives, including identifying and reviewing potential candidates for a strategic transaction, on September 20, 2022, we, Seahawk Merger Sub, Inc., a Delaware corporation and our wholly-owned subsidiary ("Merger Sub"), and CARISMA Therapeutics Inc. ("Carisma"), entered into the Agreement and Plan of Merger and Reorganization dated as of September 20, 2022, as amended by the First Amendment thereto dated as of December 29, 2022 and the Second Amendment thereto dated as of February 13, 2023 (the "Merger Agreement"), pursuant to which, among other things, and subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement, Merger Sub will merge with and into Carisma, with Carisma continuing as our wholly-owned subsidiary and the surviving corporation of the merger (the "Merger"). Our board of directors unanimously approved the Merger Agreement and resolved to recommend that our stockholders approve the proposals described in the Merger Agreement. If the Merger is completed, the business of Carisma will continue as the business of the combined company.

We continue to believe that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with a larger infrastructure, and as such, we are seeking a partner that can execute further development to realize the full potential of Vicineum. As a result of such decision and our subsequent decision to enter into the proposed Merger with Carisma, we no longer plan to pursue regulatory approval of Vicineum for NMIBC in the European Union (the "E.U.") and have started to wind down certain of our manufacturing operations and business development partnerships. Additionally, we are seeking a partner for the further development of Vicineum and have initiated a formal process and engaged a financial advisor for the potential sale of Vicineum. If the proposed Merger is consummated, the combined company does not expect to pursue further development of Vicineum.

### ***Anticipated Merger with CARISMA Therapeutics Inc.***

The Merger is expected to be completed during the first quarter of 2023. In connection with the Merger, we are seeking the approval of our stockholders to, among other things, (a) issue the shares of our common stock issuable in connection with the Merger pursuant to the rules of The Nasdaq Stock Market LLC ("Nasdaq"), and (b) amend our amended and restated Certificate of Incorporation to effect a reverse stock split of the outstanding shares of our common stock at a ratio of 1-for-20 (clauses (a) and (b), collectively, the "Sesen Bio Voting Proposals"). The special meeting of stockholders in which our stockholders will be asked to vote on the Sesen Bio Voting Proposals (the "Special Meeting") will be held on March 2, 2023 at 10:00 a.m. Eastern Time.

Consummation of the Merger is subject to certain closing conditions, including, among other things, (a) approval by our stockholders of the Sesen Bio Voting Proposals as described in the Merger Agreement, (b) approval by Carisma’s stockholders of, among other things, the adoption of the Merger Agreement, (c) Nasdaq’s approval of the listing of the shares of our common stock to be issued in connection with the Merger, (d) the effectiveness of a registration statement on Form S-4 to register the shares of our common stock to be issued in connection with the Merger, and (e) our having net cash as of closing of the Merger greater than or equal to \$70.0 million.

The Merger Agreement contains certain termination rights of each of us and Carisma. Upon termination of the Merger Agreement under specified circumstances, we may be required to pay Carisma a termination fee of \$7.6 million and/or reimburse Carisma's expenses up to a maximum of \$1.75 million, and Carisma may be required to pay us a termination fee of \$5.49 million and/or reimburse our expenses up to a maximum of \$1.75 million.

Subject to the terms and conditions of the Merger Agreement, at the closing of the Merger, (a) each then outstanding share of Carisma common stock and Carisma preferred stock (including shares of Carisma's common stock issued in connection with the pre-closing financing described below) will be converted into the right to receive a number of the shares of our common stock calculated in accordance with the Merger Agreement (the "Exchange Ratio"), and (b) each then outstanding Carisma stock option to purchase Carisma's common stock will be assumed by us, subject to adjustment as set forth in the Merger Agreement.

Concurrently with the execution and delivery of the Merger Agreement, Carisma entered into a subscription agreement with certain investors named therein, pursuant to which such investors have agreed, subject to the terms and conditions of such subscription agreement, to purchase prior to the consummation of the Merger shares of Carisma's common stock for an aggregate purchase price of approximately \$30.6 million (the "Carisma Pre-Closing Financing"). The consummation of the Carisma Pre-Closing Financing is conditioned on the satisfaction or waiver of the conditions set forth in the Merger Agreement. Shares of Carisma's common stock issued pursuant to the Carisma Pre-Closing Financing will be converted into shares of our common stock in the Merger in accordance with the Exchange Ratio.

At or prior to the effective time of the Merger, we will enter into a Contingent Value Rights Agreement (the "CVR Agreement") with a rights agent (the "Rights Agent") pursuant to which we intend to declare a dividend payable to our stockholders of record as of a date agreed to by us and Carisma prior to the effective time of the Merger with respect to the receipt of one contingent value right (each, a "CVR"), for each outstanding share of our common stock held by such stockholders on such date. Each CVR will represent the contractual right to receive (i) contingent cash payments upon the receipt by us of certain proceeds payable by Roche, if any, pursuant to the asset purchase agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (collectively, "Roche") (the "Roche Asset Purchase Agreement"), upon the achievement by Roche of a specified milestone set forth in the Roche Asset Purchase Agreement as well as (ii) proceeds from any sale of our legacy assets, including Vicineum, subject to certain customary deductions, including for expenses and taxes, in the event any sale occurs prior to March 31, 2027. The contingent payments under the CVR Agreement, if they become due, will be payable to the Rights Agent for subsequent distribution to the holders of the CVRs. In the event that no such proceeds are received, holders of the CVRs will not receive any payment pursuant to the CVR Agreement. There can be no assurance that any cash payment will be made or that any holders of CVRs will receive any amounts with respect thereto.

Also in connection with the Merger, we intend to declare a one-time \$75.0 million cash dividend payable to our stockholders of record as of a date prior to the effective time of the Merger, subject to the terms and condition set forth in the Merger Agreement.

On February 13, 2023, a group of our significant stockholders (the "Investor Group") entered into a voting and support agreement with us and Carisma (the "Support Agreement") pursuant to which the Investor Group agreed to vote, at the Special Meeting, any and all of their shares of our common stock in favor of the Merger and related matters, subject to the terms and conditions set forth in the Support Agreement.

Our future operations are highly dependent on the success of the Merger and there can be no assurances that the Merger will be successfully consummated. In the event that we do not complete the Merger with Carisma, we may decide to pursue a dissolution under Delaware law. In a dissolution, there can be no assurances as to the amount or timing of available cash, if any, to distribute to our stockholders after paying our debts and other obligations and setting aside funds for reserves.

### ***Other Recent Events***

#### ***2022 Restructuring Plan***

On July 15, 2022, we approved a restructuring plan to reduce operating expenses and better align our workforce with the needs of our business following the decision to voluntarily pause further development of Vicineum in the United States (the "2022 Restructuring Plan"). Execution of the 2022 Restructuring Plan is expected to be substantially completed in connection with the closing of the Merger, which is expected to occur in the first quarter of 2023. The 2022 Restructuring Plan includes an incremental reduction in our workforce as well as additional cost-saving initiatives intended to preserve capital during the pendency of the Merger and while we seek a potential partner for the further development of Vicineum. We also incurred one-time cash costs associated with the termination of certain contracts and all other activities under the 2022 Restructuring Plan.

#### ***2022 Retention Program***

On August 28, 2022, our board of directors and the compensation committee of the board of directors approved a retention program for certain employees pursuant to which we will provide a cash incentive designed to retain such employees (the

“2022 Retention Program”). Pursuant to the 2022 Retention Program, certain of our employees, including certain executive officers other than our Chief Executive Officer, were to have received a cash bonus award, vesting in full upon the earlier of (a) the completion of a strategic transaction and (b) the termination of such employee without cause, subject to the employee’s continued employment through that time. On February 7, 2023, the compensation committee of the board of directors approved a modification to the 2022 Retention Program, such that the vesting of the retention bonus awards for employees, other than executive officers, will occur upon the earlier of (a) 5:00 pm Eastern Time on the second business day following the date of the Special Meeting regardless of the results of the Special Meeting and (b) the termination of the Merger Agreement in accordance with its terms. The terms of the 2022 Retention Program for those executive officers participating in the 2022 Retention Program were not modified.

#### *Nasdaq Delisting Notice*

On January 25, 2023, we were notified by the Listing Qualifications Department (the “Staff”) of Nasdaq that, based upon our non-compliance with the \$1.00 bid price requirement for continued listing on The Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550(a)(2) (the “Bid Price Rule”), our common stock will be delisted from Nasdaq unless we timely request a hearing before a Nasdaq Hearings Panel (the “Panel”).

We requested a hearing before the Panel, which stayed any delisting action by the Staff and ensured our common stock remains listed and eligible for trading on Nasdaq pending a determination by the Panel. The hearing had been scheduled for March 16, 2023. On February 24, 2023, we received a determination from the Nasdaq Office of General Counsel that the Panel granted us an exception from our non-compliance with the Bid Price Rule to complete the Merger by March 10, 2023. Pursuant to Nasdaq Listing Rule 5110(a), we must demonstrate compliance with all initial listing requirements of Nasdaq upon the closing of the Merger. We are seeking approval for the Merger and the implementation of a reverse stock split of our common stock at the Special Meeting. In the event we fail to establish compliance with the initial listing standards by March 10, 2023, our common stock will be delisted from Nasdaq, unless granted an additional exception by the Panel.

As previously disclosed, on January 24, 2022, we received written notice from the Staff indicating that, based upon the closing bid price for our common stock for the previous 30 consecutive business days, we no longer satisfied the Bid Price Rule and, in accordance with the Nasdaq Listing Rules, were afforded an initial grace period of 180 calendar days, through July 25, 2022, and a second 180-calendar day period, through January 23, 2023, to regain compliance with the Bid Price Rule. We did not regain compliance with the Bid Price Rule by January 23, 2023, which resulted in the Staff’s January 25, 2023, determination.

#### *Sale of EBI-031 Legacy Technology to Roche*

In June 2016, we entered into a license agreement with Roche (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 “Roche Licensed Intellectual Property”). Under the Roche License Agreement, Roche was 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 and pursue ongoing patent prosecution, at its cost. At the time of entering into 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.

On July 15, 2022, we entered into the Roche Asset Purchase Agreement pursuant to which Roche purchased all patent rights and know-how related to the monoclonal antibody EBI-031 and all other IL-6 antagonist monoclonal antibody technology owned by us for up to \$70.0 million. As a result of the Roche Asset Purchase Agreement, the Roche License Agreement was terminated resulting in no further diligence, milestone, or royalty payment obligations under the Roche License Agreement. Pursuant to the Roche Asset Purchase Agreement, Roche made a \$40.0 million payment to us upon execution of the Roche Asset Purchase Agreement. The Roche Asset Purchase Agreement also provides that Roche will make an additional \$30.0 million payment to us upon Roche’s initiation of a Phase 3 clinical trial with EBI-031 for a defined indication if initiated prior to December 31, 2026.

Additionally, in connection with the Merger, each CVR will represent the contractual right to receive contingent cash payments upon the receipt by us of certain proceeds payable by Roche, if any, pursuant to the Roche Asset Purchase Agreement, upon the achievement by Roche of a specified milestone set forth in the Roche Asset Purchase Agreement as well as proceeds from any sale of our legacy assets, including Vicineum.

#### **Our Historical TFPT Platform**

Our historical 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 antibody drug conjugates and were 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 antibody

fragments, which include Fabs, single chain variable domains ("scFvs"), and non-covalent scFv dimers, derived from the domains of antibodies that confer antigen recognition. We selected antibody fragments for our historical product candidates depending upon the target therapeutic indication. We targeted tumor cell surface antigens showing limited expression on normal cells and once bound, is rapidly internalized into the targeted cancer cell. For local administrations, we utilized an immunogenic cytotoxic protein payload designed to both target cancer cells and promote a heightened local immune response against the tumor. Our most advanced locally administered TFPT product candidate was Vicineum, in development for the treatment of non-muscle invasive carcinoma in situ ("CIS") of the bladder in patients previously treated with adequate or less than adequate bacillus Calmette-Guérin ("BCG"). For systemic administrations, we used 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.

#### *Vicineum for the treatment of NMIBC*

We completed the follow-up stage of our single-arm, multi-center, open-label Phase 3 clinical trial of Vicineum as a monotherapy in patients with BCG-unresponsive NMIBC (the "VISTA Trial") in May 2022.

The VISTA Trial completed enrollment in April 2018 with a total of 133 patients. 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 Prescription Drug User Fee Act date for a decision on the BLA of August 18, 2021. On August 13, 2021, we 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 chemistry, manufacturing, and controls ("CMC") issues pertaining to a pre-approval inspection and product quality. On August 20, 2021, we withdrew our marketing authorization application ("MAA") to the European Medicines Agency (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 E.U. until there was more clarity from the FDA on next steps for Vicineum in the United States. Vysyneum is the proprietary brand name conditionally approved by the EMA for oportuzumab monatox in the E.U. In October 2021, the EMA issued its Withdrawal Assessment Report relating to its MAA for Vysyneum, as is consistent with the EMA's standard practice when an MAA is withdrawn. The EMA Withdrawal Assessment Report reflected the initial assessment and corresponding questions from the EMA and identified major objections in the areas of quality, good clinical practice, efficacy, and safety. As a result of our decision on July 15, 2022 to pause further development of Vicineum in the United States, we no longer plan to pursue regulatory approval of Vysyneum for NMIBC in the E.U.

In October 2021 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 would be required for a potential resubmission of a BLA. In March 2022, we participated in a Type C meeting with the FDA. During the Type C meeting, the FDA agreed to a majority of our proposed protocol and statistical analysis plan design elements for an additional Phase 3 clinical trial. On July 11, 2022, we participated in a Type B meeting with the FDA to discuss outstanding items related to our proposed protocol and statistical analysis plan design elements for an additional Phase 3 clinical trial.

As discussed above, on July 15, 2022, we made the strategic decision to voluntarily pause further development of Vicineum in the United States. If the Merger is consummated, the combined company does not expect to pursue further development of Vicineum.

#### *Phase 3 Clinical Trial – VISTA Trial*

In the third quarter of 2015, in the United States and Canada, through our subsidiary Viventia Bio, Inc., we commenced the VISTA Trial in patients with BCG-unresponsive NMIBC who had received adequate BCG and whose disease was-then BCG-unresponsive, and for whom the then-current standard of care was radical cystectomy. 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. In May 2022, we completed the follow up phase of the VISTA Trial.

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

|                          |   |
|--------------------------|---|
| <b>Dose</b>              | 30 mg of Vicineum (in 50 mL of saline)  |
| <b>Total enrollment</b>  | 133 patients, including 93 CIS patients whose disease is BCG-unresponsive   |
| <b>Primary endpoints</b> | Complete response rate (“CRR”) at 3 months in patients with CIS (with or without papillary disease) whose disease is BCG-unresponsive<br>Kaplan-Meier estimate of duration of response (“DoR”) for BCG-unresponsive CIS patients who experience a Complete Response (“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.

|                            |  |
|----------------------------|--|
| <b>Secondary endpoints</b> | 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   |
|                            | Progression free survival (PFS) in all patients  |
|                            | Overall Survival (OS) in all patients  |
|                            | Safety and tolerability of Vicineum therapy in all patients                                      |

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

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

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

| <b>Time Point</b> | <b>Evaluable Patients*</b> | <b>Complete Response Rate (95% Confidence Interval)</b> |
|-------------------|----------------------------|---|
| 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) was 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) showed 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 showed 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) was 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 OS 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.

### **Components of Our Results of Operations**

#### ***License Revenue***

License revenue consists of revenue recognized pursuant to our former commercialization partnership agreements, including the exclusive license agreement entered into with Qilu Pharmaceutical, Co., Ltd. ("Qilu") (the "Qilu License Agreement") and an asset purchase agreement, which is assessed under ASC Topic 606, *Revenue* ("ASC 606").

#### ***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;
- 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.

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. On July 15, 2022, we made the strategic decision to voluntarily pause further development of Vicineum in the United States.

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

|  | <b>Year ended December 31,</b> |                  |                  |
|--|--------------------------------|------------------|------------------|
|  | <b>2022</b>                    | <b>2021</b>      | <b>2020</b>      |
| <b>Programs:</b>                         |                                |                  |                  |
| Vicineum for the treatment of NMIBC      | \$ 29,947                      | \$ 15,110        | \$ 22,234        |
| Total direct program expenses            | 29,947                         | 15,110           | 22,234           |
| <b>Personnel and other expenses:</b>     |                                |                  |                  |
| Employee and contractor-related expenses | 7,584                          | 8,977            | 5,775            |
| Platform-related lab expenses            | 100                            | 172              | 303              |
| Facility expenses                        | 478                            | 524              | 442              |
| Other expenses                           | 485                            | 529              | 437              |
| Total personnel and other expenses       | 8,647                          | 10,202           | 6,957            |
| <b>Total Research and Development</b>    | <b>\$ 38,594</b>               | <b>\$ 25,312</b> | <b>\$ 29,191</b> |

### ***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 July 15, 2022, we approved the 2022 Restructuring Plan to reduce operating expenses and better align our workforce with the needs of our business following the decision to voluntarily pause further development of Vicineum in the United States. Execution of the 2022 Restructuring Plan is expected to be substantially completed in connection with the closing of the Merger, which is expected to occur during the first quarter of 2023. The 2022 Restructuring Plan includes an incremental reduction in our workforce as well as additional cost-saving initiatives intended to preserve capital during the pendency of the Merger and while we seek a potential partner for the further development of Vicineum. We also incurred one-time cash costs associated with the termination of certain contracts and all other activities under the 2022 Restructuring Plan. Restructuring costs related to the Restructuring Plan were recorded in operating expenses in our Consolidated Statements of Operations and Comprehensive Loss.

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 "2021 Restructuring Plan"). The 2021 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 2021 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 United States and E.U. 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 acquisition of all outstanding capital stock of Viventia Bio, Inc. 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 (Expense), Net***

Other income (expense), net consists primarily of interest income earned on cash, cash equivalents and marketable securities and, to a lesser extent, any gains or losses on foreign exchange.

***Benefit (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 former OUS business development partnership agreements, including the Qilu License Agreement.

## Our Results of Operations

### Comparison of the Years ended December 31, 2022 and 2021

|  | Year Ended December 31, |                 | Increase/(Decrease) |                |
|--|-------------------------|-----------------|---------------------|----------------|
|  | 2022                    | 2021            | Dollars             | Percentage     |
| (in thousands, except percentages)               |                         |                 |                     |                |
| Revenue:   |                         |                 |                     |                |
| License and related revenue                      | \$ 40,000               | \$ 26,544       | \$ 13,456           | 51 %           |
| Total revenue                                    | 40,000                  | 26,544          | 13,456              | 51 %           |
| Operating expenses:                              |                         |                 |                     |                |
| Research and development                         | \$ 38,594               | \$ 25,312       | \$ 13,282           | 52 %           |
| General and administrative                       | 39,787                  | 29,393          | 10,394              | 35 %           |
| Restructuring charge                             | 11,764                  | 5,528           | 6,236               | 113 %          |
| Intangibles impairment charge                    | 27,764                  | 31,700          | (3,936)             | (12) %         |
| Change in fair value of contingent consideration | (52,000)                | (56,840)        | 4,840               | (9) %          |
| Total operating expenses                         | 65,909                  | 35,093          | 30,816              | 88 %           |
| Loss from Operations                             | (25,909)                | (8,549)         | (17,360)            | 203 %          |
| Other income (expense):                          |                         |                 |                     |                |
| Interest income                                  | 1,854                   | 17              | 1,837               | 10,806 %       |
| Other income (expense), net                      | 296                     | (77)            | 373                 | (484) %        |
| <b>Net Loss Before Taxes</b>                     | <b>(23,759)</b>         | <b>(8,609)</b>  | <b>(15,150)</b>     | <b>176 %</b>   |
| Benefit from income taxes                        | 3,875                   | 8,273           | (4,398)             | (53) %         |
| <b>Net Loss After Taxes</b>                      | <b>\$ (19,884)</b>      | <b>\$ (336)</b> | <b>\$ (19,548)</b>  | <b>5,818 %</b> |

#### License Revenue

Revenue for the year ended December 31, 2022 was \$40.0 million, which was due to the execution of the Roche Asset Purchase Agreement for EBI-031 and all other IL-6 antagonist monoclonal antibody technology. Revenue for the year ended December 31, 2021 was \$26.5 million, primarily due to the \$20.0 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 Investigational New Drug application 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 exclusive license agreement with Hikma Pharmaceuticals LLC (the “Hikma License Agreement”).

#### Research and Development

Research and development expenses were \$38.6 million for the year ended December 31, 2022, compared to \$25.3 million for the year ended December 31, 2021. The increase of \$13.3 million was primarily driven by the expense of prepaid balances related to consumables and manufacturing reservations as the balances were deemed to have no future value due to the strategic decision to voluntarily pause further development of Vicineum in the United States (\$25.2 million). Additionally, employee-related compensation increased, primarily due to the retention programs implemented in the fourth quarter of 2021 and third quarter of 2022 (\$1.0 million). The increase was partially offset by decreased costs associated with manufacturing (\$8.9 million), clinical and manufacturing related consulting fees (\$2.3 million) and other individually immaterial research and development costs (\$0.2 million), driven by the strategic decision to voluntarily pause further development of Vicineum in the United States in the third quarter of 2022. Additionally, one-time regulatory milestone payments (\$1.5 million) related to the filing of the BLA to the FDA for Vicineum and MAA to the EMA for Vysyneum were made in 2021.

#### General and Administrative

General and administrative expenses were \$39.8 million for the year ended December 31, 2022, compared to \$29.4 million for the year ended December 31, 2021. The increase of \$10.4 million was primarily due to an increase in legal expense (\$13.1 million) driven by the settlements of the securities and derivative litigation net of insurance recovery (\$8.2 million) and our

assessment of strategic alternatives (\$3.8 million). Additionally, legal fees for securities and derivative litigation counseling (\$0.6 million), general business counseling (\$0.3 million), and other legal expenses (\$0.2 million) increased. We also incurred \$1.2 million in connection with the fairness opinions related to the proposed Merger and increased other individually immaterial expenses of (\$0.2 million). This was partially offset by decreases in 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.

#### *Restructuring Charge*

On July 15, 2022, we approved the 2022 Restructuring Plan to reduce operating expenses and better align our workforce with the needs of our business following the decision to voluntarily pause further development of Vicineum in the United States. Execution of the 2022 Restructuring Plan is expected to be substantially completed in connection with the closing of the Merger with Carisma, which is expected to occur during the first quarter of 2023. The 2022 Restructuring Plan includes an incremental reduction in our workforce as well as additional cost-saving initiatives intended to preserve capital during the pendency of the Merger with Carisma and while we seek a potential partner for the further development of Vicineum. We also incurred one-time cash costs associated with the termination of certain contracts and all other activities under the 2022 Restructuring Plan.

On August 30, 2021, we approved the 2021 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 2021 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 \$11.8 million for the year ended December 31, 2022, compared to \$5.5 million for the year ended December 31, 2021. The expense for the year ended December 31, 2022 consisted of severance and other employee-related costs (\$7.0 million) and termination of certain contracts and other associated costs (\$4.8 million) following the decision to pause further development of Vicineum in the United States. The expense for the year ended December 31, 2021 consisted of severance and other employee-related costs (\$2.8 million) and termination of certain contracts (\$2.7 million) following the receipt of the CRL in August 2021.

#### *Intangibles Impairment Charge*

Intangibles impairment charge was \$27.8 million for the year ended December 31, 2022, compared to \$31.7 million for the year ended December 31, 2021.

During the second quarter of 2022, we observed an evolution of the current market treatment paradigm in NMIBC, with substantial uptake of intravesical chemotherapy (monotherapy and combination therapy) during the ongoing BCG shortage. We also experienced a sustained decline in our share price and a resulting decrease in our market capitalization. On July 15, 2022 we made the strategic decision to voluntarily pause further development in the United States of Vicineum and are seeking a partner for the further development of Vicineum. The decision was based on a thorough reassessment of Vicineum, which included the incremental development timeline and associated costs for an additional Phase 3 clinical trial for the treatment of NMIBC, following discussions with the FDA and the updated market data obtained through market research during the ongoing BCG shortage. We identified these changes as potential impairment indicators and performed a quantitative impairment analysis for our intangible asset of Vicineum E.U. rights. As a result of the impairment test, we concluded that the carrying value of our intangible asset of Vicineum E.U. rights of \$14.7 million and Goodwill of \$13.1 million were fully impaired and written off during the second quarter of 2022.

In August 2021, we received a CRL from the FDA regarding the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. As a result, an impairment analysis was conducted, which concluded that the carrying value of our intangible asset of Vicineum United States rights of \$31.7 million was fully impaired during the third quarter of 2021.

#### *Change in Fair Value of Contingent Consideration*

The non-cash change in fair value of contingent consideration was a gain of \$52.0 million for the year ended December 31, 2022, compared to gain of \$56.8 million for the year ended December 31, 2021. The change in the fair value of contingent consideration of \$52.0 million for the year ended December 31, 2022 was driven by our strategic decision to voluntarily pause further development of Vicineum in the United States and our conclusion that we no longer expect to owe any future earnout and milestone payments. The decision was based on a thorough reassessment of Vicineum following discussions with the FDA, which had implications for the size, timeline and costs for an additional Phase 3 clinical trial for the treatment of NMIBC. Additionally, during the second quarter of 2022, we observed an evolution of the current market treatment paradigm in NMIBC, with substantial uptake of intravesical chemotherapy (monotherapy and combination therapy) during the ongoing BCG shortage. We continue to believe that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with a larger infrastructure, and as such, are seeking a partner that can execute further development to realize the full potential of Vicineum. We expect that any partner who acquires Vicineum from us will be obligated to make any payments to the former shareholders of Viventia under the Share Purchase Agreement.

The change in fair value of contingent consideration was a gain of \$56.8 million for the year ended December 31, 2021. This was primarily driven by the receipt of a CRL in August 2021, in which the FDA determined that it could not approve the BLA for Vicineum in its present form. Due to the inherent uncertainty in the path forward for Vicineum at the time, 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 possibility of success ("POS"); we expected delays in the start of commercialization and estimated lower POS as a direct result of the CRL. We anticipated needing to conduct an additional clinical trial, which would lead to delays in the start of commercialization globally. We had assessed a range of commercialization timeline assumptions and applied a probability to each outcome based on management's best estimate. In addition, we assumed a lower POS in achieving certain clinical and regulatory milestones in the range of approximately 45% to 55% globally. The milestone payments constitute debt-like obligations, and the high-yield debt index rate applied to the milestones in order to determine the estimated fair value was 8.0% as of December 31, 2021. The discount rate applied to the 2% earnout payment due on then-forecasted Vicineum revenues was derived from our estimated weighted average cost of capital ("WACC"), and this WACC-derived discount rate was 9.3% as of December 31, 2021.

#### *Interest income*

Interest income was \$1.9 million for the year ended December 31, 2022, compared to de minimis for the year ended December 31, 2021. The increase was primarily due to higher yield earned on our investment account during 2022.

#### *Benefit from Income Taxes*

For the year ended December 31, 2022, we recorded a benefit from income taxes of \$3.9 million. In the second quarter of 2022, we determined that the fair value of the Vicineum E.U. in-process research and development asset was zero, which resulted in an impairment charge of \$14.7 million. In connection with this impairment charge, in the second quarter of 2022, we wrote-down the associated deferred tax liability by \$3.9 million as a benefit. For the year 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 9, "Intangibles and Goodwill," in our consolidated financial statements, which begin on page F-1 of this Annual Report on Form 10-K for further information regarding the impairment charge.

#### ***Comparison of the years ended December 31, 2021 and 2020***

For a comparison of our results of operations for the years ended December 31, 2021 and 2020, 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, 2021, filed with the United States Securities and Exchange Commission ("SEC") on February 28, 2022.

### **Liquidity and Capital Resources**

#### ***Overview***

As of December 31, 2022, we had cash, cash equivalents, and marketable securities of \$166.9 million, net working capital of \$158.2 million and an accumulated deficit of \$336.1 million. We incurred positive cash flows from operating activities of \$24.9 million for the year ended December 31, 2022 and negative cash flows from operating activities of \$68.9 million and \$30.8 million for the years ended December 31, 2021 and 2020, respectively. We believe that, based on the wind down of our operations and financial forecasts, our cash, cash equivalents, and marketable securities of \$166.9 million as of December 31, 2022, are sufficient to fund operations for at least twelve months from the date of this Form 10-K filing, February 28, 2023.

Following an extensive process of evaluating strategic alternatives, including identifying and reviewing potential candidates for a strategic transaction, on September 20, 2022, we entered into the Merger Agreement with Carisma and Merger Sub, pursuant to which, among other things, and subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement, Merger Sub will merge with and into Carisma, with Carisma continuing as our wholly-owned subsidiary and the surviving corporation of the Merger. Our board of directors unanimously approved the Merger Agreement and resolved to recommend that our stockholders approve the proposals described in the Merger Agreement. If the Merger is completed, the business of Carisma will continue as the business of the combined company.

The Merger is expected to be completed during the first quarter of 2023. Consummation of the Merger is subject to certain closing conditions, including, among other things, (a) approval by our stockholders of the proposals described in the Merger Agreement, (b) approval by Carisma's stockholders of, among other things, the adoption of the Merger Agreement, (c) Nasdaq's approval of the listing of the shares of our common stock to be issued in connection with the Merger, (d) the effectiveness of a registration statement on Form S-4 to register the shares of our common stock to be issued in connection with the Merger, and (e) our having net cash as of closing of the Merger greater than or equal to \$70.0 million.

The Merger Agreement contains certain termination rights of each of us and Carisma. Upon termination of the Merger Agreement under specified circumstances, we may be required to pay Carisma a termination fee of \$7.6 million and/or reimburse Carisma's expenses up to a maximum of \$1.75 million, and Carisma may be required to pay us a termination fee of \$5.49 million and/or reimburse our expenses up to a maximum of \$1.75 million.

Our future operations are highly dependent on the success of the Merger and there can be no assurances that the Merger will be successfully consummated. In the event that we do not complete the Merger with Carisma, we may continue to explore strategic alternatives, including, without limitation, a dissolution of our company.

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. 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 former OUS business development partnerships and license agreements, sale of assets, and, to a lesser extent, from a collaboration.

We have entered into an Open Market Sale Agreement with Jefferies LLC ("Jefferies") dated November 29, 2019, as amended by Amendment No. 1 dated October 30, 2020, Amendment No. 2 dated February 17, 2021 and Amendment No. 3, dated June 1, 2021 (as amended, the "Sale Agreement"), under which we may issue and sell shares of our common stock, par value \$0.001 per share from time to time through Jefferies (the "ATM Offering"). 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 \$200.0 million of our common stock pursuant to the Sale Agreement of which \$97.8 million of common shares remain available for future issuance as of December 31, 2022. Sales 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 Stock Market or any other existing trading market for our common stock. 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 did not sell any shares of common stock pursuant to the Sale Agreement during the year ended December 31, 2022. 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. Share issue costs, including sales agent commissions, related to the ATM Offering totaled \$5.4 million for the year ended December 31, 2021.

### ***Funding Requirements***

Our future funding requirements will depend on the outcome of the proposed Merger with Carisma.

We are subject to a number of risks similar to other clinical companies that have determined to focus primarily on pursuing a strategic transaction, including, but not limited to, those which are described under Part I Item 1A. Risk Factors of this Annual Report on Form 10-K.

We will incur substantial expenses if and as we:

- address our ongoing litigation related to the Merger;
- maintain and protect our intellectual property portfolio;
- reduce our personnel and incur related severance and employee-related costs;
- explore, evaluate and pursue any strategic alternatives if the Merger is not completed.

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

- the outcome and the timing of the proposed Merger with Carisma;
- the outcome and timing of any pending or future litigation involving us or our business;
- the costs and timing of maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- our obligation to make milestone, royalty, and other payments to third-party licensors under our licensing agreements.

Until such time, if ever, as we can generate substantial revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, or government or other third-party funding. 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 are unable to raise

additional funds when needed, we may be required to delay, limit, reduce or terminate our assessment of strategic alternatives. If we do not successfully consummate the proposed Merger with Carisma, our board of directors may decide to explore other strategic alternatives, including, without limitation, a dissolution of our company.

### ***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 8 “Property and Equipment,” and the description of our license agreement and collaborations in Note 18, “License Agreements,” in our consolidated financial statements, which begin on page F-1 of this Annual Report on Form 10-K.

### ***Cash Flows***

The following table sets forth a summary of our cash flows for the years ended December 31, 2022, 2021 and 2020 (in thousands):

|  | <b>Year ended December 31,</b> |                   |                 |
|--|--------------------------------|-------------------|-----------------|
|  | <b>2022</b>                    | <b>2021</b>       | <b>2020</b>     |
| Net Cash Provided by (Used in) Operating Activities                          | \$ 24,895                      | \$ (68,878)       | \$ (30,837)     |
| Net Cash Used in Investing Activities  | (53,969)                       | (4)               | (8)             |
| Net Cash Provided by Financing Activities                                    | 1                              | 176,129           | 38,113          |
| <b>Net (Decrease) Increase in Cash, Cash Equivalents and Restricted Cash</b> | <b>\$ (29,073)</b>             | <b>\$ 107,247</b> | <b>\$ 7,268</b> |

#### *Net Cash Used in Operating Activities*

Net cash provided by operating activities was \$24.9 million for the year ended December 31, 2022 and consisted primarily of a net loss of \$19.9 million, adjusted for non-cash items including a decrease in the fair value of contingent consideration (\$52.0 million), intangible impairment charge of (\$27.8 million), share-based compensation (\$6.9 million), and a net increase in operating assets and liabilities (\$63.0 million).

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 former OUS partner for Greater China, and license revenue for additional purchase price due to the recovery of VAT by our former 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 share-based compensation of \$1.8 million, a change in the fair value of contingent consideration of \$11.2 million and a net decrease in operating assets and liabilities of \$0.9 million.

#### *Net Cash Used in Investing Activities*

Net cash used in investing activities was \$54.0 million for the year ended December 31, 2022 and consisted of marketable security purchases.

Net cash used in investing activities consisted of de minimis purchases and sales of property and equipment during the years ended December 31, 2021 and 2020.

#### *Net Cash Provided by Financing Activities*

Net cash provided by financing activities was de minimis for the year ended December 31, 2022.

Net cash provided by financing activities was \$176.1 million for the year ended December 31, 2021 and consisted of \$175.0 million 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.

## **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 consisted 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.

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.

During the second quarter of 2022, we observed an evolution of the current market treatment paradigm in NMIBC, with substantial uptake of intravesical chemotherapy (monotherapy and combination therapy) during the ongoing BCG shortage. We have also experienced a sustained decline in share price and a resulting decrease in our market capitalization. On July 15, 2022, we made the strategic decision to voluntarily pause further development of Vicineum in the United States. The decision was based on a thorough reassessment of Vicineum following discussions with the FDA, which had implications on the size, timeline, and costs of an additional Phase 3 clinical trial for the treatment of NMIBC. Management updated the discounted cash flow model using the market participant approach and considered preliminary terms of potential partnering deal to conclude the fair value of our intangible asset of Vicineum E.U. rights. We concluded that the carrying value of our intangible asset of Vicineum E.U. rights of \$14.7 million was fully impaired as of June 30, 2022 and was reduced to zero in the second quarter of 2022.

In August 2021, we received a CRL from the FDA regarding the 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 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 United States market.

### ***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.

During the second quarter of 2022, we observed continued trends in our market capitalization as compared to the carrying value of our single reporting unit as well as changes in certain assumptions in the fair value of the business including market share, size, length and cost of a clinical trial, and time to potential market launch. We identified these changes as potential impairment indicators and performed a quantitative impairment analysis in advance of our typical annual assessment date of October 1, 2022. We reassessed the underlying assumptions used to develop our revenue projections, which were then used as significant inputs to determine the fair value of equity. We updated our revenue forecast models based on further expected launch delays in both United States and OUS regions. We also recently observed an evolution of the current treatment paradigm in NMIBC, with substantial uptake of intravesical chemotherapy (monotherapy and combination therapy) during the ongoing BCG shortage resulting in lower projected peak market share for Vicineum. We also considered other factors including the preliminary valuations of strategic alternatives during the fair value assessment. As a result of the interim impairment test, we concluded that the carrying value of our goodwill of \$13.1 million was fully impaired as of June 30, 2022.

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

The estimated fair value of our contingent consideration was determined using probabilities of successful achievement of regulatory milestones and commercial sales, the period in which these milestones and sales were expected to be achieved through 2033, the level of commercial sales of Vicineum then-forecasted for the United States, Europe, Japan, China, and other potential markets. Earnouts were 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 was derived from our estimated weighted-average cost of capital, which was 9.3% as of December 31, 2021. Milestone payments constitute debt-like obligations, and therefore a high-yield debt index rate was applied to the milestones in order to determine the estimated fair value. This index rate was 8.0% as of December 31, 2021.

On July 15, 2022, we made the strategic decision to voluntarily pause further development of Vicineum in the United States. The decision was based on a thorough reassessment of Vicineum following discussions with the FDA, which had implications on the size, timeline, and costs of an additional Phase 3 clinical trial for the treatment of NMIBC. We continue to believe that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with a larger infrastructure, and as such, we are seeking a partner for the further development of Vicineum. Accordingly, during the second quarter of 2022, we concluded that we are no longer expected to pay related milestone and earnout payments to the former shareholders of Viventia, with the exception of the potential 2% earnout payment related to the Greater China region since those territory rights had been out-licensed. We and Qilu were in the process of negotiating a termination of the Qilu License Agreement, which was terminated on December 23, 2022. Accordingly, as of September 30, 2022, we concluded that we no longer expected to owe any future earnout payments related to the Greater China region and reduced our remaining \$1.8 million of contingent consideration liabilities to zero as of September 30, 2022.

### ***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 not recognize revenue until the subsequent sale of a licensed product occurs. For arrangements with more than one performance obligation, 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 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 principal 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, 2022.

### **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 2022 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, 2022 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP.

### **Changes in Internal Control over Financial Reporting**

There have not been changes in our internal control over financial reporting during the quarter ended December 31, 2022 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.sesbio.com](http://www.sesbio.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 2023 Proxy Statement or in an amendment to this Form 10-K to be filed with the SEC within 120 days of December 31, 2022 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 2023 Proxy Statement or in an amendment to this Form 10-K to be filed with the SEC within 120 days of December 31, 2022 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 2023 Proxy Statement or in an amendment to this Form 10-K to be filed with the SEC within 120 days of December 31, 2022 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 2023 Proxy Statement or in an amendment to this Form 10-K to be filed with the SEC within 120 days of December 31, 2022 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 2023 Proxy Statement or in an amendment to this Form 10-K to be filed with the SEC within 120 days of December 31, 2022 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

| <b>Exhibit No.</b> | <b>Description</b>  |
|--------------------|---|
| 2.1 <sup>^</sup>   | <u>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. Incorporated by reference to Exhibit 2.1 to our Current Report on Form 8-K filed on September 21, 2016 (File No. 001-36296).</u> |
| 2.2 <sup>^</sup>   | <u>Agreement and Plan of Merger, dated as of September 20, 2022, by and among Sesen Bio, Inc., Seahawk Merger Sub, Inc. and Carisma. Incorporated by reference to Exhibit 2.1 to our Current Report on Form 8-K filed on September 21, 2022 (File No. 001-36296).</u>   |
| 2.3 <sup>^</sup>   | <u>First Amendment to Agreement and Plan of Merger and Reorganization, dated as of December 29, 2022, by and among Sesen Bio, Inc., Seahawk Merger Sub, Inc., and Carisma. Incorporated by reference to Exhibit 2.1 to our Current Report on Form 8-K filed on December 29, 2022 (File No. 001-36296).</u>                                      |
| 2.4 <sup>^</sup>   | <u>Second Amendment to Agreement and Plan of Merger and Reorganization, dated as of February 13, 2023, by and among Sesen Bio, Inc., Seahawk Merger Sub, Inc., and Carisma. Incorporated by reference to Exhibit 2.1 to our Current Report on Form 8-K filed on February 14, 2023 (File No. 001-36296).</u>                                     |
| 2.5                | <u>Form of Carisma Support Agreement, by and between the Sesen Bio, Inc., Carisma and certain stockholders of Carisma. Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed on September 21, 2022 (File No. 001-36296).</u>  |
| 2.6                | <u>Form of Sesen Bio Support Agreement, by and between the Sesen Bio, Inc., Carisma and certain stockholders of Sesen Bio, Inc. Incorporated by reference to Exhibit 10.3 to our Current Report on Form 8-K filed on September 21, 2022 (File No. 001-36296).</u>   |
| 2.7                | <u>Form of Lock-Up Agreement, by and between Sesen Bio, Inc., Carisma and certain stockholders of Sesen Bio, Inc. and Carisma. Incorporated by reference to Exhibit 10.4 to our Current Report on Form 8-K filed on September 21, 2022 (File No. 001-36296).</u>  |
| 2.8                | <u>Form of Contingent Value Rights Agreement by and among Sesen Bio, Inc. and the Rights Agent. Incorporated by reference to Exhibit D to Exhibit 2.1 to our Current Report on 8-K filed on February 14, 2023 (File No. 001-36296).</u>   |
| 3.1                | <u>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).</u>  |
| 3.2                | <u>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).</u>   |
| 3.3                | <u>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).</u>  |
| 3.4                | <u>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).</u>   |
| 4.1*               | <u>Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.</u>   |

- 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. Incorporated by reference to Exhibit 10.8 to our Annual Report on Form 10-K, filed on February 28, 2022 (File No. 001-36296).
- 10.9+ 2014 Employee Stock Purchase Plan. Incorporated by reference to Exhibit 10.13 to our Registration Statement on Form S-1/A filed on January 23, 2014 (Reg. No. 333-193131).
- 10.10† 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 Quarterly Report on Form 10-Q filed on May 9, 2022 (File No. 001-36296).
- 10.11† 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).
- 10.12† 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).
- 10.13+ 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).
- 10.14 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).

- 10.15 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).
- 10.16+ 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).
- 10.17+ 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).
- 10.18+ 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).
- 10.19+ 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).
- 10.20+ 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).
- 10.21 Open Market Sale Agreement<sup>SM</sup>, 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).
- 10.22 Amendment No. 1 to the Open Market Sale Agreement<sup>SM</sup>, 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).
- 10.23† 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).
- 10.24 Amendment No. 2 to the Open Market Sale Agreement<sup>SM</sup>, 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).
- 10.25+ 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).
- 10.26+ 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).
- 10.27 Amendment No. 3 to the Open Market Sale Agreement<sup>SM</sup>, 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).
- 10.28+ Form of RSU Award Agreement for Retention Awards. Incorporated by reference to Exhibit 10.30 to our Annual Report on Form 10-K filed on February 28, 2022 (File No. 001-36296).
- 10.29+ Form of PSU Award Agreement for Retention Awards. Incorporated by reference to Exhibit 10.31 to our Annual Report on Form 10-K filed on February 28, 2022 (File No. 001-36296).
- 10.30† Asset Purchase Agreement, dated as of July 15, 2022 by and among Sesen Bio, Inc., F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, filed on July 18, 2022 (File No. 001-36296).
- 10.31† Employment Agreement, dated January 5, 2022, by and between Sesen Bio, Inc. and Minori Rosales. Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q/A filed on August 25, 2022 (File No. 001-36296).
- 10.32^ Voting and Support Agreement, dated February 13, 2023, by and among the Radoff Family Foundation, Bradley L. Radoff, JEC II Associates, LLC, the K. Peter Heiland 2008 Irrevocable Trust, Michael Torok, CARISMA Therapeutics, Inc. and Sesen Bio, Inc. Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on February 14, 2023 (File No. 001-36296).

|         |   |
|---------|---|
| 21.1*   | <u>Subsidiaries of Sesen Bio, Inc.</u>  |
| 23.1*   | <u>Consent of Ernst &amp; Young LLP.</u>  |
| 31.1*   | <u>Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>  |
| 31.2*   | <u>Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>  |
| 32.1*   | <u>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.</u>         |
| 32.2*   | <u>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.</u>         |
| 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).   |

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\* 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 pursuant to Item 601(b)(10)(iv) of Regulation S-K.

^ Certain schedules and exhibits have been omitted pursuant to Item 601 of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

**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, 2023

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.

| <u>Signature</u>  | <u>Capacity</u>  | <u>Date</u>          |
|---|--|----------------------|
| <u>/s/ Thomas R. Cannell, D.V.M.</u><br>Thomas R. Cannell, D.V.M. | President, Chief Executive Officer and Director<br>(Principal Executive Officer) | February 28,<br>2023 |
| <u>/s/ Monica Forbes</u><br>Monica Forbes                         | Chief Financial Officer<br>(Principal Financial Officer)                         | February 28,<br>2023 |
| <u>/s/ Elly Ryu</u><br>Elly Ryu                                   | Corporate Controller<br>(Principal Accounting Officer)                           | February 28,<br>2023 |
| <u>/s/ Jay S. Duker, M.D.</u><br>Jay S. Duker, M.D.               | Chair of the Board of Directors  | February 28,<br>2023 |
| <u>/s/ Carrie L. Bourdow</u><br>Carrie L. Bourdow                 | Director   | February 28,<br>2023 |
| <u>/s/ Jason A. Keyes</u><br>Jason A. Keyes                       | Director   | February 28,<br>2023 |
| <u>/s/ Peter K Honig, M.D.</u><br>Peter K Honig, M.D.             | Director   | February 28,<br>2023 |
| <u>/s/ Michael A.S. Jewett, M.D.</u><br>Michael A.S. Jewett, M.D. | Director   | February 28,<br>2023 |

## INDEX TO FINANCIAL STATEMENTS

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# 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, 2022 and 2021, the related consolidated statements of operations, comprehensive loss, stockholders’ equity (deficit), and cash flows for each of the three years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

### Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

### Critical Audit Matter

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

### ***Impairment Evaluation of Goodwill and Indefinite-Lived Intangible Assets***

*Description of  
the Matter*

As discussed in Notes 3 and 9 to the consolidated financial statements under the captions “Indefinite-Lived Intangible Assets” and “Goodwill,” the Company’s intangible assets consisted of indefinite-lived, acquired in-process research and development (IPR&D) product rights to Vicineum as a result of the acquisition of Viventia in 2016. Goodwill on the Company's consolidated balance sheets was 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.

While management concluded the carrying value of its goodwill and IPR&D intangible asset were fully impaired as of June 30, 2022, and recorded impairment charges of \$13.1 million and \$14.7 million, respectively, the impairment assessments required a high degree of subjectivity to estimate the assumptions underlying Vicineum revenue projections which contributes to the fair value estimates of goodwill and of the IPR&D.

*How We  
Addressed the  
Matter in Our  
Audit*

To test the impairment evaluations over goodwill and the IPR&D asset, 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 data, external data sources, probability of success benchmarks, regulatory factors, and draft term sheets which provided value indication for the business and Vicineum. 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. 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, 2023

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

|   | December 31,      |                   |
|---|-------------------|-------------------|
|   | 2022              | 2021              |
| <b>Assets</b>   |                   |                   |
| Current assets:   |                   |                   |
| Cash and cash equivalents   | \$ 112,553        | \$ 162,636        |
| Short term marketable securities  | 54,366            | —                 |
| Restricted cash   | 21,000            | —                 |
| Accounts receivables  | —                 | 21,011            |
| Other receivables   | 825               | 3,482             |
| Prepaid expenses and other current assets   | 400               | 18,476            |
| Total current assets  | 189,144           | 205,605           |
| Non-current assets:   |                   |                   |
| Restricted cash   | 30                | 20                |
| Property and equipment, net   | —                 | 43                |
| Intangible assets   | —                 | 14,700            |
| Goodwill  | —                 | 13,064            |
| Long term prepaid expenses  | —                 | 7,192             |
| Other assets  | —                 | 123               |
| Total non-current assets  | 30                | 35,142            |
| Total Assets  | <u>\$ 189,174</u> | <u>\$ 240,747</u> |
| <b>Liabilities and Stockholders' Equity</b>   |                   |                   |
| Current liabilities:  |                   |                   |
| Accounts payable  | \$ 1,233          | \$ 2,853          |
| Accrued expenses  | 29,636            | 8,255             |
| Other current liabilities   | 115               | 460               |
| Total current liabilities   | 30,984            | 11,568            |
| Non-current liabilities:  |                   |                   |
| Contingent consideration  | —                 | 52,000            |
| Deferred tax liability  | —                 | 3,969             |
| Deferred revenue  | —                 | 1,500             |
| Total non-current liabilities   | —                 | 57,469            |
| Total Liabilities   | 30,984            | 69,037            |
| Stockholders' Equity:   |                   |                   |
| Preferred stock, \$0.001 par value per share; 5,000,000 shares authorized at December 31, 2022 and 2021; no shares issued and outstanding at December 31, 2022 and 2021                                       | —                 | —                 |
| Common stock, \$0.001 par value per share; 400,000,000 shares authorized at December 31, 2022 and 2021; 202,759,043 and 199,463,645 shares issued and outstanding at December 31, 2022 and 2021, respectively | 202               | 199               |
| Additional paid-in capital  | 494,675           | 487,768           |
| Accumulated deficit   | (336,141)         | (316,257)         |
| Other comprehensive loss  | (546)             | —                 |
| Total Stockholders' Equity  | 158,190           | 171,710           |
| Total Liabilities and Stockholders' Equity  | <u>\$ 189,174</u> | <u>\$ 240,747</u> |

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

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

Year Ended December 31,

|  | 2022        | 2021       | 2020        |
|--|-------------|------------|-------------|
| Revenue:   |             |            |             |
| License and related revenue                                      | \$ 40,000   | \$ 26,544  | \$ 11,236   |
| Total revenue  | 40,000      | 26,544     | 11,236      |
| Operating expenses:  |             |            |             |
| Research and development   | 38,594      | 25,312     | 29,191      |
| General and administrative                                       | 39,787      | 29,393     | 14,302      |
| Restructuring charge   | 11,764      | 5,528      | —           |
| Intangibles impairment charge                                    | 27,764      | 31,700     | —           |
| Change in fair value of contingent consideration                 | (52,000)    | (56,840)   | (11,180)    |
| Total operating expenses   | 65,909      | 35,093     | 32,313      |
| Loss from Operations   | \$ (25,909) | \$ (8,549) | \$ (21,077) |
| Interest income  | 1,854       | 17         | 224         |
| Other income (expense), net                                      | 296         | (77)       | (99)        |
| Loss Before Taxes  | \$ (23,759) | \$ (8,609) | \$ (20,952) |
| Benefit (provision) from income taxes                            | \$ 3,875    | \$ 8,273   | \$ (1,445)  |
| Net Loss After Taxes   | \$ (19,884) | \$ (336)   | \$ (22,397) |
| Deemed Dividend  | \$ —        | \$ —       | \$ (147)    |
| Net loss attributable to common stockholders - basic and diluted | \$ (19,884) | \$ (336)   | \$ (22,544) |
| Net loss per common share - basic and diluted                    | \$ (0.10)   | \$ —       | \$ (0.19)   |
| Weighted-average common shares outstanding - basic and diluted   | \$ 200,546  | \$ 182,323 | \$ 118,221  |

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

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

|  | Year Ended December 31, |          |             |
|--|-------------------------|----------|-------------|
|  | 2022                    | 2021     | 2020        |
| Net loss                                 | \$ (19,884)             | \$ (336) | \$ (22,397) |
| Unrealized loss on marketable securities | 546                     | —        | —           |
| Total comprehensive loss                 | \$ (20,430)             | \$ (336) | \$ (22,397) |

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

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

|   | Common Stock       |               | Additional<br>Paid-in<br>Capital | Other<br>Comprehensive<br>Loss<br>Investments | Accumulated<br>Deficit | Stockholders'<br>Equity<br>(Deficit) |
|---|--------------------|---------------|----------------------------------|---|------------------------|--------------------------------------|
|   | Shares             | Amount        |                                  |   |                        |                                      |
| <b>Balance at December 31, 2019</b>   | 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<br>2014 ESPP  | 28,186             | —             | 11                               | —   | —                      | 11                                   |
| Exercises of common stock<br>warrants   | 238,110            | —             | 131                              | —   | —                      | 131                                  |
| Issuance of common stock<br>under ATM Offering, net of<br>issuance costs of \$1.2 million | 33,369,942         | 33            | 37,925                           | —   | —                      | 37,958                               |
| <b>Balance at December 31, 2020</b>   | <b>140,449,647</b> | <b>140</b>    | <b>306,554</b>                   | <b>—</b>                                      | <b>(315,921)</b>       | <b>(9,227)</b>                       |
| Net loss  | —                  | —             | —                                | —   | (336)                  | (336)                                |
| Share-based compensation  | —                  | —             | 5,143                            | —   | —                      | 5,143                                |
| Exercises of stock options  | 33,610             | —             | 42                               | —   | —                      | 42                                   |
| Exercises of common stock<br>warrants   | 2,048,059          | 2             | 1,124                            | —   | —                      | 1,126                                |
| Issuance of common stock<br>under ATM Offering, net of<br>issuance costs of \$5.4 million | 56,932,329         | 57            | 174,905                          | —   | —                      | 174,962                              |
| <b>Balance at December 31, 2021</b>   | <b>199,463,645</b> | <b>199</b>    | <b>487,768</b>                   | <b>—</b>                                      | <b>(316,257)</b>       | <b>171,710</b>                       |
| Net loss  | —                  | —             | —                                | —   | (19,884)               | (19,884)                             |
| Share-based compensation  | —                  | —             | 6,909                            | —   | —                      | 6,909                                |
| Exercises of stock options  | 2,031              | —             | 1                                | —   | —                      | 1                                    |
| Unrealized loss on marketable<br>securities   | —                  | —             | —                                | (546)   | —                      | (546)                                |
| Issuance of common stock for<br>RSU vesting   | 3,293,367          | 3             | (3)                              | —   | —                      | —                                    |
| <b>Balance at December 31, 2022</b>   | <b>202,759,043</b> | <b>\$ 202</b> | <b>\$ 494,675</b>                | <b>\$ (546)</b>                               | <b>\$ (336,141)</b>    | <b>\$ 158,190</b>                    |

*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, |                   |                  |
|--|-------------------------|-------------------|------------------|
|  | 2022                    | 2021              | 2020             |
| <b>Cash Flows from Operating Activities:</b>                                     |                         |                   |                  |
| Net loss   | \$ (19,884)             | \$ (336)          | \$ (22,397)      |
| Adjustments to reconcile net loss to net cash used in operating activities:      |                         |                   |                  |
| Depreciation   | 13                      | 85                | 122              |
| Share-based compensation   | 6,909                   | 5,143             | 1,757            |
| Change in fair value of contingent consideration                                 | (52,000)                | (56,840)          | (11,180)         |
| Intangibles impairment charge  | 27,764                  | 31,700            | —                |
| Net amortization of discounts and premiums on marketable securities              | (913)                   | —                 | —                |
| Changes in operating assets and liabilities:                                     |                         |                   |                  |
| Accounts receivable (net)  | 21,010                  | (24,493)          | —                |
| Other receivables  | 2,658                   | —                 | —                |
| Prepaid expenses and other assets  | 18,076                  | (17,964)          | (1,304)          |
| Long term prepaid expenses   | 7,192                   | —                 | —                |
| Other assets   | 123                     | —                 | —                |
| Accounts payable   | (1,620)                 | (249)             | 1,200            |
| Accrued expenses and other liabilities   | 17,067                  | (4,424)           | (2,035)          |
| Deferred revenue   | (1,500)                 | (1,500)           | 3,000            |
| Net cash provided by (used in) operating activities                              | <b>24,895</b>           | <b>(68,878)</b>   | <b>(30,837)</b>  |
| <b>Cash Flows from Investing Activities:</b>                                     |                         |                   |                  |
| Purchase of marketable securities  | (128,999)               | —                 | —                |
| Proceeds from maturity of marketable securities                                  | 75,000                  | —                 | —                |
| Disposal (purchases) of equipment  | 30                      | (4)               | (8)              |
| Net cash used in investing activities  | <b>(53,969)</b>         | <b>(4)</b>        | <b>(8)</b>       |
| <b>Cash Flows from Financing Activities:</b>                                     |                         |                   |                  |
| Proceeds from issuance of common stock under ATM Offering, net of issuance costs | —                       | 174,962           | 37,958           |
| Proceeds from exercises of stock options   | 1                       | 42                | 13               |
| Proceeds from exercises of common stock warrants                                 | —                       | 1,126             | 131              |
| Proceeds from sale of common stock pursuant to ESPP                              | —                       | —                 | 11               |
| Net cash provided by financing activities  | <b>1</b>                | <b>176,129</b>    | <b>38,113</b>    |
| Net (decrease) increase in cash, cash equivalents and restricted cash            | (29,073)                | 107,247           | 7,268            |
| Cash, cash equivalents and restricted cash - beginning of period                 | 162,656                 | 55,409            | 48,141           |
| Cash, cash equivalents and restricted cash - end of period                       | <b>\$ 133,583</b>       | <b>\$ 162,656</b> | <b>\$ 55,409</b> |
| <b>Reconciliation of cash, cash equivalents and restricted cash:</b>             |                         |                   |                  |
| Cash and cash equivalents  | \$ 112,553              | \$ 162,636        | \$ 52,389        |
| Short term restricted cash   | 21,000                  | —                 | 3,000            |
| Long term restricted cash  | 30                      | 20                | 20               |
| Total cash, cash equivalents and restricted cash                                 | <b>\$ 133,583</b>       | <b>\$ 162,656</b> | <b>\$ 55,409</b> |
| Supplemental cash flow disclosure:   |                         |                   |                  |
| Cash paid for amounts included in the measurement of lease liabilities           | \$ 127                  | \$ 174            | \$ 154           |
| Supplemental disclosure of non-cash operating activities:                        |                         |                   |                  |
| 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 Bio" or the "Company"), a Delaware corporation formed in February 2008, is a late-stage clinical company that previously focused on 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 bladder cancer ("NMIBC"). On July 15, 2022, the Company made the strategic decision to voluntarily pause further development of Vicineum in the United States. The decision was based on a thorough reassessment of Vicineum following discussions with the United States Food and Drug Administration ("FDA"), which had implications on the size, timeline and costs of an additional Phase 3 clinical trial, which the FDA previously confirmed would be required for a potential resubmission of a biologics license application ("BLA") for Vicineum for the treatment of NMIBC. As a result of this decision, the Company turned its primary focus to consummating a strategic transaction with the goal of maximizing stockholder value.

Following an extensive process of evaluating strategic alternatives, including identifying and reviewing potential candidates for a strategic transaction, on September 20, 2022, the Company, Seahawk Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of the Company ("Merger Sub"), and CARISMA Therapeutics Inc. ("Carisma"), entered into the Agreement and Plan of Merger and Reorganization dated as of September 20, 2022, as amended by the First Amendment thereto dated as of December 29, 2022 and the Second Amendment thereto dated as of February 13, 2023 (the "Merger Agreement"), pursuant to which, among other things, and subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement, Merger Sub will merge with and into Carisma, with Carisma continuing as a wholly-owned subsidiary of the Company and the surviving corporation of the merger (the "Merger"). The Company's board of directors unanimously approved the Merger Agreement and resolved to recommend that its stockholders approve the proposals described in the Merger Agreement. If the Merger is completed, the business of Carisma will continue as the business of the combined company.

The Company continues to believe that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with a larger infrastructure, and as such, it is seeking a partner that can execute further development to realize the full potential of Vicineum. As a result of such decision and the Company's subsequent decision to enter into the proposed Merger with Carisma, it no longer plans to pursue regulatory approval of Vicineum for NMIBC in the European Union (the "E.U.") and has started to wind down certain of its manufacturing operations and business development partnerships. Additionally, the Company is seeking a partner for the further development of Vicineum and has initiated a formal process and engaged a financial advisor for the potential sale of Vicineum. If the proposed Merger is consummated, the combined company does not expect to pursue further development of Vicineum.

***Anticipated Merger with CARISMA Therapeutics Inc.***

The Merger is expected to be completed during the first quarter of 2023. In connection with the Merger, the Company is seeking the approval of its stockholders to, among other things, (a) issue the shares of its common stock issuable in connection with the Merger pursuant to the rules of The Nasdaq Stock Market LLC ("Nasdaq"), and (b) amend its amended and restated Certificate of Incorporation (the "Certificate of Incorporation") to effect a reverse stock split of the outstanding shares of its common stock at a ratio of 1-for-20 (clauses (a) and (b), collectively, the "Sesen Bio Voting Proposals"). The special meeting of stockholders in which the Company's stockholders will be asked to vote on the Sesen Bio Voting Proposals (the "Special Meeting") will be held on March 2, 2023 at 10:00 a.m. Eastern Time.

Sesen Bio's future operations are highly dependent on the success of the Merger and there can be no assurances that the Merger will be successfully consummated. In the event that Sesen Bio does not complete the Merger with Carisma, Sesen Bio may continue to review and evaluate strategic alternatives, including, without limitation, a dissolution of Sesen Bio.

***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, 2022, none of these individuals are active employees or members of the Company's board of directors.

### ***Liquidity and Capital Resources***

As of December 31, 2022, the Company had cash, cash equivalents, and marketable securities of \$166.9 million and an accumulated deficit of \$336.1 million. The Company incurred positive cash flows from operating activities of \$24.9 million for the year ended December 31, 2022. The Company incurred negative cash flows from operating activities \$68.9 million and \$30.8 million for the years ended December 31, 2021 and 2020, 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 close the Merger with Carisma. 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, out-license agreements and an asset purchase agreement. See "Note 13. Stockholders' Equity (Deficit)" 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, 2022 will be sufficient to fund the Company's operations for at least the next twelve months from the date these consolidated financial statements were issued.

### ***Funding Requirements***

The Company's future funding requirements will depend on the outcome of the proposed Merger with Carisma.

The Company is subject to a number of risks similar to other clinical companies that have determined to focus primarily on pursuing a strategic transaction, including, but not limited to, those which are described under Part I Item 1A. Risk Factors of this Annual Report on Form 10-K.

The Company will incur substantial expenses if and as it:

- addresses its ongoing litigation related to the Merger;
- maintains and protects its intellectual property portfolio;
- reduces its personnel and incurs related severance and employee-related costs;
- explores, evaluates and pursues any strategic alternatives if the Merger is not completed.

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

- the outcome and the timing of the proposed Merger with Carisma;
- the outcome and timing of any pending or future litigation involving the Company or its business;
- the costs and timing of maintaining and enforcing the Company's intellectual property rights and defending any intellectual property-related claims; and
- its obligation to make milestone, royalty and other payments to third-party licensors under its licensing agreements.

Until such time, if ever, as the Company can generate substantial revenues, the Company expects to finance the cash needs through a combination of equity offerings, debt financings, or government or other third-party funding. To the extent that the Company raises additional capital through the sale of equity or convertible debt securities, the ownership interests of existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include liens or other restrictive covenants limiting the Company's ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If the Company is unable to raise additional funds when needed, it may be required to delay, limit,

reduce or terminate its assessment of strategic alternatives. If the Company does not successfully consummate the proposed Merger with Carisma, its board of directors may decide to explore other strategic alternatives, including, without limitation, a dissolution of the company.

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

### ***Principles of Consolidation***

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

### ***Foreign Currency Translation***

The functional currency of the Company and each of its subsidiaries is the United States 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, marketable securities, and accounts receivable. The Company limited its credit risk associated with cash equivalents and marketable securities by investing in highly-rated money market funds, US government securities, and treasury securities. The Company does not believe that it is subject to any significant concentrations of credit risk from these financial institutions.

### ***Marketable Securities***

The Company classifies all of its marketable securities as available-for-sale. The marketable securities consist of holdings in US treasury securities and US government securities, with maturity dates ranging from March 2023 to November 2023, which is consistent with the Company's investment policy. Accordingly, these investments are recorded at fair value which is determined based on quoted market prices. Amortization and accretion of discounts and premiums are recorded as interest income. Realized gains and losses are included in other income (expense), net. Unrealized gains and losses are included in other comprehensive loss as a component of stockholder's equity (deficit) until realized.

### ***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 consisted 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.

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.

During the second quarter of 2022, the Company observed an evolution of the current market treatment paradigm in NMIBC, with substantial uptake of intravesical chemotherapy (monotherapy and combination therapy) during the ongoing BCG shortage. The Company has also experienced a sustained decline in share price and a resulting decrease in its market capitalization. On July 15, 2022, the Company made the strategic decision to voluntarily pause further development of Vicineum in the United States. The decision was based on a thorough reassessment of Vicineum following discussions with the FDA, which had implications on the size, timeline, and costs of an additional Phase 3 clinical trial for the treatment of NMIBC. Management updated the discounted cash flow model using the market participant approach and considered preliminary terms of potential partnering deal to conclude the fair value of its intangible asset of Vicineum E.U. rights. The Company concluded that the carrying value of its intangible asset of Vicineum E.U. rights of \$14.7 million was fully impaired as of June 30, 2022 and was reduced to zero in the second quarter of 2022.

In August 2021, the Company received a Complete Response Letter ("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 chemistry, manufacturing, and controls ("CMC") issues pertaining to a recent pre-approval inspection and product quality. Given the inherent uncertainty in the development plans for Vicineum (and Vysyenum 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 United States 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 United States market.

### ***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.

During the second quarter of 2022, the Company observed continued trends in its market capitalization as compared to the carrying value of its single reporting unit as well as changes in certain assumptions in the fair value of the business including market share, size, length and cost of a clinical trial, and time to potential market launch. The Company identified these changes as potential impairment indicators and performed a quantitative impairment analysis in advance of its typical annual assessment

date of October 1. The Company reassessed the underlying assumptions used to develop its revenue projections, which were then used as significant inputs to determine the fair value of equity. The Company updated its revenue forecast models based on further expected launch delays in both United States and outside of the United States ("OUS") regions. The Company also recently observed an evolution of the current treatment paradigm in NMIBC, with substantial uptake of intravesical chemotherapy (monotherapy and combination therapy) during the ongoing BCG shortage resulting in lower projected peak market share for Vicineum. The Company also considered other factors including the preliminary valuations of strategic alternatives during the fair value assessment. As a result of the interim impairment test, the Company concluded that the carrying value of its goodwill of \$13.1 million was fully impaired as of June 30, 2022.

Based on the annual testing and quarterly reviews performed, the Company concluded that there was no goodwill impairment during the year ended December 31, 2021.

### ***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" above 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.

The estimated fair value of its contingent consideration was determined using probabilities of successful achievement of regulatory milestones and commercial sales, the period in which these milestones and sales were expected to be achieved through 2033, the level of commercial sales of Vicineum then-forecasted for the United States, Europe, Japan, China and other potential markets. Earnouts were 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 was derived from the Company's estimated weighted-average cost of capital, which has fluctuated from 9.3% as of December 31, 2021. Milestone payments constitute debt-like obligations, and therefore a high-yield debt index rate was applied to the milestones in order to determine the estimated fair value. This index rate was 8.0% as of December 31, 2021.

On July 15, 2022, the Company made the strategic decision to voluntarily pause further development of Vicineum in the United States. The decision was based on a thorough reassessment of Vicineum following discussions with the FDA, which had implications on the size, timeline, and costs of an additional Phase 3 clinical trial for the treatment of NMIBC. The Company continues to believe that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with a larger infrastructure, and as such, it is seeking a partner for the further development of Vicineum. Accordingly, during the second quarter of 2022, the Company concluded that it is no longer expected to pay related milestone and earnout payments to the former shareholders of Viventia, with the exception of the potential 2% earnout payment related to China, Hong Kong, Macau and Taiwan (collectively, "Greater China") region since those territory rights had been out-licensed. Qilu Pharmaceutical, Co., Ltd. ("Qilu") held the exclusive license to develop Vicineum in the Greater China region, and accordingly, the \$1.8 million estimated earnout payment in the Greater China region remained as long-term contingent consideration as of June 30, 2022.

During the third quarter of 2022, Qilu informed the Company that it no longer intended to commercialize Vicineum, due to additional effort and costs required to gain regulatory approval in that region without prior US approval. As such, the Company and Qilu were in the process of negotiating a termination of the Qilu License Agreement, which was terminated on December 23, 2022. Accordingly, the Company concluded that it no longer expected to owe any future earnout payments related to the Greater China region and reduced its remaining \$1.8 million of contingent consideration liabilities to zero as of September 30, 2022.

### ***Leases***

The Company accounts for operating leases under ASC Topic 842, *Leases*. The Company's lease portfolio as of December 31, 2022 includes a property lease for its headquarters in Cambridge, MA. 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, 2022, 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. 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, 2022, 2021 and 2020 was determined using the following methods and assumptions:

- *Expected Term.* 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, 2022 and 2021, the Company did not have any uncertain tax positions.

### ***Revenue Recognition***

The Company recorded revenue from former out-license agreements and OUS business development partnership agreements, including the former license agreement (the “Roche License Agreement”) with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (collectively, “Roche”) and its former 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 periods. 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 \$40.0 million of license revenue related to the asset purchase agreement with Roche during the year ended December 31, 2022 and \$26.5 million of license revenue related to the Roche, Qilu and Hikma License Agreements during the year ended December 31, 2021.

### ***Comprehensive Loss***

Comprehensive loss includes net loss and other comprehensive loss. For the year ended December 31, 2022, other comprehensive loss included changes in unrealized income and loss on marketable securities. For the years ended December 31, 2021 and 2020 comprehensive loss was equal to net loss.

#### 4. RECENT ACCOUNTING PRONOUNCEMENTS

##### *Adopted in 2022*

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity* ("ASU 2020-06"). ASU 2020-06 simplifies the complexity associated with applying US GAAP for certain financial instruments with characteristics of both liability and equity. More specifically, the amendments focus on the guidance for convertible instruments and derivative scope exception for contracts in an entity’s own equity. The ASU also amends the diluted earnings per share ("EPS") guidance, including the requirement to use the if-converted method for all convertible instruments. ASU 2020-06 is effective for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2021, and should be applied on a full or modified retrospective basis. The Company adopted this guidance on a modified retrospective basis effective January 1, 2022 and it did not have an impact on the Company's financial position, results of operations including per-share amounts, or cash flows.

In May 2021, the FASB issued ASU No. 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Issuer’s Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options* ("ASU 2021-04"). ASU 2021-04 clarifies and reduces diversity in an issuer’s accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. ASU 2021-04 is effective for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2021, and should be applied on a prospective basis. The Company adopted this guidance effective January 1, 2022 and it did not have an impact on the Company's financial position, results of operations including per-share amounts, or cash flows.

Other recent accounting pronouncements issued, but not yet effective, are not expected to be applicable to the Company or have a material effect on the consolidated financial statements upon future adoption.

#### 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, 2022 and 2021 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, 2022 and 2021 (in thousands):

|  |                            | <b>December 31, 2022</b>               |  |  |  |           |
|--|----------------------------|--|--|--|--|-----------|
|  |                            | <b>Fair Value Measurement Based on</b> |  |  |  |           |
|  | <b>Carrying<br/>Amount</b> | <b>Fair Value</b>                      | <b>Quoted<br/>Prices in<br/>Active<br/>Markets<br/>(Level 1)</b> | <b>Significant<br/>Other<br/>Observable<br/>Inputs<br/>(Level 2)</b> | <b>Significant<br/>Unobservable<br/>Inputs<br/>(Level 3)</b> |           |
| <b>Assets:</b>                           |                            |  |  |  |  |           |
| Cash equivalents:                        |                            |  |  |  |  |           |
| Money market funds                       | \$ 76,728                  | \$ 76,728                              | \$ 76,728  | \$ —   | \$ —   | \$ —      |
| Marketable securities:                   |                            |  |  |  |  |           |
| US government securities                 | \$ 49,431                  | \$ 49,431                              | \$ —   | \$ 49,431  | \$ —   | \$ —      |
| US treasury securities                   | \$ 4,935                   | \$ 4,935                               | \$ —   | \$ 4,935   | \$ —   | \$ —      |
|  |                            | <b>December 31, 2021</b>               |  |  |  |           |
|  |                            | <b>Fair Value Measurement Based on</b> |  |  |  |           |
|  | <b>Carrying<br/>Amount</b> | <b>Fair Value</b>                      | <b>Quoted<br/>Prices in<br/>Active<br/>Markets<br/>(Level 1)</b> | <b>Significant<br/>Other<br/>Observable<br/>Inputs<br/>(Level 2)</b> | <b>Significant<br/>Unobservable<br/>Inputs<br/>(Level 3)</b> |           |
| <b>Assets:</b>                           |                            |  |  |  |  |           |
| Money market funds<br>(cash equivalents) | \$ 16,382                  | \$ 16,382                              | \$ 16,382  | \$ —   | \$ —   | \$ —      |
| <b>Liabilities:</b>                      |                            |  |  |  |  |           |
| Contingent consideration - long term     | \$ 52,000                  | \$ 52,000                              | \$ —   | \$ —   | \$ —   | \$ 52,000 |

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, 2022.

The Company considers valuations obtained from third party pricing sources when estimating the fair value of marketable securities.

### ***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, and the level of commercial sales of Vicineum then-forecasted for the United States, Europe, Japan, China, and other potential markets. Earnouts were 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 was derived from its estimated weighted-average cost of capital, which was 9.3% as of December 31, 2021. Milestone payments constitute debt-like obligations, and therefore a high-yield debt index rate was applied to the milestones in order to determine the estimated fair value. This index rate was 8.0% as of December 31, 2021.

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, 2022.

|  |           |          |
|--|-----------|----------|
| <b>Balance at December 31, 2021</b>                          | \$        | 52,000   |
| Change in fair value of contingent consideration - long term |           | (52,000) |
| <b>Balance at December 31, 2022</b>                          | <b>\$</b> | <b>—</b> |

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 weighted average cost of capital, which was 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 was 8.0% as of December 31, 2021.

On July 15, 2022, the Company made the strategic decision to voluntarily pause further development of Vicineum in the United States. The decision was based on a thorough reassessment of Vicineum following discussions with the FDA, which had implications on the size, timeline, and costs of an additional Phase 3 clinical trial for the treatment of NMIBC. The Company continues to believe that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with a larger infrastructure, and as such, it is seeking a partner for the further development of Vicineum. Accordingly, the Company concluded that it is no longer expected to pay related milestone and earnout payments to the former shareholders of Viventia. Therefore, the Company's contingent consideration liability as of December 31, 2022 was zero.

## 6. RESTRICTED CASH AND MARKETABLE SECURITIES

The Company's short-term restricted cash balance as of December 31, 2022 was \$21.0 million. This represents the settlement amount of the Securities Litigation (as defined below in Note 11. "Commitment and Contingencies"), including the insurance carriers' coverage, which was funded into an escrow account in the fourth quarter of 2022. On January 31, 2023, the court issued an order granting final approval of the settlement of the Securities Litigation. Accordingly, this matter is now resolved.

The following table sets forth the composition of the Company's marketable securities:

|                                    | <b>December 31, 2022</b>  |                             |                              |                   |
|------------------------------------|---------------------------|-----------------------------|------------------------------|-------------------|
|                                    | <b>Amortized<br/>Cost</b> | <b>Unrealized<br/>Gains</b> | <b>Unrealized<br/>Losses</b> | <b>Fair Value</b> |
| US government securities           | \$ 49,939                 | \$ —                        | \$ (508)                     | \$ 49,431         |
| US treasury securities             | 4,973                     | —                           | (38)                         | 4,935             |
| <b>Total Marketable Securities</b> | <b>\$ 54,912</b>          | <b>\$ —</b>                 | <b>\$ (546)</b>              | <b>\$ 54,366</b>  |

The Company had no marketable securities as of December 31, 2021.

## 7. RECEIVABLES

The accounts receivable balance as of December 31, 2021 was \$21.0 million, comprised primarily of a \$20.0 million milestone achieved in December 2021 due to Roche initiating a Phase II clinical trial. The Company invoiced Roche \$20.0 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 \$20.0 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 Bio an amount equal to its recovery of VAT. The Company received this payment in the second quarter of 2022.

The other receivable balance as of December 31, 2022 was \$0.8 million, primarily consisting of German VAT recovery related to drug substance sent to Baxter. The Company expects to collect the remaining balance in 2023.

The other receivable balance as of December 31, 2021 was \$3.5 million, primarily consisting of German VAT recovery related to drug substance sent to Baxter.

## 8. PROPERTY AND EQUIPMENT

The following table sets forth the composition of property and equipment, net as of December 31, 2022 and 2021 (in thousands):

|  | December 31, |              |
|--|--------------|--------------|
|  | 2022         | 2021         |
| Lab equipment                            | \$ 94        | \$ 569       |
| Furniture and fixtures                   | —            | 16           |
| Computer equipment                       | 7            | 99           |
| Software                                 | 4            | 32           |
| Leasehold improvements                   | —            | 293          |
| Property and equipment, gross            | 105          | 1,009        |
| Less: accumulated depreciation           | (105)        | (966)        |
| <b>Total Property and Equipment, Net</b> | <b>\$ —</b>  | <b>\$ 43</b> |

Depreciation expense was de minimis, \$0.1 million and \$0.1 million for the years ended December 31, 2022, 2021 and 2020, respectively.

## 9. INTANGIBLES AND GOODWILL

### *Intangibles*

Intangible assets on the Company's consolidated balance sheet were the result of the Viventia Acquisition in September 2016. The following table sets forth the composition of intangible assets as of December 31, 2022 and 2021 (in thousands):

|                                | December 31, |                  |
|--------------------------------|--------------|------------------|
|                                | 2022         | 2021             |
| IPR&D intangible assets:       |              |                  |
| Vicineum United States rights  | \$ —         | \$ —             |
| Vicineum European Union rights | —            | 14,700           |
| <b>Total Intangibles</b>       | <b>\$ —</b>  | <b>\$ 14,700</b> |

The fair value of the acquired intangible assets for the United States and E.U. 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.

During the second quarter of 2022, the Company observed an evolution of the current market treatment paradigm in NMIBC, with substantial uptake of intravesical chemotherapy (monotherapy and combination therapy) during the ongoing BCG shortage. The Company has also experienced a sustained decline in share price and a resulting decrease in its market capitalization. On July 15, 2022, the Company made the strategic decision to voluntarily pause further development of Vicineum in the United States. The decision was based on a thorough reassessment of Vicineum following discussions with the FDA, which had implications on the size, timeline, and costs of an additional Phase 3 clinical trial for the treatment of NMIBC. Management updated the discounted cash flow model using the market participant approach and considered preliminary terms of potential partnering deal to conclude the fair value of its intangible asset of Vicineum E.U. rights. The Company concluded that the carrying value of its intangible asset of Vicineum E.U. rights of \$14.7 million was fully impaired as of June 30, 2022 and was reduced to zero in the second quarter of 2022.

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 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 United States 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 United States market.

### **Goodwill**

Goodwill on the Company's consolidated balance sheet is the result of the Viventia Acquisition in September 2016. Goodwill had no carrying value as of December 31, 2022 and had a carrying value of \$13.1 million as of December 31, 2021.

During the second quarter of 2022, the Company observed continued trends in its market capitalization as compared to the carrying value of its single reporting unit as well as changes in certain assumptions in the fair value of the business including market share, size, length and cost of a clinical trial, and time to potential market launch. The Company identified these changes as potential impairment indicators and performed a quantitative impairment analysis in advance of its typical annual assessment date of October 1. The Company reassessed the underlying assumptions used to develop its revenue projections, which were then used as significant inputs to determine the fair value of equity. The Company updated its revenue forecast models based on further expected launch delays in both United States and OUS regions. The Company also recently observed an evolution of the current treatment paradigm in NMIBC, with substantial uptake of intravesical chemotherapy (monotherapy and combination therapy) during the ongoing BCG shortage resulting in lower projected peak market share for Vicineum. The Company also considered other factors including the preliminary valuations of strategic alternatives during the fair value assessment. As a result of the interim impairment test, the Company concluded that the carrying value of its goodwill of \$13.1 million was fully impaired as of June 30, 2022.

Based on the annual testing and quarterly reviews performed, the Company concluded that there was no goodwill impairment during the year ended December 31, 2021.

## **10. ACCRUED EXPENSES**

The following table sets forth the composition of accrued expenses as of December 31, 2022 and 2021 (in thousands):

|  | <b>December 31,</b> |                 |
|--|---------------------|-----------------|
|  | <b>2022</b>         | <b>2021</b>     |
| Research and development   | \$ 40               | \$ 1,841        |
| Payroll-related expenses   | 1,404               | 2,967           |
| Restructuring charge related   | 5,733               | 1,497           |
| Professional fees  | 301                 | 597             |
| Legal expenses, including the preliminary securities litigation settlement | 21,919              | 1,344           |
| Other  | 239                 | 9               |
| <b>Total Accrued Expenses</b>  | <b>\$ 29,636</b>    | <b>\$ 8,255</b> |

## **11. 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 United States District Court for the Southern District of New York. The three complaints alleged violations of Sections 10(b)

and 20(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Rule 10b-5 promulgated thereunder based on statements made by the Company concerning the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. The three complaints sought 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 (collectively, the "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. On November 24, 2021, defendants filed a motion to transfer venue to the United States District Court for the District of Massachusetts. That motion was fully briefed as of December 13, 2021, but the court has not ruled on that motion. On December 6, 2021, the Lead Plaintiffs filed an amended class action complaint (the "Amended Complaint"). The Amended Complaint alleged 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. The defendants moved to dismiss the Amended Complaint on March 7, 2022, and that motion was fully briefed on May 6, 2022. On June 3, 2022, before the court ruled on the motion to dismiss, the parties requested that the court hold any decision on the motion to dismiss in abeyance to provide the parties with an opportunity to engage in mediation. On June 30, 2022 and July 6, 2022, the Company and the plaintiffs engaged in mediation sessions in an attempt to resolve the Securities Litigation and continued to discuss a potential settlement over the following weeks. On July 19, 2022, the parties reached an agreement in principle to settle the Securities Litigation. Pursuant to that agreement, the Company and the individual defendants will pay or cause to be paid to members of the class who submit timely and valid proofs of claims. In exchange, the Lead Plaintiffs will dismiss the action and all class members who do not timely and validly opt-out of the settlement will provide broad customary releases to the Company and the individual defendants. On August 3, 2022, the parties entered into a Stipulation and Agreement of Settlement to settle the Securities Litigation, which was filed with the court on August 17, 2022. The Stipulation and Agreement of Settlement related to the Securities Litigation provides for a settlement payment of \$21.0 million to the class and the dismissal of all claims against the Company and the other defendants. On September 1, 2022, the United States District Court for the Southern District of New York issued an order denying the motions to appoint a different lead plaintiff. On September 28, 2022, the court issued an order granting preliminary approval of the proposed settlement of the Securities Litigation. The settlement payment of \$21.0 million, including the insurance carriers coverage, was funded into an escrow account in the fourth quarter of 2022. Accordingly, \$21.0 million remained in restricted cash on the Company's balance sheet as of December 31, 2022. On January 31, 2023, the court issued an order granting final approval of the settlement of the Securities Litigation. Accordingly, this matter is now resolved.

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 United States 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 (the "State Derivative Litigation"). The three derivative complaints alleged breach of fiduciary duties, waste of corporate assets, and violations of federal securities laws based on statements made by the Company concerning the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. The D'Arcy complaint further alleged unjust enrichment, abuse of control, gross mismanagement and aiding and abetting thereof. The three derivative complaints sought 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. On May 1, 2022, the plaintiffs filed a verified consolidated shareholder derivative complaint in the Federal Derivative Litigation. On May 18, 2022, the court entered a joint stipulation among the parties to stay the State Derivative Litigation until after a ruling on any motion to dismiss filed by defendants in the Securities Litigation. On July 6, 2022, the Company and the plaintiffs to the Federal Derivative Litigation and the State Derivative Litigation engaged in mediation in an attempt to resolve the litigation, with settlement discussions continuing over the following days. On July 19, 2022, the parties reached an agreement in principle to settle the Federal Derivative Litigation, the State Derivative Litigation and other potential related derivative claims (collectively, the "Derivative Litigation"). Pursuant to that agreement, the individual defendants will cause the Company to adopt certain enhancements to its corporate governance policies and procedures. In exchange, plaintiffs will dismiss the Derivative Litigation and, on behalf of the Company, provide broad customary releases to the individual defendants. On August 22, 2022, the parties entered into a Stipulation of Settlement to settle the Derivative Litigation, which was filed with the court on August 30, 2022. The Stipulation of Settlement related to the Derivative Litigation confirms that the Company previously adopted certain corporate governance enhancements in response to, among other things, the filing of the Derivative Litigation, and that, subject to final court approval, the Company will adopt additional corporate governance enhancements. The Stipulation of Settlement also provides for a \$630,000 payment for plaintiffs' attorneys' fees due to the benefits the corporate governance enhancements are intended to provide to the Company. The payment of plaintiffs' attorneys' fees is being funded by the Company. On September 2, 2022, the court issued

an order granting preliminary approval of the Stipulation of Settlement related to the Derivative Litigation. On November 8, 2022, the court issued an order granting final approval of the Stipulation of Settlement related to the Derivative Litigation. Accordingly, this matter is now resolved.

On November 28, 2022, a purported stockholder filed a complaint in the United States District Court for the Southern District of New York against the Company and its board of directors, captioned *Keller v. Sesen Bio, Inc., et al.*, Case No. 1:22-cv-10085 (S.D.N.Y.) (the “Original Keller Complaint”). The Original Keller Complaint asserted claims against the Company and its board of directors under Section 14(a) of the Exchange Act and Rule 14a-9 promulgated thereunder for allegedly false and misleading statements in the proxy statement/prospectus filed as part of the Registration Statement on Form S-4 (File No. 333-267891) (the “Registration Statement”) in connection with the Merger and under Section 20(a) of the Exchange Act for alleged “control person” liability with respect to such allegedly false and misleading statements and sought, among other relief, an order enjoining the Merger and an award for plaintiffs’ fees and costs. On December 20, 2022, the purported stockholder voluntarily dismissed the Original Keller Complaint and on December 21, 2022, filed a new complaint as a putative class action in the Court of Chancery for the State of Delaware, captioned *Keller v. Sesen Bio, Inc., et al.*, Case No. 2022-1186 (Del. Ch. Dec. 21, 2022) (the “New Keller Complaint”). Along with the complaint, the purported stockholder filed motions for expedited proceedings and for a preliminary injunction to enjoin the Special Meeting. The New Keller Complaint and associated filings contain substantially the same assertions as the Original Keller Complaint, and seek, among other relief, an order enjoining the Merger and an award for plaintiffs’ fees and costs.

On February 3, 2023, a purported stockholder filed a complaint in the United States District Court for the District of Delaware against the Company and its board of directors, captioned *Plumley v. Sesen Bio, Inc., et al.*, Case No. 1:23-cv-00131 (D. Del.) (the “Plumley Complaint”). The Plumley Complaint asserts claims under Section 14(a) of the Exchange Act and Rule 14a-9 promulgated thereunder for allegedly false and misleading statements in the proxy statement/prospectus filed as part of the Registration Statement in connection with the Merger and under Section 20(a) of the Exchange Act for alleged “control person” liability with respect to such allegedly false and misleading statements and seeks, among other relief, an order enjoining the Merger and an award for plaintiffs’ fees and costs. On February 7, 2023, another purported stockholder filed a complaint in the United States District Court for the Southern District of New York against the Company and its board of directors, captioned *Franchi v. Sesen Bio, Inc., et al.*, 1:23-cv-01041 (S.D.N.Y.) (the “Franchi Complaint”). The Franchi Complaint contains substantially similar allegations and claims and seeks substantially similar relief as the Plumley Complaint. Additionally, on February 9, 2023, another purported stockholder filed a complaint in the United States District Court for the Southern District of New York against the Company and its board of directors, captioned *Menzer v. Sesen Bio, Inc., et al.*, 23-cv-01119 (S.D.N.Y.) (the “Menzer Complaint”). The Menzer Complaint contains substantially similar allegations and claims and seeks substantially similar relief as the Plumley Complaint and the Franchi Complaint.

On October 21, 2022, November 4, 2022, February 8, 2023, February 13, 2023 (as updated on February 15, 2023) and February 17, 2023, the Company received letters from purported stockholders (collectively, the “Demand Letters”) demanding that the Company amend the Registration Statement to provide additional disclosures that such stockholders allege were improperly omitted from the Registration Statement, including information regarding the financial projections for Carisma, the financial analyses performed by the Company’s financial advisor in support of its fairness opinion, and the background and process leading to the execution of the Merger Agreement. In addition, the Company received a books and records demand, dated November 18, 2022 (the “Section 220 Demand”), on behalf of a purported stockholder of the Company seeking access to certain relevant books and records of the Company’s pursuant to Section 220 of the Delaware General Corporation Law in connection with the Merger and the securities and derivative litigations arising out of the CRL that the Company received from the FDA. The Section 220 Demand states that the purpose of the demand is to, among other things, investigate purported questions of director independence and disinterestedness and the possibility of wrongdoing, mismanagement, and/or material non-disclosure related to the Company board’s approval of the Merger and the other transactions contemplated thereby and to determine whether suit should be brought in connection therewith.

The Company believes that the claims asserted in the Demand Letters, the Section 220 Demand, the New Keller Complaint, the Plumley Complaint, the Franchi Complaint and the Menzer Complaint are without merit and intends to vigorously defend against them. 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.

## 12. LEASES

The Company accounts for operating leases under ASC Topic 842, *Leases*. The Company's lease portfolio included an operating lease for its 31,100 square foot facility in Winnipeg, Manitoba which consisted of manufacturing, laboratory, warehouse, and office space. During the third quarter of 2022, the Company entered into a Lease Termination Agreement (the "Lease Termination Agreement") pursuant to which the Company terminated its operating lease agreement. As part of the execution of the Lease Termination Agreement, the Company paid the landlord the all-inclusive sum of CAD \$1.2 million (USD \$0.9 million). Operating lease cost under this lease were \$0.2 million for the year ended December 31, 2022 and \$0.3 million for the year ended December 31, 2021.

The right of use asset total was zero as of December 31, 2022 and \$123,300 as of December 31, 2021. As of December 31, 2021, the asset component of the Company's operating leases was recorded as operating lease right-of-use assets and reported within other assets on the Company's condensed consolidated balance sheets. The short-term lease liability was zero as of December 31, 2022 and \$123,300 as of December 31, 2021. As of December 31, 2021, the short-term lease liability was recorded in other current liabilities on the Company's condensed consolidated balance sheets. There was no long-term operating lease liability as of December 31, 2022 or December 31, 2021. 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 minimum monthly rent for these office spaces is \$2,500 and \$18,000, respectively. The Company terminated the Philadelphia lease on December 31, 2022 and plans to terminate the Cambridge lease in connection with the closing of the anticipated Merger with Carisma. The short-term lease in Cambridge ends in June 2023.

The components of lease cost for the years ended December 31, 2022 and 2021 is as follows (in thousands):

|   | <b>Year Ended<br/>December 31, 2022</b> | <b>Year Ended<br/>December 31, 2021</b> |
|---|---|---|
| <b>Lease Cost:</b>                                  |   |   |
| Operating lease (including related operating costs) | \$ 245                                  | \$ 327                                  |
| Short term property leases                          | 213                                     | 262                                     |
| Total lease costs                                   | <b>\$ 458</b>                           | <b>\$ 589</b>                           |

| <b>Supplemental Information:</b>                  | <b>Year Ended<br/>December 31, 2022</b> | <b>Year Ended<br/>December 31, 2021</b> |
|---|---|---|
| Weighted-average remaining lease term (years)     | 0                                       | 0.75                                    |
| Weighted-average discount rate - operating leases | — %                                     | 12 %                                    |

## 13. STOCKHOLDERS' EQUITY (DEFICIT)

### *Equity Financings*

#### *ATM Offering*

In November 2019, the Company entered into an Open Market Sale Agreement<sup>SM</sup> (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 \$35.0 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 \$200.0 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 Capital 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 did not sell any shares of common stock pursuant to the Sale Agreement during the year ended December 31, 2022. 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. Share issuance costs, including sales agent commissions, related to the ATM Offering totaled \$5.4 million during the year ended December 31, 2021.

#### *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 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, 2022 and 2021.

#### *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 203 million and 199 million shares were issued and outstanding as of December 31, 2022 and 2021, 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, 2022 and 2021 (in thousands):

|  | <b>December 31,</b> |                |
|--|---------------------|----------------|
|  | <b>2022</b>         | <b>2021</b>    |
| Shares of common stock issued  | 202,759             | 199,464        |
| Shares of common stock reserved for issuance for:                    |                     |                |
| Warrants   | 187                 | 199            |
| Stock options  | 15,304              | 15,703         |
| RSUs   | 4,695               | 3,041          |
| Shares available for grant under 2014 Stock Incentive Plan           | 4,532               | 8,933          |
| Shares available for sale under 2014 Employee Stock Purchase Plan    | 2,300               | 2,300          |
| <b>Total shares of common stock issued and reserved for issuance</b> | <b>229,777</b>      | <b>229,640</b> |

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 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, 2022 (in thousands):

| <b>Issued</b> | <b>Exercise Price</b> | <b>Expiration</b> | <b>December 31, 2021</b> | <b>Issued</b> | <b>(Exercised)</b> | <b>(Cancelled)</b> | <b>December 31, 2022</b> |
|---------------|-----------------------|-------------------|--------------------------|---------------|--------------------|--------------------|--------------------------|
| Mar-2018      | \$0.55*               | Mar-2023          | 132                      | —             | —                  | —                  | 132                      |
| Nov-2017      | \$0.55*               | Nov-2022          | 12                       | —             | —                  | (12)               | —                        |
| May-2015      | \$11.83               | Nov-2024          | 28                       | —             | —                  | —                  | 28                       |
| Nov-2014      | \$11.04               | Nov-2024          | 27                       | —             | —                  | —                  | 27                       |
|               |                       |                   | <b>199</b>               | <b>—</b>      | <b>—</b>           | <b>(12)</b>        | <b>187</b>               |

\* Exercise price shown (i) reflects modification described below and (ii) subject to further adjustment based on down round provision added by amendment described below.

### **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' Equity (Deficit).

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, 2022, there has been no adjustment to the exercise price of these warrants.

## 14. 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, 2022, 2021 and 2020 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, 2022, 2021 and 2020 have been excluded from the denominator of the diluted loss per share of common stock outstanding calculation (in thousands):

|               | December 31,  |               |               |
|---------------|---------------|---------------|---------------|
|               | 2022          | 2021          | 2020          |
| Warrants      | 187           | 199           | 2,247         |
| Stock options | 15,304        | 15,703        | 10,147        |
| RSUs and PSUs | 4,695         | —             | —             |
| <b>Total</b>  | <b>20,186</b> | <b>15,902</b> | <b>12,394</b> |

## 15. 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, 2022, 2021 and 2020 (in thousands):

|                                       | Year Ended December 31, |                 |                 |
|---------------------------------------|-------------------------|-----------------|-----------------|
|                                       | 2022                    | 2021            | 2020            |
| Research and development              | \$ 1,985                | \$ 973          | \$ 350          |
| General and administrative            | 4,924                   | 4,170           | 1,407           |
| <b>Total Share Based Compensation</b> | <b>\$ 6,909</b>         | <b>\$ 5,143</b> | <b>\$ 1,757</b> |

### *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 4.5 million shares of common stock available for issuance under the 2014 Plan as of December 31, 2022.

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 12.2 million stock options outstanding under the 2014 Plan as of December 31, 2022.

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 vested 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 \$2.5 million for retention-related RSUs for the year ended December 31, 2022.

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 of December 31, 2022, achievement was deemed probable for only the cash management milestone, representing \$87,000 (or 20% of the PSU awards). Therefore, \$55,000 was expensed during the year ended December 31, 2022, and \$32,000 remains measured but unrecognized.

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

|                               | <b>Restricted Stock<br/>Units<br/>(in thousands)</b> |
|-------------------------------|--|
| Unvested at December 31, 2021 | 3,041  |
| Granted RSU                   | 4,160  |
| Granted PSU                   | 1,004  |
| Vested                        | (3,293)  |
| Canceled or forfeited         | (217)  |
| Unvested at December 31, 2022 | <u><u>4,695</u></u>                                  |

The weighted average remaining contractual life of unvested RSUs and PSUs as of December 31, 2022 is 2.67 years. The weighted average remaining contractual life of unvested RSUs and PSUs as of December 31, 2021 is 9.75 years.

### ***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, 2022.

### ***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 2.9 million stock options outstanding which were granted as employment inducement awards outside of the 2014 Plan as of December 31, 2022.

## 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, 2022, 2021 and 2020:

|                                  | Number of<br>Shares under<br>Option<br>(in thousands) | Weighted-<br>Average<br>Exercise Price | Weighted-<br>Average<br>Remaining<br>Contractual<br>Life<br>(in years) | Aggregate<br>Intrinsic<br>Value<br>(in thousands) |
|----------------------------------|---|--|--|---|
| 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   |
| Granted                          | 1,510   | \$0.72                                 |  |   |
| Exercised                        | (2)   | \$0.32                                 |  |   |
| Canceled or forfeited            | (1,907)   | \$1.90                                 |  |   |
| Outstanding at December 31, 2022 | 15,304  | \$1.82                                 | 7.19   | \$ 3  |
| Exercisable at December 31, 2022 | 10,427  | \$1.72                                 | 6.77   | DM  |

The Company recognized share-based compensation expense of \$6.9 million, \$5.1 million, and \$1.8 million for the years ended December 31, 2022, 2021, and 2020, respectively. The stock option related expenses were \$4.3 million, \$4.6 million and \$1.8 million for the years ended December 31, 2022, 2021 and 2020, respectively. The RSU related expense was \$2.5 million and \$0.5 million for the years ended December 31, 2022 and 2021, respectively. The Company did not record RSU related expenses for the year ended December 31, 2020. As of December 31, 2022, there was \$5.5 million of total unrecognized compensation cost related to non-vested stock options which the Company expects to recognize over a weighted-average period of 1.88 years. The weighted-average grant-date fair value of stock options granted during the year ended December 31, 2022, 2021 and 2020 were \$0.46, \$2.16 and \$0.56, respectively. The total intrinsic value of stock options exercised for the years ended December 31, 2022, 2021 and 2020 was de minimis.

For the years ended December 31, 2022, 2021 and 2020, 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, |        |        |
|--------------------------|-------------------------|--------|--------|
|                          | 2022                    | 2021   | 2020   |
| Fair market value        | \$0.72                  | \$3.32 | \$0.87 |
| Grant exercise price     | \$0.72                  | \$3.32 | \$0.87 |
| Expected term (in years) | 6.0                     | 6.0    | 6.1    |
| Risk-free interest rate  | 2.1%                    | 0.9%   | 1.3%   |
| Expected volatility      | 71.8%                   | 74.6%  | 71.5%  |
| Dividend yield           | —%                      | —%     | —%     |

## 16. 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, 2022, 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, 2022, 2021 and 2020, respectively.

### *Defined Contribution Plans*

#### *United States - 401(k) Plan*

The Company maintains a 401(k) defined contribution retirement plan which covers all of its United States 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, 2022, 2021 and 2020, 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, 2022, 2021 and 2020, respectively.

## 17. INCOME TAXES

The following table sets forth the components of the Company's loss before income taxes by country (in thousands):

| Country                               | Year Ended December 31, |                   |                    |
|---------------------------------------|-------------------------|-------------------|--------------------|
|                                       | 2022                    | 2021              | 2020               |
| United States                         | \$ (37,289)             | \$ (32,757)       | \$ (35,529)        |
| Canada                                | 13,530                  | 24,148            | 14,577             |
| <b>Total Loss Before Income Taxes</b> | <b>\$ (23,759)</b>      | <b>\$ (8,609)</b> | <b>\$ (20,952)</b> |

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

|                                      | <b>Year Ended December 31,</b> |                        |                          |
|--------------------------------------|--------------------------------|------------------------|--------------------------|
|                                      | <b>2022</b>                    | <b>2021</b>            | <b>2020</b>              |
| <b>Current Tax Provision</b>         |                                |                        |                          |
| Federal                              | \$ —                           | \$ —                   | \$ —                     |
| State                                | —                              | —                      | —                        |
| Foreign                              | (94)                           | (286)                  | (1,445)                  |
| Total current (provision)            | <u>\$ (94)</u>                 | <u>\$ (286)</u>        | <u>\$ (1,445)</u>        |
| <b>Deferred tax provision</b>        |                                |                        |                          |
| Federal                              | \$ —                           | \$ —                   | \$ —                     |
| State                                | —                              | —                      | —                        |
| Foreign                              | 3,969                          | 8,559                  | —                        |
| Total deferred benefit (provision)   | <u>\$ 3,969</u>                | <u>\$ 8,559</u>        | <u>\$ —</u>              |
| <b>Total Tax Benefit (Provision)</b> | <u><u>\$ 3,875</u></u>         | <u><u>\$ 8,273</u></u> | <u><u>\$ (1,445)</u></u> |

The following table sets forth a reconciliation of the statutory United States federal income tax rate to the Company's effective income tax rate:

|   | <b>Year ended December 31,</b> |                      |                       |
|---|--------------------------------|----------------------|-----------------------|
|   | <b>2022</b>                    | <b>2021</b>          | <b>2020</b>           |
| United States federal statutory income tax rate | 21.0 %                         | 21.0 %               | 21.0 %                |
| Impact of foreign rate differential             | (3.3)                          | (15.9)               | (4.2)                 |
| State taxes, net of federal benefit             | 0.9                            | 2.3                  | 2.0                   |
| Stock option cancellations                      | —                              | (1.1)                | (0.2)                 |
| Contingent consideration                        | 59.1                           | 178.2                | 14.4                  |
| General business credits and other credits      | 0.5                            | 2.4                  | 6.6                   |
| Goodwill write-off                              | (14.8) %                       | — %                  | — %                   |
| Permanent differences                           | (1.9)                          | (1.4)                | 0.2                   |
| Other   | (0.2)                          | (13.8)               | (2.1)                 |
| Foreign taxes                                   | —                              | (3.3)                | (6.9)                 |
| Change in valuation allowance                   | (44.6)                         | (72.3)               | (37.7)                |
| <b>Effective Income Tax Rate</b>                | <u><u>16.7 %</u></u>           | <u><u>96.1 %</u></u> | <u><u>(6.9) %</u></u> |

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):

|                                   | <b>December 31,</b> |                          |                           |
|-----------------------------------|---------------------|--------------------------|---------------------------|
|                                   | <b>2022</b>         | <b>2021</b>              | <b>2020</b>               |
| Deferred tax assets:              |                     |                          |                           |
| NOL carryforwards                 | \$ 66,374           | \$ 63,381                | \$ 57,935                 |
| R&D credit carryforwards          | 4,489               | 4,316                    | 3,787                     |
| IRC 174 Capitalized R&D           | 6,214               | —                        | —                         |
| Accruals and other                | 5,326               | 4,058                    | 3,811                     |
| Capitalized start-up costs        | 34                  | 53                       | 70                        |
| Other                             | 16                  | 41                       | 28                        |
| Gross deferred tax assets         | <u>82,453</u>       | <u>71,849</u>            | <u>65,631</u>             |
| Deferred tax liabilities:         |                     |                          |                           |
| IPR&D                             | —                   | (3,969)                  | (12,528)                  |
| Gross deferred tax liabilities    | —                   | (3,969)                  | (12,528)                  |
| Valuation allowance               | (82,453)            | (71,849)                 | (65,631)                  |
| <b>Net Deferred Tax Liability</b> | <b><u>\$ —</u></b>  | <b><u>\$ (3,969)</u></b> | <b><u>\$ (12,528)</u></b> |

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 \$82.5 million, \$71.8 million and \$65.6 million have been established as of December 31, 2022, 2021 and 2020, respectively. The \$10.6 million increase in the valuation allowance was attributable to the NOL for the year ended December 31, 2022.

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, 2022 (in millions):

|  | <b>Amount</b> | <b>Expiration<br/>Beginning in</b> | <b>Through</b> |
|--|---------------|------------------------------------|----------------|
| United States:   |               |                                    |                |
| Federal NOL carryforwards - indefinite   | \$ 101.2      | None                               | None           |
| Federal NOL carryforwards  | \$ 117.7      | 2030                               | 2038           |
| State NOL carryforwards  | \$ 138.4      | 2030                               | 2041           |
| Federal R&D credit carryforwards   | \$ 2.6        | 2027                               | 2041           |
| State R&D credit carryforwards   | \$ 0.9        | 2027                               | 2041           |
| Canada:  |               |                                    |                |
| Federal non-capital loss carryforwards   | \$ 43.2       | 2035                               | 2041           |
| Federal scientific research and experimental development expense carryforwards | \$ 5.1        | 2032                               | 2041           |
| Federal and provincial investment tax credit carryforwards                     | \$ 1.2        | 2032                               | 2041           |

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.

The Company assesses the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where it has operations to determine the potential effect on its business and any assumptions it has made about its future taxable income. The Company 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 its 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, the Company has no assurance that the provision will be repealed or otherwise modified.

As of December 31, 2022, 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 2021 remain subject to examination by the taxing jurisdictions. There are currently no audits in process in any of the Company's tax filing jurisdictions.

## **18. 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 expenses of \$0.3 million and \$0.5 million related to meeting a development milestone, the submission of the Company's BLA with the FDA in December 2020, and a regulatory milestone, the Company's receipt of the CRL from the FDA in August 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 (which are now expired) cover some key aspects of Vicineum. Under the terms of the Micromet License Agreement, as of December 31, 2022, even though the patents have expired, 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 \$2.6 million at exchange rates in effect on December 31, 2022). The Company is also required to pay up to a 3.5% royalty on the net sales for products covered by the

agreement, which includes Vicineum. The royalty rate owed to Micromet in a particular country will be reduced to 1.5% if there are no valid claims covering the product in that country. The obligation to pay royalties in a particular country expires upon the later of the expiration date of the last valid claim covering the product and the tenth anniversary of the first commercial sale of the product in such country. Finally, the Company is required to pay to Micromet an annual license maintenance fee of €50,000, which can be credited towards any royalty payment the Company owes to Micromet. The Company recorded an expense of €0.7 million (\$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. For the year ended December 31, 2022, the Company recorded an expense of €50,000 (\$51,770) related to the annual license maintenance fee. Vysyneum is the proprietary brand name conditionally approved by the EMA for oportuzumab monatox in the E.U.

#### *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 (which are now expired) 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, even though the patents have expired, 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. 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.

On July 15, 2022, the Company entered into an asset purchase agreement with Roche (the "Roche Asset Purchase Agreement") pursuant to which Roche purchased all patent rights and know-how related to the monoclonal antibody EBI-031 and all other IL-6 antagonist monoclonal antibody technology owned by the Company for up to \$70.0 million. As a result of the Roche Asset Purchase Agreement, the Roche License Agreement was terminated resulting in no further diligence, milestone or royalty payment obligations under the Roche License Agreement. Pursuant to the Roche Asset Purchase Agreement, Roche made a \$40.0 million payment to the Company upon execution of the Roche Asset Purchase Agreement, which was recorded as license revenue in the third quarter of 2022. The Roche Asset Purchase Agreement also provides that Roche will make an additional \$30.0 million payment to the Company upon Roche's initiation of a Phase 3 clinical trial with EBI-031 for a defined indication if initiated prior to December 31, 2026. Pursuant to ASC 606, the variable consideration of \$30.0 million is constrained. Therefore, the amount was not recorded as revenue during the year ended December 31, 2022.

At or prior to the effective time of the Merger, the Company will enter into a Contingent Value Rights Agreement (the "CVR Agreement") with a rights agent ("Rights Agent") pursuant to which the Company intends to declare a dividend payable to the Company's stockholders of record as of a date agreed to by the Company and Carisma prior to the effective time of the Merger with respect to the receipt of one contingent value right (each, a "CVR") for each outstanding share of the Company's common stock held by such stockholders on such date. Each CVR will represent the contractual right to receive (i) contingent cash payments upon the receipt by the Company of certain proceeds payable by Roche, if any, pursuant to the Roche Asset Purchase Agreement, upon the achievement by Roche of a specified milestone set forth in the Roche Asset Purchase Agreement, as well as (ii) proceeds from any sale of the Company's legacy assets, including Vicineum, subject to certain customary deductions, including for expenses and taxes, in the event any sale occurs prior to March 31, 2027. The contingent payments under the CVR Agreement, if they become due, will be payable to the Rights Agent for subsequent distribution to the holders of the CVRs. In the event that no such proceeds are received, holders of the CVRs will not receive any payment pursuant to the CVR

Agreement. There can be no assurance that any cash payment will be made or that any holders of CVRs will receive any amounts with respect thereto.

## **Former 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.

On December 23, 2022, the Company terminated the Qilu License Agreement. In connection with the termination of the Qilu License Agreement, the Company agreed to make an aggregate payment to Qilu of \$1.4 million, which consists of a \$1.2 million termination fee payable upon the termination of the Qilu License Agreement, which was paid in the fourth quarter of 2022, and a \$200,000 payment payable upon our receipt of certain clinical data and chemistry, manufacturing, and controls data from Qilu, which such payment was not made as of December 31, 2022. Accordingly, \$0.2 million remained on the Company's balance sheet in accrued liabilities as of December 31, 2022.

### ***Hikma 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 (the “Hikma License Agreement”). The Company retained 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 Hikma 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 Hikma License Agreement.

On July 20, 2022, the Company provided notice of termination of the Hikma License Agreement as a result of the Company’s strategic decision to voluntarily pause further development of Vicineum in the United States. In connection with such termination, the Company refunded to Hikma the \$3.0 million upfront payment.

### ***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 was entitled to receive an upfront payment of \$1.5 million. The Company and EIP have subsequently amended the license agreement to defer EIP's payment of the upfront payment to coincide with the potential FDA approval of Vicineum. The Company would have been eligible to receive additional regulatory and commercial milestone payments of \$2.0 million and also to receive a 30% royalty on net sales in Turkey and Northern Cyprus.

On July 20, 2022, the Company provided notice of termination of the EIP License Agreement as a result of the Company's strategic decision to voluntarily pause further development of Vicineum in the United States. The EIP License Agreement was terminated on October 20, 2022.

## 19. RESTRUCTURING AND RELATED ACTIVITIES

On July 15, 2022, the Company approved a restructuring plan to reduce operating expenses and better align its workforce with the needs of its business following the decision to voluntarily pause further development of Vicineum in the United States (the "2022 Restructuring Plan"). Execution of the 2022 Restructuring Plan is expected to be substantially completed in connection with the closing of the Merger with Carisma, which is expected to occur in the first quarter of 2023. The 2022 Restructuring Plan includes an incremental reduction in the Company's workforce as well as additional cost-saving initiatives intended to preserve capital during the pendency of the Merger with Carisma and while the Company seeks a potential partner for the further development of Vicineum.

The Company also incurred one-time cash costs associated with the termination of certain contracts and all other activities under the 2022 Restructuring Plan. The following is a summary of accrued restructuring costs related to the 2022 Restructuring Plan, (in thousands):

|   | <b>2022 Restructuring Plan</b> |              |
|---|--------------------------------|--------------|
| Severance and benefits costs                    | \$                             | 6,976        |
| Contract termination and other associated costs |                                | 4,788        |
| Total restructurings costs                      |                                | 11,764       |
| Cash payments                                   |                                | (6,031)      |
| <b>Balance at December 31, 2022</b>             | <b>\$</b>                      | <b>5,733</b> |

Restructuring costs related to the 2022 Restructuring Plan were recorded in operating expenses in the Company's Condensed Consolidated Statements of Operations and Comprehensive Loss in the year ended December 31, 2022. The Company expects that substantially all accrued restructuring costs as of December 31, 2022 will be paid in cash in connection with the closing of the Merger with Carisma, which is expected to be completed in the first quarter of 2023.

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 "2021 Restructuring Plan").

The 2021 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 2021 Restructuring Plan), as well as additional cost-saving initiatives intended to preserve capital while the Company continued development of Vicineum. The following is a summary of accrued restructuring costs related to the 2021 Restructuring Plan:

|                                     | <b>2021 Restructuring Plan</b> |          |
|-------------------------------------|--------------------------------|----------|
| Balance as of December 31, 2021     | \$                             | 1,497    |
| Cash payments                       |                                | (1,497)  |
| <b>Balance at December 31, 2022</b> | <b>\$</b>                      | <b>—</b> |

Restructuring costs related to the 2021 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.

## 20. SUBSEQUENT EVENTS

### Nasdaq Delisting Notice

In connection with the Merger with Carisma, the Company is seeking the approval of its stockholders to, among other things, (a) issue the shares of its common stock issuable in connection with the Merger pursuant to the rules of Nasdaq, and (b) amend its amended and restated Certificate of Incorporation to effect a reverse stock split of the outstanding shares of its common stock at a ratio of 1-for-20 (clauses (a) and (b), collectively, the “Sesen Bio Voting Proposals”). The special meeting of stockholders in which the Company’s stockholders will be asked to vote on the Sesen Bio Voting Proposals will be held on March 2, 2023 at 10:00 a.m. Eastern Time (the “Special Meeting”).

On January 25, 2023, the Company was notified by the Listing Qualifications Department (the “Staff”) of Nasdaq that, based upon the Company’s non-compliance with the \$1.00 bid price requirement for continued listing on The Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550(a)(2) (the “Bid Price Rule”), the Company’s common stock will be delisted from Nasdaq unless it timely requests a hearing before a Nasdaq Hearings Panel (the “Panel”).

The Company requested a hearing before the Panel, which stayed any delisting action by the Staff and ensured the Company’s common stock remains listed and eligible for trading on Nasdaq pending a determination by the Panel. The hearing had been scheduled for March 16, 2023.

On February 24, 2023, the Company received a determination from the Nasdaq Office of General Counsel that the Panel granted the Company an exception from its non-compliance with the Bid Price Rule to complete the Merger by March 10, 2023. Pursuant to Nasdaq Listing Rule 5110(a), the Company must demonstrate compliance with all initial listing requirements of Nasdaq upon the closing of the Merger. The Company is seeking approval for the Merger and the implementation of a reverse stock split of its common stock at the Special Meeting. In the event the Company fails to establish compliance with the initial listing standards by March 10, 2023, the common stock will be delisted from Nasdaq, unless granted an additional exception by the Panel.

As previously disclosed, on January 24, 2022, the Company received written notice from the Staff indicating that, based upon the closing bid price for its common stock for the previous 30 consecutive business days, the Company no longer satisfied the Bid Price Rule and, in accordance with the Nasdaq Listing Rules, was afforded an initial grace period of 180 calendar days, through July 25, 2022, and a second 180-calendar day period, through January 23, 2023, to regain compliance with the Bid Price Rule. The Company did not regain compliance with the Bid Price Rule by January 23, 2023, which resulted in the Staff’s January 25, 2023, determination.

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## **BOARD OF DIRECTORS**

**Steven Kelly**  
*President, Chief Executive Officer  
and Director*

**Sanford Zweifach**  
*Chair of the Board  
Founder and President, Pelican  
Consulting Group*

**Regina Hodits, Ph.D.**  
*Managing Partner, Wellington Life  
Sciences Venture Capital Consulting  
GmbH*

**Briggs Morrison, M.D.**  
*President, Head of Research and  
Development, Syndax  
Pharmaceuticals Inc.*

**Björn Odlander, M.D., Ph.D.**  
*Co-Founder, HealthCap VII L.P.*

**Michael Torok**  
*Co-Founder and Managing Director,  
JEC Capital Partners, LLC*

**Chidozie Ugwumba**  
*Managing Partner, SymBiosis II,  
LLC*

## **EXECUTIVE OFFICERS**

**Steven Kelly**  
*President, Chief Executive  
Officer and Director*

**Richard Morris**  
*Chief Financial Officer*

**Michael Klichinsky,  
Pharm.D., Ph.D.**  
*Chief Scientific Officer*

## **CORPORATE HEADQUARTERS**

3675 Market Street, Suite 200  
Philadelphia, PA 19104

## **INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

KPMG LLP  
Philadelphia, PA

## **TRANSFER AGENT**

Computershare Trust Company, N.A.  
Attn: Carisma Therapeutics Inc.  
P.O. Box 43001  
Providence, RI 02940-3001

## **INVESTOR RELATIONS**

[investors@carismatx.com](mailto:investors@carismatx.com)

## **ANNUAL MEETING**

Our 2023 Annual Meeting of  
Stockholders will be held via the  
Internet at a virtual audio web  
conference at  
[www.meetnow.global/M2S4S4W](http://www.meetnow.global/M2S4S4W) on  
Tuesday, June 6, 2023 at 9:00 a.m.,  
Eastern Time.

