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

FORM 10-Q

(Mark One)

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

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

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

Not applicable

(Former name, former address and former fiscal year, if changed since last report)

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

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

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

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

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

Large accelerated filer	☒	Smaller reporting company	☐
Accelerated filer	☐	Emerging growth company	☐
Non-accelerated filer	☐		

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

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

There were 199,463,645 shares of the registrant's common stock outstanding as of May 2, 2022.

SESEN BIO, INC.

Quarterly Report on Form 10-Q for the Quarterly Period Ended March 31, 2022

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 169,790	$ 162,636
Accounts receivables	1,011	21,011
Other receivables	1,041	3,482
Prepaid expenses and other current assets	8,795	18,476
Total current assets	180,637	205,605
Non-current assets:		
Restricted cash	20	20
Property and equipment, net	33	43
Intangible assets	14,700	14,700
Goodwill	13,064	13,064
Long term prepaid expenses	17,301	7,192
Other assets	85	123
Total non-current assets	**$ 45,203**	**$ 35,142**
Total Assets	**$ 225,840**	**$ 240,747**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 666	$ 2,853
Accrued expenses	7,278	8,255
Other current liabilities	530	460
Total current liabilities	8,474	11,568
Non-current liabilities:		
Contingent consideration	39,100	52,000
Deferred tax liability	3,969	3,969
Deferred revenue	1,500	1,500
Total non-current liabilities	44,569	57,469
Total Liabilities	53,043	69,037
Stockholders' Equity:		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized at March 31, 2022 and December 31, 2021; no shares issued and outstanding at March 31, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value per share; 400,000,000 shares authorized at March 31, 2022 and December 31, 2021; 199,463,645 shares issued and outstanding at March 31, 2022 and December 31, 2021	199	199
Additional paid-in capital	489,662	487,768
Accumulated deficit	(317,064)	(316,257)
Total Stockholders' Equity	172,797	171,710
Total Liabilities and Stockholders' Equity	**$ 225,840**	**$ 240,747**

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

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

	Three Months Ended March 31,	
	2022	**2021**
Revenue:		
License and related revenue	$ —	$ 4,310
Total Revenue	—	4,310
Operating expenses:		
Research and development	4,760	6,078
General and administrative	8,975	5,293
Change in fair value of contingent consideration	(12,900)	48,160
Total operating expenses	835	59,531
Loss from Operations	$ (835)	$ (55,221)
Other income (expense), net	28	(3)
Loss Before Taxes	$ (807)	$ (55,224)
Provision for income taxes	—	(288)
Net Loss and Comprehensive Loss After Taxes	$ (807)	$ (55,512)
Net loss attributable to common stockholders - basic and diluted	$ (807)	$ (55,512)
Net loss per common share - basic and diluted	$ 0.00	$ (0.35)
Weighted-average common shares outstanding - basic and diluted	$ 199,464	$ 157,033

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2021	199,463,645	$ 199	$ 487,768	$ (316,257)	$ 171,710
Net loss	—	—	—	(807)	(807)
Share-based compensation	—	—	1,894	—	1,894
Balance at March 31, 2022	**199,463,645**	**$ 199**	**$ 489,662**	**$ (317,064)**	**$ 172,797**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2020	140,449,647	$ 140	$ 306,554	$ (315,921)	$ (9,227)
Net loss	—	—	—	(55,512)	(55,512)
Share-based compensation	—	—	958	—	958
Exercises of stock options	30,610	—	39	—	39
Exercises of common stock warrants	852,840	1	468	—	469
Issuance of common stock under ATM Offering, net of issuance costs of $2.2 million	30,645,702	31	72,512	—	72,543
Balance at March 31, 2021	**171,978,799**	**$ 172**	**$ 380,531**	**$ (371,433)**	**$ 9,270**

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

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

	Three Months Ended March 31,	
	2022	**2021**
Cash Flows from Operating Activities:		
Net loss	$ (807)	$ (55,512)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	10	30
Share-based compensation	1,894	958
Change in fair value of contingent consideration	(12,900)	48,160
Changes in operating assets and liabilities:		
Accounts receivable (net)	20,000	(2,886)
Other receivables	2,441	—
Prepaid expenses and other current assets	9,682	(6,250)
Long term prepaid expenses	(10,109)	—
Other assets	38	91
Accounts payable	(2,187)	(1,098)
Accrued expenses and other liabilities	(908)	(468)
Deferred revenue	—	(1,500)
Net cash provided (used in) operating activities	**7,154**	**(18,475)**
Cash Flows from Investing Activities:		
Net cash used in investing activities	**—**	**—**
Cash Flows from Financing Activities:		
Proceeds from exercises of common stock warrants	—	469
Proceeds from issuance of common stock under ATM Offering, net of issuance costs	—	72,543
Proceeds from exercises of stock options	—	39
Net cash provided by financing activities	—	**73,051**
Net increase in cash, cash equivalents and restricted cash	7,154	54,576
Cash, cash equivalents and restricted cash - beginning of period	162,656	55,409
Cash, cash equivalents and restricted cash - end of period	**$ 169,810**	**$ 109,985**
Supplemental cash flow disclosure:		
Cash paid for amounts included in the measurement of lease liabilities	$ 43	$ 43

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

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

1. DESCRIPTION OF BUSINESS

Sesen Bio, Inc. ("Sesen" or the "Company"), a Delaware corporation formed in February 2008, is a late-stage clinical company advancing targeted fusion protein therapeutics ("TFPTs") for the treatment of patients with cancer. The Company's most advanced product candidate, Vicineum™, also known as VB4-845, is a locally-administered targeted fusion protein composed of an anti-epithelial cell adhesion molecule ("EpCAM") antibody fragment tethered to a truncated form of Pseudomonas exotoxin A for the treatment of non-muscle invasive bladder cancer ("NMIBC"). The Company is in the follow-up stage of its single-arm, multi-center, open-label Phase 3 clinical trial of Vicineum as a monotherapy in patients with bacillus Calmette-Guérin ("BCG")-unresponsive NMIBC (the "VISTA Trial"). The VISTA Trial completed enrollment in April 2018 with a total of 133 patients. On December 18, 2020, the Company submitted its completed Biologics License Application (the "BLA") for Vicineum for the treatment of BCG-unresponsive NMIBC to the United States Food and Drug Administration ("FDA"). On February 12, 2021, the FDA notified the Company that it had accepted the BLA file. The FDA also granted Priority Review for the BLA and set a target Prescription Drug User Fee Act ("PDUFA") date for a decision on the BLA of August 18, 2021. On August 13, 2021, the Company received a complete response letter ("CRL") from the FDA indicating that the FDA had determined that it could not approve the BLA for Vicineum in its present form and provided recommendations specific to additional clinical/statistical data and analyses in addition to chemistry, manufacturing and controls ("CMC") issues pertaining to a recent pre-approval inspection and product quality.

In October 2021 and December 2021, the Company participated in a CMC Type A meeting and a Clinical Type A meeting, respectively, with the FDA to discuss issues raised in the CRL and design elements of an additional Phase 3 clinical trial for Vicineum, which the FDA confirmed will be required for a potential resubmission of a BLA. In March 2022, the Company participated in a Type C meeting with the FDA. During the Type C meeting, the FDA agreed to a majority of the Company's proposed protocol and statistical analysis plan design elements for an additional Phase 3 clinical trial for potential resubmission of a BLA for Vicineum for the treatment of NMIBC. The Company plans to further engage the FDA in the coming months to align on the remaining outstanding items related to the additional Phase 3 clinical trial.

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.

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 March 31, 2022, none of these individuals are active employees or members of the Company's board of directors.

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 Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASUs"), promulgated by the Financial Accounting Standards Board ("FASB").

Interim Financial Statements

The accompanying unaudited interim condensed consolidated financial statements have been prepared from the books and records of the Company in accordance with GAAP for interim financial information and Rule 10-01 of Regulation S-X promulgated by the United States Securities and Exchange Commission ("SEC"), which permit reduced disclosures for interim periods. All adjustments, consisting only of normal recurring adjustments, which are, in the opinion of management, necessary for a fair presentation of the accompanying condensed consolidated balance sheets and statements of operations and comprehensive (loss) income, stockholders' equity (deficit) and cash flows have been made. Although these interim financial statements do not include all of the information and footnotes required for complete annual financial statements, management believes the disclosures are adequate to make the information presented not misleading. These unaudited interim results of operations and cash flows for the three months ended March 31, 2022 are not necessarily indicative of the results that may be expected for the full year. These unaudited interim condensed consolidated financial statements and footnotes should be read in conjunction with the Company's audited annual consolidated financial statements and footnotes included in its Annual Report on Form 10-K, as filed with the SEC on February 28, 2022, wherein a more complete discussion of significant accounting policies and certain other information can be found.

Use of Estimates

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

Principles of Consolidation

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

Foreign Currency Translation

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

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The Company's complete summary of significant accounting policies can be found in "Item 15. Exhibits and Financial Statement Schedules - Note 3. Summary of Significant Accounting Policies" in the audited annual consolidated financial statements included in its Annual Report on Form 10-K for the year ended December 31, 2021.

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 condensed consolidated balance sheets approximated their fair values as of March 31, 2022 and December 31, 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 March 31, 2022 and December 31, 2021 (in thousands):

	March 31, 2022				
			Fair Value Measurement Based on		
	Carrying Amount	Fair Value	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:					
Money market funds (cash equivalents)	$ 16,378	$ 16,378	$ 16,378	$ —	$ —
Liabilities:					
Contingent consideration	$ 39,100	$ 39,100	$ —	$ —	$ 39,100

	December 31, 2021				
			Fair Value Measurement Based on		
	Carrying Amount	Fair Value	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:					
Money market funds (cash equivalents)	$ 16,382	$ 16,382	$ 16,382	$ —	$ —
Liabilities:					
Contingent consideration	$ 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 quarter ended March 31, 2022.

Contingent Consideration

On September 20, 2016, the Company acquired Viventia through the issuance of shares of common stock plus contingent consideration, pursuant to the terms of a Share Purchase Agreement. The Company recorded the acquired assets and liabilities based on their estimated fair values as of the acquisition date and finalized its purchase accounting for the Viventia Acquisition during the third quarter of 2017. The contingent consideration relates to amounts potentially payable to the former shareholders of Viventia under the Share Purchase Agreement. Contingent consideration is measured at its estimated fair value at each reporting period, with fluctuations in value resulting in a non-cash charge to earnings (or loss) during the period. The estimated fair value measurement is based on significant inputs, including internally developed financial forecasts, probabilities of success, and the timing of certain milestone events and achievements, which are not observable in the market, representing a Level 3 measurement within the fair value hierarchy. 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 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 through 2033, the level of commercial sales of Vicineum forecasted for the US, Europe, Japan, China and other potential markets and discount rates ranging from 9.0% to 9.7% as of March 31, 2022 and 8.0% to 9.3% as of December 31, 2021. There have been no changes to the valuation methods utilized during the three months ended March 31, 2022.

The following table sets forth a summary of the change in the fair value of the Company's contingent consideration liability, measured on a recurring basis at each reporting period, for the quarter ended March 31, 2022, (in thousands).

Balance at December 31, 2021	$ 52,000
Change in fair value of contingent consideration	(12,900)
Balance at March 31, 2022	**$ 39,100**

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 (“WACC”), which has fluctuated from 9.3% as of December 31, 2021 to 9.0% as of March 31, 2022. Milestone payments constitute debt-like obligations, and therefore a high-yield debt index rate is applied to the milestones in order to determine the estimated fair value. This index rate changed from 8.0% as of December 31, 2021 to 9.7% as of March 31, 2022. The decrease in the fair value of contingent consideration of $12.9 million for the three months ended March 31, 2022 was driven by changes in underlying assumptions used to develop the revenue projections.

In March 2022, the Company participated in a Type C meeting with the FDA. During the Type C meeting, the FDA agreed to a majority of the Company's proposed protocol and statistical analysis plan design elements for an additional Phase 3 clinical trial for potential resubmission of a BLA for Vicineum for the treatment of NMIBC. The Company also learned during the meeting that the FDA is trending away from accepting single arm trials across therapeutic areas, including NMIBC, and has a strong preference for randomized controlled trials. The Company plans to further engage the FDA in the coming months to align on the remaining outstanding items related to the additional Phase 3 clinical trial. Incorporating the FDA feedback from the Type C meeting, plans for further discussions with the FDA prior to initiation of the additional Phase 3 clinical trial, as well as updates to the competitive landscape, the Company reassessed the underlying assumptions used to develop the revenue projections upon which the fair value of its contingent consideration is based. The most significant and impactful assumptions in the Company's revenue projection models are timing of potential commercial product launch, probabilities of clinical and regulatory success, and market share. The Company anticipates further delays in the start of commercialization due to the likelihood of the requirement to conduct a randomized controlled trial which will require more patients to be enrolled, lengthen the duration of the study, and increase study costs. The company is also projecting lower estimated market share as a result of recent clinical and regulatory progress made by competitors. The Company has assessed a commercialization timeline assumption and applied a probability to each outcome based on management's best estimate. The Company continues to assume a POS in achieving certain clinical and regulatory milestones in the range of approximately 45% to 55% globally. Any changes in these assumptions and estimates, or other information obtained, may have a significant impact on the remeasurement of the contingent consideration liability in the future.

6. RECEIVABLES

The accounts receivable balance as of March 31, 2022 is $1.0 million compared to $21.0 million as of December 31, 2021. The decrease is driven by the receipt of the $20.0 million milestone from F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (collectively, "Roche") for the initiation of a Phase II clinical trial in the fourth quarter of 2021.

The other receivable balance as of March 31, 2022 is $1.0 million compared to $3.5 million as of December 31, 2021. The decrease is driven primarily by the receipt of $1.8 million for German VAT recovery related to drug substance sent to Baxter in 2020 and 2019.

7. INTANGIBLES AND GOODWILL

Intangibles

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

	March 31, 2022	December 31, 2021
IPR&D intangible assets:		
Vicineum European Union rights	$ 14,700	$ 14,700
Total Intangibles	**$ 14,700**	**$ 14,700**

The fair value of the acquired intangible assets for the EU rights of Vicineum is determined using a risk-adjusted discounted cash flow approach, which includes probability adjustments for projected revenues and operating expenses based on the success rates assigned to each stage of development for each geographical region; as well as discount rates applied to the projected cash flows. In August 2021, the Company received a CRL from the FDA regarding its BLA for Vicineum for the treatment of BCG-unresponsive NMIBC, the Company's lead product candidate. In the CRL, the FDA determined that it could not approve the BLA for Vicineum in its present form and provided recommendations specific to additional clinical/statistical data and analyses in addition to CMC issues pertaining to a recent pre-approval inspection and product quality. Also in August 2021, the Company withdrew its MAA to the EMA for Vysyneum for the treatment of BCG-unresponsive NMIBC in order to pause its plans to pursue regulatory approval of Vysyneum in the EU until there is more clarity from the FDA on next steps for Vicineum in the United States. Given the inherent uncertainty in the development plans for Vicineum as a result of the CRL and the Company's withdrawal of its MAA, an impairment analysis was conducted in the third quarter of 2021, which concluded that the carrying value of the Company's intangible asset of Vicineum United States rights was fully impaired as of September 30, 2021. The $31.7 million of impairment charges as of September 30, 2021 were due to delays in the expected start of commercialization and lower probabilities of success, combined with higher operating expenses expected to be incurred prior to commercialization, resulting in lower expected future cash flows estimated in the US market. At that time, management assessed that the carrying value of the Vicineum EU rights was not at significant risk of impairment in the future within the

current range of commercialization timelines and POS assumptions. This was primarily due to the fact that the EU asset is burdened with significantly less expense than the US asset, as the Company's strategic operating plan is to sublicense Vicineum to business development partners in all regions outside the US, including the EU, with it earning a potential combination of upfront, milestone, and royalty payments, and the business development partner bearing the majority of regulatory and commercialization costs.

In March 2022, the Company participated in a Type C meeting with the FDA. During the Type C meeting, the FDA agreed to a majority of the Company's proposed protocol and statistical analysis plan design elements for an additional Phase 3 clinical trial for potential resubmission of a BLA for Vicineum for the treatment of NMIBC. The Company also learned during the meeting that the FDA is trending away from accepting single arm trials across therapeutic areas, including NMIBC, and has a strong preference for randomized controlled trials. The Company plans to further engage the FDA in the coming months to align on the remaining outstanding items related to the additional Phase 3 clinical trial. Based on the outcome of the Type C meeting as well as updates to the competitive landscape, 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 the indefinite-lived intangible asset. Management updated the revenue forecast models based on further launch delays in both US and OUS regions as well as slightly lower market share. The Company anticipates further delays in the start of commercialization due to the likelihood of the requirement to conduct a randomized controlled trial which will require more patients to be enrolled, lengthen the duration of the study, and increase study costs. The company is also projecting lower estimated market share as a result of recent clinical and regulatory progress made by competitors. Accordingly, the Company identified this as a potential impairment indicator and performed an interim quantitative impairment assessment during the first quarter of 2022. The Company concluded that the carrying value of the Company's intangible asset of Vicineum EU rights was not impaired as of March 31, 2022.

Goodwill

Goodwill on the Company's condensed consolidated balance sheet is the result of the Viventia Acquisition in September 2016. Goodwill had a carrying value of $13.1 million as of March 31, 2022 and December 31, 2021. Based on the outcome of the Type C meeting as well as updates to the competitive landscape, 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. Management updated its revenue forecast models based on further launch delays in both US and OUS regions as well as slightly lower market share. Accordingly, the Company identified these changes to the revenue forecast, as well as the decline in the Company's stock price and market capitalization during the first quarter of 2022, as potential impairment indicators and performed a quantitative impairment analysis during the first quarter of 2022, in advance of the Company's typical annual assessment date of October 1. The Company concluded that the carrying value of its goodwill of $13.1 million was not impaired as of March 31, 2022, with the fair value of equity of the reporting unit exceeding the estimated carrying value of the reporting unit by approximately 29%.

The Company believes it has sufficient future cash flows from additional geographic regions outside the US to support the value of its goodwill. The Company projects future cash flows based on various timeline assumptions and applies a probability to each outcome based on management's best estimate. In addition, probabilities of success in achieving certain clinical and regulatory success in the Company's current development profile (ranging from 45% to 55% globally) and underlying discount rates also have a material effect on the estimated fair value of its reporting unit as of the impairment assessment date. The Company will continue to evaluate its timelines for commercialization and probability of success of development of Vicineum for the treatment of NMIBC. Further reductions to probabilities of success, decrease in market share, additional development and commercial launch delays, increases in underlying discount rates, or any decision to undertake any strategic alternative as a result of the review process that the Company has initiated, have the potential to result in future goodwill impairment.

8. ACCRUED EXPENSES

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

	March 31, 2022	December 31, 2021
Research and development	$ 981	$ 1,841
Payroll-related expenses	2,675	2,967
Restructuring charge related	990	1,497
Professional fees	2,582	1,941
Other	50	9
Total Accrued Expenses	**$ 7,278**	**$ 8,255**

9. COMMITMENTS AND CONTINGENCIES

Legal Proceedings

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

On August 19, 2021, August 31, 2021, and October 7, 2021, three substantially identical securities class action lawsuits captioned Bibb v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-07025, Cizek v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-07309, and Markman v. Sesen Bio, Inc. et al., Case No. 1:21-cv-08308 were filed against the Company and certain of its officers in the US District Court for the Southern District of New York. The three complaints alleged violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder based on statements made by the Company concerning its BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. The three complaints 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 November 1, 2021, two stockholders filed motions to reconsider asking the court to appoint a different lead plaintiff. The court has not ruled on those motions at this time. On November 24, 2021, defendants filed a motion to transfer venue to the US District Court for the District of Massachusetts. That motion was fully briefed as of December 13, 2021, but the court has not yet ruled on that motion. On December 6, 2021, the Lead Plaintiffs filed an amended class action complaint (the "Amended Complaint"). The Amended Complaint alleges the same violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder on the same theory as the prior complaints. The defendants moved to dismiss the Amended Complaint on March 7, 2022. The plaintiffs filed their opposition to that motion on April 6, 2022 and Defendants filed their reply in further support of the motion to dismiss on May 6, 2022. The court has not yet ruled on the motion.

On September 20, 2021 and September 24, 2021, two substantially similar derivative lawsuits captioned Myers v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-11538 and D'Arcy v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-11577 were filed against the Company's board of directors and certain of its officers in the US District Court for the District of Massachusetts, with the Company named as a nominal defendant. On January 12, 2022, a third derivative complaint captioned Tang v. Sesen Bio, Inc., et al., was filed in Superior Court in Massachusetts against the Company's board of directors and certain of its officers in the US District Court for the District of Massachusetts, with the Company named as nominal defendant. The three derivative complaints allege breach of fiduciary duties, waste of corporate assets, and violations of federal securities laws based on statements made by the Company concerning its BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. The D'Arcy complaint further alleges unjust enrichment, abuse of control, gross mismanagement and aiding and abetting thereof.

The three derivative complaints seek unspecified damages, restitution and disgorgement of profits, benefits and compensation obtained by the defendants and costs and expenses, including attorneys' fees. On October 18, 2021, the court consolidated the two federal 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. Defendants intend to seek a similar stay of the state court derivative litigation.

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

Executive Employment Agreements

The Company has entered into employment agreements or offer letters with certain of its key executives, providing for separation payments and benefits in certain circumstances, as defined in the agreements.

10. LEASES

The Company accounts for operating leases under ASC Topic 842, *Leases.* The Company's lease portfolio includes an operating lease for its 31,100 square foot facility in Winnipeg, Manitoba which consists of manufacturing, laboratory, warehouse and office space. In September 2020, the Company entered into an extension of this lease for an additional two years, through September 2022, with a right to extend the lease for one subsequent three-year term. The minimum monthly rent under this lease is CAD $18,100 (approximately $14,500 at exchange rates in effect on March 31, 2022). In addition to rent expense, the Company expects to incur CAD $18,200 per month related to operating expenses (approximately $14,500 at exchange rates in effect on March 31, 2022). Operating lease cost under this lease, including the related operating costs, were $0.1 million for the three months ended March 31, 2022 and March 31, 2021.

The asset component of the Company's operating leases is recorded as operating lease right-of-use assets and reported within other assets on the Company's condensed consolidated balance sheets. The right of use asset total was $0.1 million as of March 31, 2022 and December 31, 2021. The short-term lease liability is recorded in other current liabilities and the long-term lease liability is recorded in other liabilities on the Company's condensed consolidated balance sheets. The short-term lease liability was $0.1 million as of March 31, 2022 and December 31, 2021. There was no long-term operating lease liability as of March 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 short-term leases renew every six to twelve months and currently extend through June 2023 and May 2023, respectively. The minimum monthly rent for these office spaces is $2,100 and $18,400, respectively, which is subject to change if and as the Company adds space to or deducts space from the leases.

11. STOCKHOLDERS' EQUITY

Equity Financings

ATM Offering

The Company has entered into an Open Market Sale Agreement [SM] 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 the Company may issue and sell shares of its common stock, par value $0.001 per share, from time to time through Jefferies (the "ATM Offering"). In June and July 2021, the Company filed prospectus supplements with the SEC in connection with the offer and sale of up to an aggregate of $200 million of common stock pursuant to the Sale Agreement of which $97.8 million of common stock remain available for future issuance as of March 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, as amended, including but not limited to sales made directly on or through the Nasdaq Global Market or any other existing trading market for the Company's common stock. The Company may sell shares of its common stock efficiently from time to time but has no obligation to sell any of its common stock and may at any time suspend offers under the Sale Agreement or terminate the Sale Agreement. Subject to the terms and conditions of the Sale Agreement, Jefferies will use its commercially reasonable efforts to sell common stock from time to time, as the sales agent, based upon the Company's instructions, which include a prohibition on sales below a minimum price set by the Company from time to time. The Company has provided Jefferies with customary indemnification rights, and Jefferies is entitled to a commission at a fixed rate equal to 3.0% of the gross proceeds for each sale of common stock under the Sale Agreement. The Company did not sell any shares of common stock pursuant to the Sale Agreement during the three months ended March 31, 2022. The Company raised $72.6 million of net proceeds from the sale of 30.6 million shares

of common stock at a weighted-average price of $2.44 per share during the three months ended March 31, 2021. Share issuance costs, including sales agent commissions, related to the ATM Offering totaled $2.2 million during the three months ended March 31, 2021.

Preferred Stock

Pursuant to its Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation"), the Company is authorized to issue 5.0 million shares of "blank check" preferred stock, $0.001 par value per share, which enables its board of directors, from time to time, to create one or more series of preferred stock. Each series of preferred stock issued shall have the rights, preferences, privileges and restrictions as designated by the board of directors. The issuance of any series of preferred stock could affect, among other things, the dividend, voting and liquidation rights of the Company's common stock. The Company had no preferred stock issued and outstanding as of March 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 199 million shares were issued and outstanding as of March 31, 2022 and December 31, 2021. In addition, the Company had reserved for issuance the following amounts of shares of its common stock for the purposes described below as of March 31, 2022 and December 31, 2021 (in thousands):

	March 31, 2022	December 31, 2021
Shares of common stock issued	199,464	199,464
Shares of common stock reserved for issuance for:		
Warrants	199	199
Stock options	16,783	15,703
Restricted stock units	4,965	3,041
Shares available for grant under 2014 Stock Incentive Plan	3,564	8,933
Shares available for sale under 2014 Employee Stock Purchase Plan	2,300	2,300
Total shares of common stock issued and reserved for issuance	**227,275**	**229,640**

The voting, dividend and liquidation rights of holders of shares of common stock are subject to and qualified by the rights, powers and preferences of holders of shares of preferred stock. Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders; provided, however, that, except as otherwise required by law, holders of common stock shall not be entitled to vote on any amendment to the Company's Certificate of Incorporation that relates solely to the terms of one or more outstanding series of preferred stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more such series, to vote thereon. There shall be no cumulative voting.

Dividends may be declared and paid on the common stock from funds lawfully available thereof as and when determined by the board of directors and subject to any preferential dividend or other rights of any then-outstanding preferred stock. The Company has never declared or paid, and for the foreseeable future does not expect to declare or pay, dividends on its common stock.

Upon the dissolution or liquidation of the Company, whether voluntary or involuntary, holders of common stock will be entitled to receive all assets of the Company available for distribution to its stockholders, subject to any preferential or other rights of any then-outstanding preferred stock.

Warrants

All of the Company's outstanding warrants are non-tradeable and equity-classified because they meet the derivative scope exception under ASC Topic 815-40, Derivatives and Hedging - Contracts in Entity's Own Equity ("ASC 815-40"). The following table sets forth the Company's warrant activity for the three months ended March 31, 2022 (in thousands):

Issued	Exercise Price	Expiration	December 31, 2021	Issued	(Exercised)	(Cancelled)	March 31, 2022
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
			199	**—**	**—**	**—**	**199**

** Exercise price shown (i) reflects modification and (ii) is subject to further adjustment based on down round provision added by amendment described in "Item 15. Exhibits and Financial Statement Schedules - Note. 12 Stockholders' Equity (Deficit)" in the audited annual consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021.*

12. 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 unvested 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.

The following potentially dilutive securities outstanding as of March 31, 2022 and 2021 have been excluded from the denominator of the diluted loss per share of common stock outstanding calculation (in thousands):

	March 31,	
	2022	**2021**
Warrants	199	1,394
Stock options	16,783	14,380
RSUs and PSUs	6,555	—
Total	**23,537**	**15,774**

13. SHARE-BASED COMPENSATION

The following table sets forth the amount of share-based compensation expense recognized by the Company by line item on its Condensed Consolidated Statements of Operations and Comprehensive Loss for three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	**2021**
Research and development	$ 502	$ 178
General and administrative	1,392	780
Total Share Based Compensation	**$ 1,894**	**$ 958**

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, restricted stock units ("RSU"), 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 3.6 million shares of common stock available for issuance under the 2014 Plan as of March 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 13.2 million stock options outstanding under the 2014 Plan as of March 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 RSU award which will vest 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.

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 March 31, 2022 achievement was deemed probable for only the cash management milestone, representing 20% of the PSU awards.

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 March 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 3.5 million stock options outstanding which were granted as employment inducement awards outside of the 2014 Plan as of March 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 three months ended March 31, 2022:

	Number of Shares under Option (in thousands)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	15,703	$1.93	8.03	$ 82
Granted	1,080	$0.71		
Exercised	—	—		
Canceled or forfeited	—	—		
Outstanding at March 31, 2022	16,783	$1.85	7.92	$ 1
Exercisable at March 31, 2022	8,513	$1.68	7.26	$ 1

The Company recognized share-based compensation expense of $1.9 million for the three months ended March 31, 2022. The stock option related expenses were $1.3 million and $1.0 million for the three months ended March 31, 2022 and 2021, respectively. As of March 31, 2022, there was $9.6 million of total unrecognized compensation cost related to unvested stock options which the Company expects to recognize over a weighted-average period of 2.56 years. The weighted-average grant-date fair value of stock options granted during the three months ended March 31, 2022 and 2021 were $0.45 and $2.05, respectively. No stock options were exercised during the three months ended March 31, 2022. The total intrinsic value of stock options exercised for the three months ended March 31, 2021 was de minimis.

For the three months ended March 31, 2022 and 2021, 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:

	Three Months Ended March 31,	
	2022	2021
Fair market value	$0.71	$3.15
Grant exercise price	$0.71	$3.15
Expected term (in years)	6.0	6.0
Risk-free interest rate	1.7%	0.8%
Expected volatility	71.9%	75.0%
Dividend yield	—%	—%

Restricted Stock Units and Performance Stock Units

The following table sets forth a summary of the Company's RSU and PSU activity for the three months ended March 31, 2022:

	Restricted Stock Units (in thousands)	Weighted Average Grant Date Fair Value
Unvested at December 31, 2021	3,041	$0.80
Granted RSU	3,960	$0.67
Granted PSU	1,004	$0.67
Unvested at March 31, 2022	**8,005**	$0.72

The Company did not grant any RSUs or PSUs during the three months ended March 31, 2021.

The share-based compensation expense related to RSUs and PSUs for the three months ended March 31, 2022 was $0.6 million. There was no shared-based compensation expense related to RSUs and PSUs for the three months ended March 31, 2021. As of March 31, 2022, there was $5.0 million of total unrecognized compensation cost related to unvested RSUs and PSUs which the Company expects to recognize over a weighted-average period of 2.94 years.

14. 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 condensed consolidated statements of changes in stockholders' equity (deficit). As of March 31, 2022, there were 2.3 million shares of common stock available for sale under the 2014 ESPP. The Company did not sell any shares under the ESPP for the three months ended March 31, 2022 and 2021.

Defined Contribution Plans

United States - 401(k) Plan

The Company maintains a 401(k) defined contribution retirement plan which covers all of its US employees. Employees are eligible to participate on the first of the month following their date of hire. Under the 401(k) plan, participating employees may defer up to 100% of their pre-tax salary, subject to certain statutory limitations. Employee contributions vest immediately. The plan allows for a discretionary match per participating employee up to a maximum of $4,000 per year. The expenses incurred for the periods presented were de minimis amount for each of the three months ended March 31, 2022 and 2021, 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 expenses incurred for the periods presented were de minimis amount for each of the three months ended March 31, 2022 and 2021, respectively.

15. 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. The Company's receipt of the CRL regarding the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC triggered a $0.5 million milestone payment to Zurich. Under the Zurich License Agreement, 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, which includes Vicineum. Royalties owed to Zurich will be reduced if the total royalty rate owed by the Company to Zurich and any other third party is 10% or greater, provided that the royalty rate to Zurich may not be less than 2% of net sales. The obligation to pay royalties in a particular country expires upon the expiration or termination of the last of the Zurich patent rights that covers the manufacture, use or sale of a product. There is no obligation to pay royalties in a country if there is no valid claim that covers the product or a method of manufacturing the product. The Company recorded an expense of $0.3 million and $0.5 million related to meeting a development milestone, (the submission of the Company’s BLA with the FDA in December 2020), in the fourth quarter of 2020, and a regulatory milestone, (the Company’s receipt of the CRL from the FDA in August 2021), in the third quarter of 2021, respectively.

License Agreement with Micromet

The Company has a License Agreement with Micromet AG ("Micromet"), now part of Amgen, Inc., which grants it nonexclusive rights, with certain sublicense rights, for know-how and patents allowing exploitation of certain single chain antibody products (the “Micromet License Agreement”). These patents cover some key aspects of Vicineum. Under the terms of the Micromet License Agreement, as of March 31, 2022, the Company may be obligated to pay up to €2.4 million in milestone payments for the first product candidate that achieves applicable regulatory and sales-based development milestones (approximately $2.7 million at exchange rates in effect on March 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 (approximately $55,559 at exchange rates in effect as of March 31, 2022), that can be credited towards any royalty payment the Company owes to Micromet. The Company recorded an expense of €0.7 million ($0.9 million) related to achievement of a development milestone in the three months ended December 31, 2020, due to the submission of the Company's BLA for Vicineum with the FDA in December 2020. The Company recorded an expense of €0.5 million ($0.6 million) related to the submission of the MAA to the EMA for Vysyneum™ in the first quarter of 2021. Vysyneum is the proprietary brand name that was conditionally approved by the EMA for oportuzumab monatox in the European Union.

License Agreement with XOMA

The Company has a license agreement with XOMA Ireland Limited ("XOMA") which grants it non-exclusive rights to certain XOMA patent rights and know-how related to certain expression technology, including plasmids, expression strains, plasmid maps and production systems (the "XOMA License Agreement"). These patents and related know-how cover some key aspects of Vicineum. Under the terms of the XOMA License Agreement, the Company is required to pay up to $0.25 million in milestone payments for a product candidate that incorporates know-how under the license and achieves applicable clinical development milestones. Based on current clinical status, the Company anticipates that these milestones may be triggered by Vicineum's clinical development pathway. The Company is also required to pay a 2.5% royalty on the net sales for products incorporating XOMA's technology, which includes Vicineum. The Company has the right to reduce the amount of royalties owed to XOMA on a country-by-country basis by the amount of royalties paid to other third parties, provided that the royalty rate to XOMA may not be less than 1.75% of net sales. In addition, the foregoing royalty rates are reduced by 50% with respect to products that are not covered by a valid patent claim in the country of sale. The obligation to pay royalties in a particular country expires upon the later of the expiration date of the last valid claim covering the product and the tenth anniversary of the first commercial sale of the product in such country.

Out-License Agreements

Roche License Agreement

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

Financial Terms

The Company received from Roche an upfront license fee of $7.5 million in August 2016 upon the effectiveness of the Roche License Agreement following approval by the Company's stockholders, and Roche agreed to pay up to an additional $262.5 million upon the achievement of specified regulatory, development and commercialization milestones with respect to up to two unrelated indications. Specifically, an aggregate amount of up to $197.5 million is payable to the Company for the achievement of specified milestones with respect to the first indication, consisting of (i) $72.5 million in development milestones, the next of which is $30 million for initiation of the first Phase III clinical trial, (ii) $50 million in regulatory milestones and (iii) $75 million in commercialization milestones. Additional amounts of up to $65 million are payable upon the achievement of specified development and regulatory milestones in a second indication.

In September 2016, Roche paid the Company the first development milestone of $22.5 million as a result of the Investigational New Drug application for EBI-031 becoming effective on or before September 15, 2016. In December 2021, a $20 million milestone was achieved due to Roche initiating a Phase II clinical trial. Management evaluated the milestone under the provisions of Accounting Standards Codification 606, Revenue from Contracts with Customers ("ASC 606"), and determined it is probable that a significant revenue reversal will not occur in future periods, which was not the case in the previous quarter. Accordingly, the Company invoiced Roche $20 million with payment terms of 30 days following the achievement of the corresponding milestone event, pursuant to the Roche License Agreement and $20 million was recorded as license revenue and accounts receivables in the fourth quarter of 2021. In January 2022, the payment of $20 million was received.

In addition, the Company is entitled to receive royalty payments in accordance with a tiered royalty rate scale, with rates ranging from 7.5% to 15% of net sales of potential future products containing EBI-031 and up to 50% of these rates for net

sales of potential future products containing other IL-6 compounds, with each of the royalties subject to reduction under certain circumstances and to the buy-out options of Roche.

Buy-Out Options

The Roche License Agreement provides for two "option periods" during which Roche may elect to make a one-time payment to the Company and, in turn, terminate its diligence, milestone and royalty payment obligations under the Roche License Agreement. Specifically, (i) Roche may exercise a buy-out option following the first dosing ("Initiation") in the first Phase 2 study for a Roche Licensed Product until the day before Initiation of the first Phase 3 study for a Roche Licensed Product, in which case Roche is required to pay the Company $135 million within 30 days after Roche's exercise of such buy-out option and receipt of an invoice from the Company, or (ii) Roche may exercise a buy-out option following the day after Initiation of the first Phase 3 study for a Roche Licensed Product until the day before the acceptance for review by the FDA or other regulatory authority of a BLA or similar application for marketing approval for a Roche Licensed Product in either the United States or in the EU, in which case Roche is required to pay the Company, within 30 days after Roche's exercise of such buy-out option and receipt of an invoice from the Company, $265 million, which amount would be reduced to $220 million if none of the Company's patent rights containing a composition of matter claim covering any compound or Roche Licensed Product has issued in the EU.

Termination

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

OUS Business Development Partnership Agreements

Qilu License Agreement

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

In consideration for the rights granted by the Company, Qilu agreed to pay to the Company a one-time upfront cash payment of $12 million, and milestone payments totaling up to $23 million upon the achievement of certain technology transfer, development and regulatory milestones. All payments were to be inclusive of value-added tax ("VAT"), which can be withheld by Qilu upon payment, and for which future recovery of such taxes may be available.

Qilu also agreed to pay the Company a 12% royalty based upon annual net sales of Qilu Licensed Products in Greater China. The royalties are payable on a Qilu Licensed Product-by-Licensed Product and region-by-region basis commencing on the first commercial sale of a Licensed Product in a region and continuing until the latest of (i) twelve years after the first commercial sale of such Qilu Licensed Product in such region, (ii) the expiration of the last valid patent claim covering or claiming the composition of matter, method of treatment, or method of manufacture of such Qilu Licensed Product in such region, and (iii) the expiration of regulatory or data exclusivity for such Qilu Licensed Product in such region (collectively, the "Royalty Terms"). The royalty rate is subject to reduction under certain circumstances, including when there is no valid claim of a licensed patent that covers a Qilu Licensed Product in a particular region or no data or regulatory exclusivity of a Qilu Licensed Product in a particular region.

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

commercialize the Qilu Licensed Product in the Field in Greater China until the Company has completed manufacturing technology transfer to Qilu and approval of a Qilu manufactured product by the National Medical Products Administration in China ("NMPA") for the Qilu Licensed Product has been obtained.

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

The Qilu License Agreement is subject to the provisions of ASC 606. In 2020, the initial transaction price was estimated to be $11.2 million and was based on the up-front fixed consideration of $12 million less amounts withheld for VAT. The Company concluded that its agreements under the Qilu License Agreement represented one bundled performance obligation that had been achieved as of September 30, 2020. As such, $11.2 million of the total $11.2 million transaction price was considered earned and the Company recorded $11.2 million of revenue during the three-month period ended September 30, 2020.

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

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

MENA License Agreement

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

The MENA License Agreement is subject to the provisions of ASC 606. The initial transaction price was estimated by management as $1.5 million as of December 31, 2020 and was based on 50% of the upfront payment, or the amount not subject to a refund if certain regulatory approvals in MENA are not obtained. The remaining upfront payment ($1.5 million) is subject to a refund if certain regulatory approvals in MENA are not obtained and recorded as deferred revenue. The Company also concluded that its agreements under the MENA License Agreement represented two distinct performance obligations, the first of which is a bundled performance obligation related to the delivery of the license, associated know-how and certain documentation. The second performance obligation relates to the delivery of manufactured product. The first performance obligation (delivery of the license, associated know-how and certain documentation) was achieved during the quarter ended March 31, 2021; as such, revenue of $1.5 million has been recognized. Additional variable consideration, determined to be allocated entirely to the bundled license performance obligation, to be paid to the Company based upon future sales levels will be recognized as revenue when the underlying sales of the licensed product occurs. In addition, variable consideration related to any future delivery of product will be recognized in future periods as the product is delivered. As of March 31, 2022, none of these additional amounts were reasonably certain to be achieved due to the nature and timing of the underlying activities.

EIP License Agreement

On August 5, 2021, the Company entered into an exclusive license agreement with EİP Eczacıbaşı İlaç Pazarlama A.Ş., ("EIP") pursuant to which it granted EIP an exclusive license to register and commercialize Vicineum for the treatment of BCG-unresponsive NMIBC in Turkey and Northern Cyprus (the "EIP License Agreement"). Under the terms of the EIP License Agreement, the Company is entitled to receive an upfront payment of $1.5 million. The Company and EIP have amended the license agreement to defer EIP's payment of the upfront payment to coincide with the potential FDA approval of Vicineum. The Company is eligible to receive additional regulatory and commercial milestone payments of $2.0 million and is also entitled to receive a 30% royalty on net sales in Turkey and Northern Cyprus. The EIP License Agreement is subject to the provisions of ASC 606 and as of March 31, 2022, none of these amounts have been received by the Company. No initial transaction price

was estimated by management, therefore no revenue was recorded as of March 31, 2022. The Company also concluded that its promises under the EIP License Agreement represented two distinct performance obligations, the first of which is a bundled performance obligation related to the delivery of the license and associated know-how. The second performance obligation relates to the delivery of manufactured product. Additional variable consideration, determined to be allocated entirely to the bundled license performance obligation, to be paid to the Company based upon future regulatory milestones will be recognized as achievement of those milestones. In addition, variable consideration related to any future delivery of product will be recognized in future periods as the product is delivered. As of March 31, 2022, none of these additional amounts were reasonably certain to be achieved due to the nature and timing of the underlying activities.

16. RESTRUCTURING AND RELATED ACTIVITIES

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

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

Balance as of December 31, 2021	$	1,497
Cash payments		(507)
Balance at March 31, 2022	$	990

The Company expects that substantially all of the accrued restructuring costs as of March 31, 2022 will be paid in cash by the end of September 2022.

17. SUBSEQUENT EVENTS

On May 3, 2022, Sesen Bio, Inc., (the "Company") announced that it has initiated a process to review strategic alternatives with the goal of maximizing shareholder value. Potential strategic alternatives to be explored and evaluated during the review process may include the sale of the Company, a merger, acquisition or other business combination, a strategic partnership with one or more parties, or the licensing, sale or divestiture of some of the Company's proprietary technologies. The Company is actively working with an investment bank in this process. Pending any decision to undertake any strategic alternative, the Company is continuing its development activities in accordance with its existing business strategy.

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

The following discussion and analysis of our financial condition and results of operations, as well as other sections in this Quarterly Report on Form 10-Q, should be read in conjunction with our unaudited interim condensed consolidated financial statements and related notes thereto appearing elsewhere herein and our audited annual consolidated financial statements and related notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" for the year ended December 31, 2021, included in our Annual Report on Form 10-K filed with the United States Securities and Exchange Commission ("SEC") on February 28, 2022. In addition to historical financial information, some of the information contained in the following discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended ("Exchange Act"). All statements other than statements of historical facts, including statements regarding our future results of operations and financial position, 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.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions.

The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements about:

- our plans and ability to resolve the issues identified in the complete response letter ("CRL") we received from the US Food and Drug Administration ("FDA") regarding our Biologics License Application ("BLA") for Vicineum™ for the treatment of bacillus Calmette-Guérin ("BCG")-unresponsive non-muscle invasive bladder cancer ("NMIBC");
- our plans and ability to resolve the concerns identified in the European Medicines Agency's ("EMA") Withdrawal Assessment Report related to our marketing authorization application ("MAA") for Vysyneum™ (the "EMA Withdrawal Report");
- our belief that we have a clear understanding of what additional information regarding chemistry, manufacturing and controls ("CMC") is required for potential resubmission of a BLA for Vicineum;
- our ability to utilize Vicineum manufactured during process validation for any future clinical trials needed to address issues raised in the CRL, including an additional Phase 3 clinical trial, and that any such future clinical trials can proceed while addressing CMC issues raised in the CRL;
- our plans to conduct an additional Phase 3 clinical trial for Vicineum for the treatment of NMIBC to address questions related to clinical matters raised in the CRL;
- our plans to further engage the FDA in the coming months to align on the remaining outstanding items related to the additional Phase 3 clinical trial;
- our plans to review strategic alternatives with the goal of maximizing shareholder value
- our plans to continue our development activities in accordance with our existing business strategy pending any decision to undertake any strategic alternative;
- our plans and ability to resubmit a BLA for Vicineum for the treatment of NMIBC to the FDA following the issuance of the CRL by the FDA, and if approved by the FDA, our ability to commercialize Vicineum for the treatment of NMIBC;
- our plans and ability to resume pursuing regulatory approval of Vysyneum™ (the proprietary brand name that was conditionally approved by the EMA for oportuzumab monatox in the European Union) of NMIBC in the European Union when there is more clarity from the FDA on next steps for Vicineum in the US;
- our intentions to work closely with the FDA to understand next steps for Vicineum for the treatment of NMIBC in the US;
- our intentions to work closely with the EMA to understand next steps for Vysyneum for the treatment of NMIBC in the European Union;
- the impact of the completion of the independent internal review completed in February 2022, including any related investigations, reviews or proceedings, shareholder lawsuits or reputational harm;
- the potential impact of the COVID-19 pandemic on our business;
- our expected future loss and accumulated deficit levels;

- the difficulties and expenses associated with obtaining and maintaining regulatory approval of Vicineum for the treatment of NMIBC in the United States, the European Union and other non-US jurisdictions, and the labeling under any approval we may obtain;
- our projected financial position and estimated cash burn rate;
- our belief that we will have sufficient future cash flows from additional geographic regions outside the US to support the value of our goodwill and EU indefinite-lived, acquired in-process research and development ("IPR&D");
- our plans to continue to evaluate timelines for commercialization and probability of success of development of Vicineum for the treatment of NMIBC;
- our estimations regarding any remeasurement of contingent consideration liability in the future;
- our estimations regarding any potential impairment to our goodwill and indefinite-lived intangible asset in the future;
- our estimates regarding expenses, future revenues, capital requirements and needs for, and ability to obtain, additional financing;
- our need to raise substantial additional capital to fund our operations;
- the success, cost and timing of our pre-clinical studies and clinical trials in the United States and other non-US jurisdictions;
- the timing and costs associated with our manufacturing process and technology transfer to Qilu Pharmaceutical Co., Ltd. (“Qilu”) for the production of Vicineum drug substance and drug product, and our reliance on Qilu to perform under our agreement with Qilu;
- the size and growth of the potential markets for our product candidates, and our ability to serve those markets;
- our ability to obtain and maintain intellectual property protection for our product candidates and our proprietary technology;
- our strategic operating plan to sublicense Vicineum for the treatment of NMIBC to business development partners in all regions outside the US, including the European Union, to earn a potential combination of upfront, milestone, and royalty payments, and the business development partner to bear the majority of regulatory and commercialization costs;
- our belief that the probability of success of future approval in the European Union for Vysyneum increases if FDA approval for Vicineum has already been obtained;
- our beliefs regarding key advantages of our targeted fusion protein therapeutics (“TFPT”) platform;
- our expectation that Vicineum may work via a dual mechanism of action to directly kill cancer cells and activate a local inflammatory process that stimulates T-cells, which then proliferate and destroy the cancer cells;
- our expectation that there may be potential for a synergistic effect when Vicineum is given in combination with checkpoint inhibitors; and
- our expectations regarding the amount and timing of milestone and royalty payments pursuant to our out-license agreements and OUS business development partnership agreements, including our license agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (collectively, “Roche”), (the “Roche License Agreement”) and our exclusive license agreement with Qilu for the development, manufacture and commercialization of Vicineum in China, Hong Kong, Macau and Taiwan ("Greater China").

The forward-looking statements in this Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q and involve known and unknown risks, uncertainties, assumptions and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, among others, the following:

- we may need to raise substantial additional capital to fund our operations;
- we may not be able to resolve the issues raised in the CRL we received from the FDA regarding our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC;
- we may not be able to resolve the concerns identified in the EMA Withdrawal Assessment Report;
- we may not determine a viable path forward for continued clinical development of Vicineum, which would prevent us from resubmitting a BLA for Vicineum;
- we may not be successful in identifying one or more strategic alternatives or ultimately pursuing a strategic alternative that delivers the anticipated benefits or enhances shareholder value;

- our exploration and evaluation of strategic alternatives or the public announcement thereof may be disruptive to our business operations or cause our stock price to fluctuate significantly;
- we may not achieve profitable operations or access needed capital;
- we may experience delays or difficulties related to the continued clinical development of Vicineum for the treatment of NMIBC, including delays in clinical trial sites receiving the supplies and materials needed to conduct clinical trials, difficulty in establishing or managing relationships with contract research organizations ("CROs"), difficulties in recruiting clinical site investigators and clinical site staff and difficulties in enrolling patients or treating patients in active trials due to COVID-19 or otherwise;
- clinical trials of Vicineum for the treatment of NMIBC, including an additional Phase 3 clinical trial for Vicineum, or any of our other product candidates, may not demonstrate safety and efficacy to the satisfaction of the FDA, EMA or other non-US regulatory authorities or otherwise produce favorable results;
- we may not obtain marketing approval of Vicineum for the treatment of NMIBC in the United States, the European Union or other non-US jurisdictions;
- Vicineum may not gain market acceptance for the treatment of NMIBC in the United States, the European Union or other non-US jurisdictions;
- the market opportunity for Vicineum may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed;
- we may experience issues or delays with third-party disposition, labelling and packaging of clinical supply of Vicineum;
- our competitors may discover, develop or commercialize products before, or more successfully than, we do;
- we may be unable to obtain, maintain, defend and enforce patent claims and other intellectual property rights;
- we may be unable to defend against pending or threatened litigation, which may be costly and time-consuming;
- we may fail to comply with all regulatory requirements or experience unanticipated problems with our products;
- we may recognize impairment of our goodwill and indefinite-lived intangible asset;
- we may not meet the Nasdaq minimum bid price requirement during any compliance period or in the future;
- we may not be granted relief from delisting from Nasdaq if necessary; and
- such other factors described throughout Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations in this Quarterly Report on Form 10-Q and throughout Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and in Part I, Item 1A. Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2021.

Our product candidates are investigational biologics undergoing clinical development and have not been approved by the FDA, EMA or other comparable non-US regulatory authorities. On August 13, 2021, we received a CRL from the FDA indicating that the FDA had determined that it could not approve the BLA for Vicineum in its present form. On August 20, 2021, we withdrew our MAA to the EMA for Vysyneum for the treatment of BCG-unresponsive NMIBC in order to pause our plans to pursue regulatory approval of Vysyneum in the European Union until there is more clarity from the FDA on next steps for Vicineum in the United States. In October and December 2021, we participated in a CMC Type A meeting and a Clinical Type A meeting, respectively, with the FDA to discuss issues raised in the CRL and design elements of an additional Phase 3 clinical trial for Vicineum, which the FDA confirmed will be required for a potential resubmission of a BLA. 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 for potential resubmission of a BLA for Vicineum for the treatment of NMIBC. We plan to further engage the FDA in the coming months to align on the remaining outstanding items related to the additional Phase 3 clinical trial. On May 3, 2022, we announced that we have initiated a process to review strategic alternatives with the goal of maximizing shareholder value. Potential strategic alternatives to be explored and evaluated during the review process may include the sale of our company, a merger, acquisition or other business combination, a strategic partnership with one or more parties, or the licensing, sale or divestiture of some of our proprietary technologies. We are actively working with an investment bank in this process. Pending any decision to undertake any strategic alternative, we are continuing our development activities in accordance with our existing business strategy.

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. 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. 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 Quarterly Report on Form 10-Q to the "Company," "Sesen," "we," "us," and "our" include Sesen Bio, Inc. and its subsidiaries.

Overview

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

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

Regulatory Update

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

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

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

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

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

On March 28, 2022, we participated in a Type C meeting with the FDA. During the meeting, the FDA agreed to a majority of our proposed protocol and statistical analysis plan design elements for an additional Phase 3 clinical trial for potential resubmission of a BLA for Vicineum for the treatment of NMIBC. We plan to further engage the FDA in the coming months to align on the remaining outstanding items related to the additional Phase 3 clinical trial.

Prior Phase 3 Clinical Trial – VISTA Trial

In the third quarter of 2015 in the United States and Canada, through our subsidiary Viventia, we commenced our single-arm, multi-center, open-label Phase 3 clinical trial ("VISTA Trial") in patients with BCG-unresponsive NMIBC who have received adequate BCG and whose disease is now BCG-unresponsive, and for whom the then-current standard of care was a radical cystectomy. Based on safety and efficacy data observed with the longer 12-week induction in our Phase 2 clinical trial, the FDA agreed to our plan to employ more frequent dosing in the VISTA Trial, in which the primary endpoints were complete response ("CR") and duration of response ("DoR") in patients with CIS whose disease is BCG-unresponsive. In November 2016, the FDA issued draft guidance regarding appropriate clinical trial design for new drugs and biologics for BCG-unresponsive NMIBC, including the use of single-arm trials. The FDA finalized this guidance in February 2018 and retained many of the recommendations from the 2016 draft guidance regarding clinical trial design, including the use of single-arm trials. We believe that our VISTA Trial design was consistent with these aspects of the FDA's guidance.

The VISTA Trial completed enrollment in April 2018 with a total of 133 patients across three cohorts based on histology and time to disease recurrence after adequate BCG treatment:

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

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

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

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

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

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

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

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

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

Pooled Cohorts 1 and 2 (n=93) Evaluable Population (n=89) Complete Response Rate, for CIS:

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

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

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

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

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

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

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

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

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

We have conducted additional analyses for secondary endpoints. These additional data include the following:

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

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

Safety Results

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

Manufacturing

In October 2018, we entered into a Master Bioprocessing Services Agreement with Fujifilm (the "Fujifilm MSA") for the manufacturing process and technology transfer of Vicineum drug substance production.

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

In August 2020, we completed manufacturing of the drug substance process performance qualification (“PPQ”) batches at Fujifilm and in September 2020, we successfully completed the drug product PPQ batches at Baxter. All of the completed drug substance PPQ batches and drug product PPQ batches met all quality acceptance criteria.

In December 2020, we received and analyzed all of the analytical comparability test results from the drug substance and drug product PPQ batches. For analytical comparability, we conducted testing across four categories: release testing, biophysical characterization, forced degradation studies, and stability studies. This approach is in alignment with requirements of the FDA, the EMA and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. The test results for Vicineum produced by Fujifilm and Baxter were found to be comparable to supply of Vicineum manufactured at our Winnipeg facility for the VISTA trial.

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

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

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

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

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

Greater China

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

During 2020, we received a total of $10 million in net proceeds associated with the Qilu License Agreement. We are also entitled to receive up to an additional $23 million upon the achievement of certain technology transfer, development and regulatory milestones, as well as a 12% royalty based upon annual net sales of Vicineum in Greater China. The royalties are payable upon the first commercial sale of Vicineum in a region and continuing until the latest of (i) twelve years after the first commercial sale of Vicineum in such region, (ii) the expiration of the last valid patent claim covering or claiming the composition of matter, method of treatment, or method of manufacture of Vicineum in such region, and (iii) the expiration of regulatory or data exclusivity for Vicineum in such region. The royalty rate is subject to reduction under certain circumstances,

including when there is no valid claim of a licensed patent that covers Vicineum in a particular region or no data or regulatory exclusivity of Vicineum in a particular region.

The Investigational New Drug application ("IND") for Vicineum submitted by Qilu to the Center for Drug Evaluation of the China National Medical Products Administration was accepted for review in January 2021 and approved in March 2021, resulting in a $3 million milestone payment from Qilu, the first milestone payment out of the $23 million in potential milestone payments. We recorded $2.8 million (net of VAT) as license revenue during the three-month period ended March 31, 2021.

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

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

MENA

On November 30, 2020, we and our wholly owned subsidiary, Viventia Bio, Inc., entered into an exclusive license agreement with Hikma Pharmaceuticals LLC, to develop and commercialize Vicineum for the treatment of BCG-unresponsive NMIBC in MENA region (20 countries in Middle East and North Africa) (the "MENA License Agreement"). In consideration for the rights granted by us, Hikma agreed to pay to us an upfront payment, sales related milestones payments, and royalties on net sales in the MENA region for the term of the Hikma License Agreement.

Turkey

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

Internal Review

On February 25, 2022, we announced the completion of an independent internal review initiated by our board of directors (the "Board") and conducted by outside counsel with the assistance of subject matter experts focusing on the conduct of, and data generated from, the clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC, and the overall safety of Vicineum (the "Review"). The Review took place over the course of five months, involved full cooperation from our management team, a review of more than 600,000 documents, and 39 interviews of current and former employees and consultants. As a result of the Review, the Board continues to fully support our current management team and believes no changes or amendments relating to our prior disclosures to the SEC or the FDA relating to Vicineum, the Phase 3 VISTA trial for Vicineum for the treatment of BCG-unresponsive NMIBC, or the BLA for Vicineum are warranted.

Review of Strategic Alternatives

On May 3, 2022, we announced that we have initiated a process to review strategic alternatives with the goal of maximizing shareholder value. Potential strategic alternatives to be explored and evaluated during the review process may include the sale of our company, a merger, acquisition or other business combination, a strategic partnership with one or more parties, or the licensing, sale or divestiture of some of our proprietary technologies. We are actively working with an investment bank in this process. Pending any decision to undertake any strategic alternative, we are continuing its development activities in accordance with our existing business strategy.

Components of Our Results of Operations

License and Related Revenue

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

Research and Development

Research and development expenses consist primarily of costs incurred for the development of Vicineum for the treatment of NMIBC, which include:

- employee-related expenses, including salaries, benefits, travel and share-based compensation expense;
- expenses incurred under agreements with CROs and investigative sites that conduct our clinical trials, including the additional Phase 3 clinical trial for Vicineum for the treatment of NMIBC;
- expenses associated with developing manufacturing capabilities;
- expenses associated with transferring manufacturing capabilities to contract manufacturing organizations ("CMOs") for commercial-scale production;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies;
- expenses associated with regulatory activities; and
- expenses associated with license milestone fees.

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

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

- the scope, progress, outcome and costs of our clinical trials, including the additional Phase 3 clinical trial, and other research and development activities;
- the efficacy and potential advantages of Vicineum for the treatment of NMIBC compared to alternative treatments, including any standard of care;
- the market acceptance of Vicineum for the treatment of NMIBC;
- the cost and timing of the implementation of commercial-scale manufacturing of Vicineum;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation;
- the impact of the COVID-19 pandemic; and
- the timing, receipt and terms of any marketing approvals.

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

We allocate direct research and development expenses, consisting principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical trials, costs related to manufacturing or purchasing clinical trial materials and technology transfer and license milestone fees, to specific product programs. We do not allocate employee and contractor-related costs, costs associated with our platform and facility expenses, including depreciation or other indirect costs, to specific product programs because these costs may be deployed across multiple product programs under research and development and, as such, are separately classified. The table below provides research and development expenses incurred for Vicineum for the treatment of NMIBC and other expenses by category. We have deferred further development of Vicineum for the treatment of SCCHN and VB6-845d in order to focus our efforts and our resources on our ongoing development and, if approved, commercialization of Vicineum for the treatment of NMIBC.

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

	Three Months Ended March 31,	
	2022	2021
Programs:		
Vicineum for the treatment of NMIBC	$ 1,461	$ 3,566
Total direct program expenses	1,461	3,566
Personnel and other expenses:		
Employee and contractor-related expenses	2,966	2,271
Platform-related lab expenses	73	50
Facility expenses	154	125
Other expenses	106	66
Total personnel and other expenses	3,299	2,512
Total Research and Development	**$ 4,760**	**$ 6,078**

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, legal, 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, and pre-commercial United States market research.

Change in Fair Value of Contingent Consideration

In connection with the Viventia Acquisition in September 2016, we recorded contingent consideration pertaining to the amounts potentially payable to Viventia's shareholders pursuant to the terms of the Share Purchase Agreement among us, Viventia and the other signatories thereto and are based on regulatory approval in certain markets and future revenue levels. The fair value of contingent consideration is assessed at each balance sheet date and changes, if any, to the fair value are recognized in earnings (or loss) for the period.

Other Income, Net

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

Provision for Income Taxes

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

Our Results of Operations

Comparison of the three months ended March 31, 2022 and 2021

	Three Months Ended March 31,		Increase/(Decrease)	
	2022	2021	Dollars	Percentage
	(in thousands, except percentages)			
Revenue:				
License and related revenue	$ —	$ 4,310	$ (4,310)	(100) %
Total revenue	—	4,310	(4,310)	(100) %
Operating expenses:				
Research and development	$ 4,760	$ 6,078	$ (1,318)	(22) %
General and administrative	8,975	5,293	3,682	70 %
Change in fair value of contingent consideration	(12,900)	48,160	(61,060)	(127) %
Total operating expenses	835	59,531	(58,696)	(99) %
Loss from Operations	(835)	(55,221)	54,386	(98) %
Other income (expense), net	28	(3)	31	(1,033) %
Loss Before Taxes	**(807)**	**(55,224)**	**54,417**	**(99)%**
Provision for income taxes	—	(288)	288	(100) %
Net Loss and Comprehensive Loss After Taxes	**$ (807)**	**$ (55,512)**	**$ 54,705**	**(99)%**

License Revenue

We did not record any revenue for the three months ended March 31, 2022. Revenue for the three months ended March 31, 2021 was $4.3 million, which was due to the recognition of revenue resulting from the delivery of the performance obligations under our agreement with our partner in MENA, and achieving the IND milestone in China pursuant to the Qilu License Agreement.

Research and Development

Research and development expenses were $4.8 million for the three months ended March 31, 2022, compared to $6.1 million for the three months ended March 31, 2021. The decrease of $1.3 million was primarily due to lower costs associated with technology transfer and manufacturing ($1.4 million), regulatory and clinical consulting fees ($0.6 million) and license milestone fees ($0.6 million), which were partially offset by increases in employee-related compensation, primarily driven by increased headcount and the retention program implemented in the fourth quarter of 2021, ($1.2 million) and other R&D expenses ($0.1 million). We anticipate that R&D expenses may increase in 2022 due to costs related to the additional Phase 3 clinical trial for Vicineum for the treatment of NMIBC.

General and Administrative

General and administrative expenses were $9.0 million for the three months ended March 31, 2022, compared to $5.3 million for the three months ended March 31, 2021. The increase of $3.7 million was primarily due to increases in legal expenses related, in part, to the independent internal review completed in February 2022 ($3.0 million), employee-related compensation ($1.1 million), primarily driven by increased headcount and the retention program implemented in the fourth quarter of 2021, insurance expense ($0.1 million) and other general expenses ($0.2 million). This was partially offset by a decrease in consultant fees incurred in preparation for commercial launch as a result of the subsequent CRL received in August 2021 ($0.7 million).

Change in Fair Value of Contingent Consideration

The non-cash change in fair value of contingent consideration was income of $12.9 million for the three months ended March 31, 2022, compared to a loss of $48.2 million for the three months ended March 31, 2021. The decrease in the fair value of contingent consideration of $12.9 million for the three months ended March 31, 2022 was driven by changes in underlying assumptions used to develop the revenue projections. 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 for potential resubmission of a BLA for Vicineum for the treatment of NMIBC. We also learned during the meeting that the FDA is trending away from accepting single arm trials across therapeutic areas, including NMIBC, and has a strong preference for randomized controlled trials. We plan to further engage the FDA in the coming months to align on the remaining outstanding items related to the additional Phase 3 clinical trial. Incorporating the FDA feedback from the Type C meeting, plans for further discussions with the FDA prior to initiation of the additional Phase 3 clinical trial, as well as updates to the competitive landscape, we reassessed the underlying assumptions used to develop our revenue projections upon which the fair value of our contingent consideration is based. The most significant and impactful assumptions in our revenue projection models are timing of potential commercial product launch, probabilities of clinical and regulatory success, and market share. We anticipate further delays in the start of commercialization due to the likelihood of the requirement to conduct a randomized controlled trial which will require more patients to be enrolled, lengthen the duration of the study, and increase study costs. We are also projecting lower estimated market share as a result of recent clinical and regulatory progress made by competitors. We have assessed a commercialization timeline assumption and applied a probability to each outcome based on management's best estimate. In addition, we continue to assume a POS in achieving certain clinical and regulatory milestones in the range of approximately 45% to 55% globally. Any changes in these assumptions and estimates, or other information obtained, may have a significant impact on the remeasurement of the contingent consideration liability in the future.

The change in fair value of contingent consideration was a loss of $48.2 million for the three months ended March 31, 2021. This was primarily attributable to changes in the competitive landscape, higher probability of regulatory success, expanded patient population, and to a lesser extent by refinement of timelines in certain markets outside the United States, which was prior to the receipt of a CRL from the FDA.

Provision for Income Taxes

No provision for income taxes was recorded for the three months ended March 31, 2022. For the three months ended March 31, 2021, we recorded a provision for income taxes of $0.3 million. This provision consisted of income taxes paid to non-US jurisdictions pursuant to our commercialization partnership agreements.

Liquidity and Capital Resources

Overview

As of March 31, 2022, we had cash and cash equivalents of $169.8 million, net working capital of $172.2 million and an accumulated deficit of $317.1 million. We generated cash flows from operating activities of $7.2 million for the three months ended March 31, 2022 compared to negative cash flows of $18.5 million for the three months ended March 31, 2021. We believe that our cash and cash equivalents of $169.8 million as of March 31, 2022, are sufficient to fund our operating plan into the fourth quarter of 2024. Our forecasted cash runway is based upon our current business plan, however if an alternative plan is enacted, this runway could vary materially.

Since our inception, we have received no revenue from sales of our products, and we anticipate that operating losses will continue for the foreseeable future as we seek to address the issues raised in the CRL we received for our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC and the concerns identified in the EMA Withdrawal Assessment Report, complete an additional Phase 3 clinical trial for Vicineum for the treatment of NMIBC, and seek marketing approval from the FDA and the European Commission and, if approved, commercialize Vicineum, or in connection with any strategic alternatives that we may pursue. We have financed our operations to date primarily through private placements of our common stock, preferred stock, common stock warrants and convertible bridge notes, venture debt borrowings, our IPO, follow-on public offerings, sales effected in ATM offerings, our OUS business development partnerships and license agreements and, to a lesser extent, from a collaboration.

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 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 March 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 Global 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 three months ended March 31, 2022. We raised $72.6 million of net proceeds from the sale of 30.6 million shares of common stock at a weighted-average price of $2.44 per share during the three months ended March 31, 2021. Share issue costs, including sales agent commissions, related to the ATM Offering totaled $2.2 million for the three months ended March 31, 2021.

We continue to monitor the effect of the outbreak of COVID-19. We are proactively executing risk mitigation strategies to attenuate the impact of COVID-19 on us, and at this time, we have not yet experienced any business disruptions as a result of the pandemic. We are continually assessing the effect of the COVID-19 pandemic on our operations, and we are monitoring the spread of COVID-19 and the actions implemented to combat the virus throughout the world.

Funding Requirements

Our future success is dependent on our ability to develop and, if approved, commercialize our product candidates, including Vicineum for the treatment of NMIBC, and ultimately upon our ability to attain profitable operations. In order to commercialize our product candidates, including Vicineum, we need to complete clinical development and comply with comprehensive regulatory requirements. Additionally, we have announced that we have initiated a process to review strategic alternatives with the goal of maximizing shareholder value. Potential strategic alternatives to be explored and evaluated during the review process may include the sale of our company, a merger, acquisition or other business combination, a strategic partnership with one or more parties, or the licensing, sale or divestiture of some of our proprietary technologies. We are actively working with an investment bank in this process. Pending any decision to undertake any strategic alternative, we are continuing our development activities in accordance with our existing business strategy. Potential strategic alternatives to be explored and evaluated during the review process may include the sale of our company, a merger, acquisition or other business combination, a strategic partnership with one or more parties, or the licensing, sale or divestiture of some of our proprietary technologies. We are actively working with an investment bank in this process. Pending any decision to undertake any strategic alternative, we are continuing our development activities in accordance with our existing business strategy.

We are subject to a number of risks similar to other late-stage clinical companies, including, but not limited to, successful discovery and development of our product candidates, raising additional capital, development and commercialization by our competitors of new technological innovations, protection of proprietary technology and market acceptance of our products. The successful discovery, development and, if approved, commercialization of product candidates, including Vicineum for the treatment of NMIBC, requires substantial working capital, and we expect to seek additional funds through equity or debt financings or through additional OUS business development partnerships, collaborations, licensing transactions or other sources. We may be unable to obtain equity or debt financings or enter into additional OUS business development partnerships, collaborations, or licensing transactions at favorable terms, or at all, and, if necessary, we may be required to implement cost reduction strategies.

We will incur substantial expenses if and as we:

- address the issues identified in the CRL we received from the FDA for our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC and the concerns identified in the EMA Withdrawal Assessment Report, including the completion of an additional Phase 3 clinical trial;
- seek marketing approvals for Vicineum for the treatment of NMIBC;
- establish and implement sales, marketing and distribution capabilities and scale up and validate external manufacturing capabilities (including completing the manufacturing process and technology transfer to any third-party manufacturers) to commercialize Vicineum for the treatment of NMIBC, if approved;
- maintain, expand and protect our intellectual property portfolio;
- add equipment and physical infrastructure to support our research and development;
- hire additional clinical, regulatory, quality control, scientific and management personnel;
- expand our operational, financial and management systems and personnel;
- conduct research and pre-clinical and clinical development of Vicineum for the treatment of NMIBC and our other product candidates;
- explore, evaluate and pursue any strategic alternatives in connection with the review process we have initiated;
- seek to discover and develop additional product candidates; and
- in-license or acquire the rights to other products, product candidates or technologies.

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

- the scope, initiation, progress, timing, costs and results of pre-clinical development and laboratory testing and clinical trials for Vicineum for the treatment of NMIBC and our other product candidates, including an additional Phase 3 clinical trial for Vicineum for the treatment of NMIBC;
- the outcome of any pending or future litigation involving us or our business;
- the outcome of the process we have initiated to review strategic alternatives, which may include the sale of our company, a merger, acquisition or other business combination, a strategic partnership with one or more parties, or the licensing, sale or divestiture of some of our proprietary technologies;
- the ongoing COVID-19 pandemic and its impact on our business;
- our ability to establish additional OUS business development partnerships, collaborations, or licensing arrangements on favorable terms, if at all, particularly manufacturing, marketing and distribution arrangements for our product candidates;
- the costs and timing of the implementation of commercial-scale manufacturing activities;
- the costs and timing of establishing and implementing sales, marketing and distribution capabilities for Vicineum for the treatment of NMIBC, if approved;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- our obligation to make milestone, royalty and other payments to third-party licensors under our licensing agreements;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- the outcome, timing and cost of regulatory review by the FDA, EMA, and comparable non-US regulatory authorities for Vicineum for the treatment of NMIBC, including the potential for the FDA or comparable non-US regulatory authorities to require that we perform more studies than those that we currently expect to perform;
- our ability to achieve certain future regulatory, development and commercialization milestones under our out-license and OUS business development partnership agreements;
- the effect of competing technological and market developments; and
- the revenue, if any, received from commercial sales of Vicineum for the treatment of NMIBC, if approved.

Until such time, if ever, as we can generate substantial product revenues from commercial sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or other third-party funding, strategic OUS business development partnerships, alliances, and licensing arrangements. We do not have any committed external source of funds other than the amounts payable under our out-license and OUS business development partnership agreements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include liens or other restrictive covenants limiting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third-party funding, strategic OUS business development partnerships, alliances or licensing arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

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

Contractual and Other Obligations

For information related to our cash requirements from known contractual and other obligations, see the description of Contingent Consideration in Note 5 “Fair Value Measurement and Financial Instruments,” as well as the description of our leases in Note 10 “Leases”, and the description of our license agreement and collaborations in Note 15, “License Agreements” of Part I - Item 1. Financial Statements - Notes to Condensed Consolidated Financial Statements.

Cash Flows

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

	Three Months Ended March 31,	
	2022	2021
Net Cash Provided By (Used in) Operating Activities	$ 7,154	$ (18,475)
Net Cash Used in Investing Activities	—	—
Net Cash Provided by Financing Activities	—	73,051
Net Increase in Cash, Cash Equivalents and Restricted Cash	**$ 7,154**	**$ 54,576**

Net Cash Provided By (Used in) Operating Activities

Net cash provided by operating activities was $7.2 million for the three months ended March 31, 2022 and consisted primarily of the $20.0 million milestone payment received from Roche for initiating a Phase II clinical trial in the fourth quarter of 2021 and the receipt of $2.4 million related to German VAT recovery, related to drug substance sent to Baxter. This was partially offset by adjustments for non-cash items including, share-based compensation of $1.9 million, a decrease in the fair value of contingent consideration of $12.9 million and a net decrease in operating assets and liabilities of $19.0 million.

Net cash used in operating activities was $18.5 million for the three months ended March 31, 2021 and consisted primarily of a net loss of $55.5 million, which includes $4.3 million of revenue recognized pursuant to the Qilu Agreement, adjusted for non-cash items, including share-based compensation of $1.0 million, an increase in the fair value of contingent consideration of $48.2 million and a net decrease in operating assets and liabilities of $12.1 million

Net Cash Used in Investing activities

Net cash used in investing activities consisted of de minimis purchases and sales or property and equipment during the three months ended March 31, 2022 and 2021.

Net Cash Provided by Financing activities

Net cash provided by financing activities was de minimis for the three months ended March 31, 2022.

Net cash provided by financing activities was $73.1 million for the three months ended March 31, 2021 and consisted of $72.6 million net proceeds from the sale of common stock under the ATM Offering and $0.5 million in proceeds from the exercise of common stock warrants.

Critical Accounting Policies and Use of Estimates

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

Fair Value of Indefinite-Lived Intangible Assets

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

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

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 for potential resubmission of a BLA for Vicineum for the treatment of NMIBC. We plan to further engage the FDA in the coming months to align on the remaining outstanding items related to the additional Phase 3 clinical trial. Based on the outcome of the Type C meeting as well as updates to the competitive landscape, we reassessed the underlying assumptions used to develop our revenue projections, which were then used as significant inputs to determine the fair value of the indefinite-lived intangible asset. Management updated the revenue forecast models based on further launch delays in both US and OUS regions as well as slightly lower market share. Accordingly, we identified this as a potential impairment indicator and performed an interim quantitative impairment assessment. We concluded that the carrying value of our intangible asset of Vicineum EU rights was not impaired as of March 31, 2022.

Goodwill

Goodwill on our condensed 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. 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 for potential resubmission of a BLA for Vicineum for the treatment of NMIBC. We plan to further engage the FDA in the coming months to align on the remaining outstanding items related to the additional Phase 3 clinical trial. Based on the outcome of the Type C meeting as well as updates to the competitive landscape, we reassessed the underlying assumptions used to develop the revenue projections, which were then used as significant inputs to determine the fair value of equity. Management updated the revenue forecast models based on further launch delays in both US and OUS regions as well as slightly lower market share. Accordingly, we identified these changes to the revenue forecast, as well as the decline in our stock price and market capitalization during the first quarter of 2022, as potential impairment indicators and performed a quantitative impairment analysis during the first quarter of 2022, in advance of our typical annual assessment date of October 1. We concluded that the carrying value of its goodwill of $13.1 million was not impaired as of March 31, 2022, with the fair value of equity of the reporting unit exceeding the estimated carrying value of the reporting unit by approximately 29%. While our stock price has declined since December 31, 2021, this is consistent with the general biotech sector overall, as world economic conditions continue to be impacted by the COVID-19 pandemic and Russia's invasion of Ukraine. We believe that we have sufficient future cash flows from additional geographic regions outside the US to support the value of goodwill. We project future cash flows based on various timeline assumptions and apply a probability to each outcome based on management's best estimate. In addition, probabilities of success in achieving certain clinical and regulatory success can also have a material effect on the estimated fair value of the equity of its reporting unit as of the impairment assessment date. We will continue to evaluate timelines for commercialization and probability of success of development of Vicineum for the treatment of NMIBC. Further reductions to probabilities of success, decrease in market share, additional development and commercial launch delays, increases in underlying discount rates, a prolonged decline in the Company's market capitalization as compared to its carrying value, or any decision to undertake any strategic alternative as a result of the review process that we have initiated, have the potential to result in future goodwill impairment.

Contingent Consideration

Contingent consideration on our condensed 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. Contingent consideration is measured at its estimated fair value on a recurring basis at each reporting period, with fluctuations in value resulting in a non-cash charge to earnings (or loss) during the period. The estimated fair value measurement is based on significant unobservable inputs (Level 3 within the fair value hierarchy), including internally developed financial forecasts, probabilities of success and timing of certain milestone events and achievements, which are unpredictable and inherently uncertain. Actual future cash flows may differ from the assumptions used to estimate the fair value of contingent consideration. The valuation of contingent consideration requires the use of significant assumptions and judgments, which management believes are consistent with those that would be made by

a market participant. Management reviews its assumptions and judgments on an ongoing basis as additional market and other data is obtained, and any future changes in the assumptions and judgments utilized by management may cause the estimated fair value of contingent consideration to fluctuate materially, resulting in earnings volatility. In 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 for potential resubmission of a BLA for Vicineum for the treatment of NMIBC. We also learned during the meeting that the FDA is trending away from accepting single arm trials across therapeutic areas, including NMIBC, and has a strong preference for randomized controlled trials. We plan to further engage the FDA in the coming months to align on the remaining outstanding items related to the additional Phase 3 clinical trial. Incorporating the FDA feedback from the Type C meeting, plans for further discussions with the FDA prior to initiation of the additional Phase 3 clinical trial, as well as updates to the competitive landscape, we reassessed the underlying assumptions used to develop the revenue projections upon which the fair value of our contingent consideration is based. The most significant and impactful assumptions in our revenue projection models are timing of product launch and probabilities of clinical and regulatory success, and market share. We anticipate further delays in the start of commercialization due to the likelihood of the requirement to conduct a randomized controlled trial which will require more patients to be enrolled, lengthen the duration of the study, and increase study costs. The company is also projecting lower estimated market share as a result of recent clinical and regulatory progress made by competitors. We have assessed a range of commercialization timeline assumptions and applied a probability to each outcome based on management's best estimate. We continue to assume a POS in achieving certain clinical and regulatory milestones in the range of approximately 45% to 55% globally. Any changes in these assumptions and estimates, or other information obtained, may have a significant impact on the remeasurement of the contingent consideration liability in the future. The fair value of our 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 our estimated weighted-average cost of capital, which has fluctuated from 9.3% as of December 31, 2021 to 9.0% as of March 31, 2022. Milestone payments constitute debt-like obligations, and therefore a high-yield debt index rate is applied to the milestones in order to determine the estimated fair value. This index rate changed from 8.0% as of December 31, 2021 to 9.7% as of March 31, 2022.

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 and research and development credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. A valuation allowance is recorded to the extent it is more likely than not that some portion or all of the deferred tax assets will not be realized.

Unrecognized income tax benefits represent income tax positions taken on income tax returns that have not been recognized in the financial statements. We recognize the benefit of an income tax position only if it is more likely than not (greater than 50%) that the tax position will be sustained upon tax examination, based solely on the technical merits of the tax position. Otherwise, no benefit is recognized. The tax benefits recognized are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. We recognize accrued interest and penalties related to uncertain tax positions as income tax expense in our condensed consolidated statements of operations. As of March 31, 2022 and December 31, 2021, we did not have any uncertain tax positions.

Research and Development Costs

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

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

Recently Issued Accounting Standards

Recently issued accounting standards are discussed in "Item 1. Financial Statements - Notes to Condensed Consolidated Financial Statements - Note 4. Recent Accounting Pronouncements" of this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures, as defined in Exchange Act Rules 13a-15(e) and 15d-15(e), that are designed to ensure information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principle financial officer, to allow timely decisions regarding required disclosure.

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 Quarterly Report on Form 10-Q. 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 March 31, 2022.

Limitations on Effectiveness of Controls and Procedures

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.

Changes in Internal Control Over Financial Reporting

During the three months ended March 31, 2022, there were no changes in our internal control over financial reporting, as defined in Exchange Act Rules 13a-15(f) and 15d-15(f), which materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

On August 19, 2021, August 31, 2021, and October 7, 2021, three substantially identical securities class action lawsuits captioned Bibb v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-07025, Cizek v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-07309 and Markman v. Sesen Bio, Inc. et al., Case No. 1:21-cv-08308 were filed against us and certain of our officers in the US District Court for the Southern District of New York. The three complaints 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 November 1, 2021, two stockholders filed motions to reconsider asking the court to appoint a different lead plaintiff. The court has not ruled on those motions at this time. On November 24, 2021, defendants filed a motion to transfer venue to the US District Court for the District of Massachusetts. That motion was fully briefed as of December 13, 2021, but the court has not yet ruled on that motion. On December 6, 2021, the Lead Plaintiffs filed an amended class action complaint (the "Amended Complaint"). The Amended Complaint alleges the same violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder on the same theory as the prior complaints. The defendants moved to dismiss the Amended Complaint on March 7, 2022. The plaintiffs filed their opposition to that motion on April 6, 2022 and Defendants filed their reply in further support of the motion to dismiss on May 6, 2022. The court has not yet ruled on the motion.

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

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

Item 1A. Risk Factors.

During the three months ended March 31, 2022, other than as set forth below, there were no material changes to the "Risk Factors" included in our Annual Report on Form 10-K for the year ended December 31, 2021. You should carefully consider the information described therein and in this Quarterly Report on Form 10-Q, which could materially affect our business condition, results of operations and cash flows.

Our exploration of strategic alternatives may not result in entering into or completing a transaction, and the process of reviewing strategic alternatives or its conclusion could adversely affect our business and our stock price.

We have initiated a process to review strategic alternatives with the goal of maximizing shareholder value. Potential strategic alternatives to be explored and evaluated during the review process may include the sale of our company, a merger, acquisition or other business combination, a strategic partnership with one or more parties, or the licensing, sale or divestiture of some of our proprietary technologies. We are actively working with an investment bank in this process. Pending any decision to undertake any strategic alternative, we are continuing our development activities in accordance with our existing business strategy.

Any potential transaction would be dependent on a number of factors that may be beyond our control, including, among other things, market conditions, industry trends, the interest of third parties in a potential transaction with us and the availability of financing to us or third parties in a potential transaction with us on reasonable terms. The process of reviewing strategic alternatives may be time consuming and disruptive to our business operations and may involve the dedication of significant resources and may require us to incur significant costs and expenses. It could divert the attention of management and our board of directors from our business, negatively impact our ability to attract, retain and motivate key employees, and expose us to potential litigation in connection with this process or any resulting transaction. If we are unable to effectively manage the process, our business, financial condition and results of operations could be adversely affected. In addition, speculation regarding any developments related to the review of strategic alternatives and perceived uncertainties related to the future of our company could cause our stock price to fluctuate significantly. Further, any strategic alternative that may be pursued and completed ultimately may not deliver the anticipated benefits or enhance shareholder value. There can be no guarantee that the process of evaluating strategic alternatives will result in our company entering into or completing a potential transaction, and we have not set a timetable for the completion of this review process.

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

We did not issue any unregistered equity securities during the three months ended March 31, 2022.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Index

Exhibit No.	Description
2.1	Share Purchase Agreement, effective as of September 20, 2016, by and between Eleven Biotherapeutics, Inc., Viventia Bio Inc. and Clairmark Investments Ltd., as representative of the selling shareholders (we hereby agree to furnish supplementally a copy of any omitted schedules to the SEC upon request). Incorporated by reference to Exhibit 2.1 to our Current Report on Form 8-K filed on September 21, 2016 (File No. 001-36296).
3.1	Restated Certificate of Incorporation of Eleven Biotherapeutics, Inc. Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed on February 18, 2014 (File No. 001-36296).
3.2	Certificate of Amendment of Certificate of Incorporation. Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed on May 17, 2018 (File No. 001-36296).
3.3	Certificate of Amendment of Certificate of Incorporation. Incorporated by reference to Exhibit 3.3 to our Quarterly Report on Form 10-Q filed on May 10, 2021 (File No. 001-36296).
3.4	Amended and Restated By-Laws. Incorporated by reference to Exhibit 3.2 to our Current Report on Form 8-K filed on May 17, 2018 (File No. 001-36296).
4.1	Specimen Stock Certificate evidencing the shares of common stock. Incorporated by reference to Exhibit 4.1 to our Registration Statement on Form S-1/A filed on January 23, 2014 (Reg. No. 333-193131).
4.2	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).
4.3	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).
4.4	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).
4.5	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).
4.6	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*†	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.
31.1*	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of the Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.

** This certification is being furnished solely to accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350 and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing of the registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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

SIGNATURES

Pursuant to the requirements 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: May 9, 2022

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

Date: May 9, 2022

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

Exhibit 10.1

Pursuant to Item 601(b)(10)(iv) of Regulation S-K, certain identified information has been omitted from this exhibit because it is both (i) not material and (ii) is the type that Sesen Bio, Inc. treats as private or confidential. Information that has been omitted is denoted as "[**]".

LICENSE AGREEMENT

This agreement ("Agreement") is made by and between

The University of Z✔rich
Rämistrasse 71, CH-8006 Z✔rich (SWITZERLAND)

(hereinafter referred to as UNIVERSITY)

and

Viventia BioInc.
147 Hamelin Street
Winnipeg MB, R3T 3Z1 (CANADA)

("LICENSEE")

This Agreement is effective January 9, 2003 ("Effective Date").

RECITALS

WHEREAS, UNIVERSITY is owner of Patent Rights as defined below on a stabilized anti-EGP-2 scFv fragment termed 4D5MOC-B ("Invention");

WHEREAS, LICENSEE entered into an Option Agreement with UNIVERSITY, effective March 19, 2002, ("Option Agreement"), for the purpose of negotiating this Agreement;

WHEREAS, UNIVERSITY is desirous that the Invention be developed and utilized to the fullest possible extent so that its benefits can be enjoyed by the general public;

WHEREAS, LICENSEE wishes to obtain, and UNIVERSITY is willing to grant, an exclusive license to the Patent Rights on the terms and conditions set out below.

NOW, THEREFORE, the parties agree:

ARTICLE I
DEFINITIONS

The terms, as defined herein, shall have the same meanings in both their singular and plural forms.

1.1 "Affiliate" means any corporation or other business entity in which LICENSEE owns or controls, directly or indirectly, at least fifty percent (50%) of the outstanding stock or other voting rights entitled to elect directors, or in which LICENSEE is owned or controlled directly or indirectly by at least fifty percent (50%) of the outstanding stock or other voting rights entitled to elect directors.

1.2 "Sublicensee" means a third party to whom LICENSEE grants a sublicense of certain rights granted to LICENSEE under this Agreement.

1.3 "Field" means the treatment, stasis, and palliation of disease in humans by anti-EGP-2 antibodies or antibody fragments, whether by themselves or in combination with other materials or methods.

1.4 "Territory" means world-wide.

1.5 "Term" means the period of time beginning on the Effective Date and ending on the expiration date of the longest-lived Patent Rights.

1.6 "Patent Rights" means any of the patent applications set forth in Attachment A to this Agreement and any other patents or patent applications now or in the future owned or controlled by UNIVERSITY, including those jointly-owned or jointly-controlled by UNIVERSITY and LICENSEE, describing or claiming the Invention (including methods of making or using same) and continuing applications thereof including divisions, substitutions, and continuations-in-part; any patents issuing on said applications including reissues, reexaminations and extensions.

1.7 "Licensed Method" means any method that is covered by Patent Rights the use of which would constitute, but for the license granted to LICENSEE under this Agreement, an infringement of any pending or issued and unexpired Valid Claim within Patent Rights.

1.8 "Licensed Product" means any composition or product that is covered by the claims of Patent Rights, or that is produced by the Licensed Method, the manufacture, use, sale, offer for sale, or importation of which would constitute, but for the license granted to LICENSEE by UNIVERSITY herein, an infringement of any pending or issued and unexpired Valid Claim within the Patent Rights.

1.9 "Net Sales" means the total of the gross invoice prices of Licensed Products sold by LICENSEE, its Sublicensee, an Affiliate, a distributor or any combination thereof, to end-user customers of Licensed Products less the sum of the following actual and customary deductions where applicable and separately itemized on the invoice and actually paid or allowed: cash, trade, or quantity discounts; value added, sales or use taxes, and custom duties; transportation charges; or credits to customers because of rejections or returns. Net Sales shall be calculated on the price from Licensee, a sublicensee, a distributor or their Affiliates to the first purchaser who is an end-user and not on sales between or among Licensee, sublicensees, distributors or their Affiliates for the purpose of resale.

1.10 "Patent Costs" means all out-of-pocket expenses for the preparation, filing, prosecution, and maintenance of all patents included in Patent Rights in at least the following countries: US, Canada, Japan, Europe (i. e. the following EPC-countries; AT, BE, CH, DE, DK, FR, GB, IT, NL, SE).

1.11 "Valid Claim" means a claim of the Patent Rights which has not been withdrawn, canceled, or disclaimed, nor held invalid by a court of competent jurisdiction in any unappealed or unappealable decision in the country where the product or process was made, use or sold by LICENSEE, its Affiliate or sublicensee.

ARTICLE II
GRANTS

1.1 License. Subject to the limitations set forth in this Agreement, UNIVERSITY hereby grants to LICENSEE, and LICENSEE hereby accepts, a royalty bearing, exclusive license (with the right to sublicense) under Patent Rights to make, have made, use, sell, offer for sale, and import Licensed Products and to practice Licensed Methods, in the Field within the Territory and during the Term.

The license granted herein is exclusive for Patent Rights and UNIVERSITY shall not grant to third parties a further license under Patent Rights in the Field, within the Territory and during the Term.

Upon expiration of each patent within the Patent Rights, Viventia shall have a fully paid-up, royalty-free license under such patent in the respective country to make, have made, use, sell, offer for sale, and import Licensed Products and to practice the Licensed Methods, in the Field.

1.2 Sublicense.

(a) The license granted in Paragraph 2.1 includes the right of LICENSEE to grant sublicense to third parties during the Term.

(b) With respect to sublicense granted pursuant to Paragraph 2.2(a), LICENSEE shall:

(1) to the extent applicable, include all of the rights of and obligations due to UNIVERSITY and contained in this Agreement;

(2) promptly provide UNIVERSITY with a copy of each sublicense issued; and

(3) collect and guarantee payment of all payments due, directly or indirectly, to UNIVERSITY from Sublicensees and summarize and deliver all reports due, directly or indirectly, to UNIVERSITY from Sublicensees.

(c) Upon termination of this Agreement for any reason, UNIVERSITY, at its sole discretion, shall determine whether LICENSEE shall cancel or assign to UNIVERSITY any and all sublicenses.

1.3 Reservation of Rights. UNIVERSITY reserves the right to:

(a) use the Invention, and Patent Rights for educational and research purposes;

(b) notwithstanding the provisions of Paragraph 5.1.b publish or otherwise disseminate any information about the Invention at any time; and

(c) allow other academic, nonprofit institutions to use Invention, and Patent Rights for educational and non-commercial research purposes in their facilities, subject to a written agreement from such institution acknowledging such restriction and agreeing that no Licensed Products will be transferred to any other person or institution. LICENSEE shall have the right to consult UNIVERSITY in setting up such written agreements and UNIVERSITY shall consider LICENSEE's comments in good faith.

ARTICLE III
CONSIDERATIONS

1.1 Fees and Royalties. The parties hereto understand that the fees and royalties payable by LICENSEE to UNIVERSITY under this Agreement are partial considerations for the license granted herein to LICENSEE under Patent Rights. LICENSEE shall pay UNIVERSITY:

(a) a **license issue fee** of fifty thousand United States Dollars (US$ 50,000) upon execution of the this Agreement;

(b) **milestone payments** in the amounts payable according to the following schedule or events by LICENSEE, its Affiliates or sublicensees with respect to the first Licensed Product:

Amount	Event
(1) US$ 250,000-	Completion of first Phase II clinical studies
(2) US$ 250,000-	First Filing of a New Drug Application (NDA) or equivalent
(3) US$ 500,000-	Within 30 days of completion of regulatory agency review of New Drug Application (NDA) or equivalent, regardless whether the NDA or equivalent is approved or not

(c) an **earned royalty** of four percent (4%) on Net Sales of Licensed Products by LICENSEE, its Affiliates, or sublicensees; If LICENSEE is required to pay royalties to third parties on sales of Licensed Products under patents claiming the composition and/or method of making or using such Licensed Products and the resulting aggregate royalty rate is 10% or greater, then the royalty rate will be adjusted as follows: The royalty rate payable to UNIVERSITY will be reduced to a rate determined by multiplying the royalty rate by a fraction, the numerator of which is 10% and the denominator of which is the aggregate royalty rate, provided that University shall not receive less than 2% royalties.

All fees and royalty payments specified in Paragraphs 3.1(a) through 3.1(c) above shall be paid by LICENSEE pursuant to Paragraph 4.3 and shall be delivered by LICENSEE to UNIVERSITY as noted in Paragraph 10.1.

1.2 Patent Costs. LICENSEE shall reimburse UNIVERSITY all Patent Costs within thirty (30) days following receipt by LICENSEE of an itemized invoice from UNIVERSITY.

1.3 Due Diligence.

(a) LICENSEE shall:

(1) diligently proceed with the development, manufacture and sale of Licensed Products;

(2) upon market entry on a country-by-country basis, use its reasonable efforts to promote the sale of the Licensed Products in the Territory as widely as its resources reasonably permit and reasonably fill the market demand for Licensed Products at any time during the term of this Agreement; and

(3) obtain all necessary governmental approvals for the manufacture, use and sale of Licensed Products.

(b) If LICENSEE fails to perform any of its obligations specified in Paragraphs 3.3(a)(1)-(3), then UNIVERSITY shall have the right to demand a development and, if applicable, marketing plan, detailing key activities and expected timetables. If UNIVERSITY rejects such a plan, the Parties shall meet to discuss in good faith possible amendments to the development and/or marketing plan. In the absence of agreement to such amendments the UNIVERSITY shall have the right and option to terminate this Agreement. If LICENSEE disagrees with such termination it shall have the right within 60 days of the notification of termination to seek arbitration as foreseen in clause 10.6. The arbitrators shall decide whether the termination is justified or not and if the conclude that the termination is not justified decide which amendments to the development and/or marketing plan shall be done.

ARTICLE IV
REPORTS, RECORDS AND PAYMENTS

1.1 Reports.

(a) **Progress Reports.**

(1) Beginning January 1, 2004 and ending on the date of first commercial sale of a Licensed Product, LICENSEE shall submit to UNIVERSITY annual progress reports covering LICENSEE's (and Affiliate's and Sublicensee's) activities to develop and test all Licensed Products and obtain governmental approvals necessary for marketing the same. Such reports shall include a summary of work completed; summary of work in progress; current schedule of anticipated events or milestones; market plans for introduction of Licensed Products; and summary of resources spent in the reporting period.

(2) LICENSEE shall also report to UNIVERSITY, in its immediately subsequent progress report, the date of first commercial sale of a Licensed Product in each country.

(b) **Royalty Reports.** After the first commercial sale of a Licensed Product anywhere in the world, LICENSEE shall submit to UNIVERSITY quarterly royalty reports on a schedule to be determined by LICENSEE based on its fiscal year or other related license agreements. Each royalty report shall cover LICENSEE's (and each Affiliate's and Sublicensee's) most recently completed quarter and shall show:

(1) the gross sales, deductions as provided in Paragraph 1.9, and Net Sales during the most recently completed quarter and the royalties payable with respect thereto;

(2) the number of each type of Licensed Product sold;

(3) sublicense fees and royalties received during the most recently completed quarter, payable with respect thereto;

(4) the method used to calculate the royalties; and

(5) the exchange rates used.

If no sales of Licensed Products has been made and no sublicense revenues has been received by LICENSEE during any reporting period, LICENSEE shall so report.

1.2 Records & Audits.

(a) LICENSEE shall keep, and shall require its Affiliates and Sublicensees to keep, accurate and correct records of all Licensed Products manufactured, used, and sold, and sublicense fees received under this Agreement. Such records shall be retained by LICENSEE for at least three (3) years following a given reporting period.

(b) All records shall be available during normal business hours for inspection at the expense of UNIVERSITY by an independent public accountant selected by UNIVERSITY and reasonably acceptable to LICENSEE and in compliance with the other terms of this Agreement for the sole purpose of verifying reports and payments; such accountant shall not be retained on a contingency-fee basis or on any other terms by which the accountant's compensation depends on the results of the audit. Such accountant shall not disclose to UNIVERSITY any information other than information relating to the accuracy of reports and payments made under this Agreement or other compliance issues. In the event that any such inspection shows an under reporting and underpayment in excess of five percent (5%) for any twelve (12) month period, then LICENSEE shall pay the reasonable cost of the audit as well as any additional sum that would have been payable to UNIVERSITY had the LICENSEE reported correctly, plus an interest charge at a rate of ten percent (10%) per year. Such interest shall be calculated from the date the correct payment was due to UNIVERSITY up to the date when such payment is actually made by LICENSEE. For underpayment not in excess of five percent (5%) for any twelve (12) month period, LICENSEE shall pay the difference within thirty (30) days without interest charge or inspection cost.

1.3 Payments.

(a) All fees due UNIVERSITY shall be paid in accordance with Attachment B:

(b) **Royalty Payments.**

(1) LICENSEE shall pay earned royalties quarterly on a schedule to be determined by LICENSEE based on its fiscal year or other related license agreements. Each such payment shall be for earned royalties accrued within LICENSEE's most recently completed calendar quarter.

(2) Royalties earned on sales occurring or under sublicense granted pursuant to this Agreement shall not be reduced by LICENSEE for any taxes, fees, or other charges imposed by the government of such country on the payment of royalty income, except that all payments made by LICENSEE in fulfillment of UNIVERSITY' tax liability in any particular country may be credited against earned royalties or fees due UNIVERSITY for that country. LICENSEE shall pay all bank charges resulting from the transfer of such royalty payments.

(3) In the event that any patent or patent claim within Patent Rights is held invalid in a final decision by a patent office from which no appeal or additional patent prosecution has been or can be taken, or by a court of competent jurisdiction and last resort and from which no appeal has or can be taken, all obligation to pay royalties based solely on that patent or claim or any claim patentably indistinct therefrom shall cease as of the date of such final decision. LICENSEE shall not, however, be relieved from paying any royalties that accrued before the date of such final decision, that are based on another patent or claim not involved in such final decision.

(c) **Late Payments.** In the event royalty, reimbursement and/or fee payments are not received by UNIVERSITY when due, LICENSEE shall pay to UNIVERSITY interest charges at a rate of ten percent (10%) per year. Such interest shall be calculated from the date payment was due until actually received by UNIVERSITY.

ARTICLE V
PATENT MATTERS

1.1 Patent Prosecution and Maintenance.

(a) LICENSEE, at its own expense, shall be responsible for and have control over the filing, prosecution and maintenance of patents and patent applications in Patent Rights, including the appointment of local patent counsel as agents of record. All patents and patent applications in Patent Rights shall be assigned solely to UNIVERSITY and LICENSEE shall be acting in the best interest of UNIVERSITY in filing, prosecuting and maintaining Patent Rights.

(b) UNIVERSITY shall provide LICENSEE with all necessary information including patent application drafts in order to enable LICENSEE to file, prosecute and maintain patents and patent applications in Patent Rights. LICENSEE shall consult in good faith with UNIVERSITY as to the content of all applications and papers to be filed, and shall act in good faith upon comments received from UNIVERSITY. UNIVERSITY shall ensure that no public disclosures are made prior to filing of patent applications. LICENSEE shall provide UNIVERSITY with copies of all documentation relating to the filing, prosecution and maintenance of Patent Rights and UNIVERSITY shall keep this documentation confidential.

(c) LICENSEE shall apply for an extension of the term of any patent in Patent Rights if appropriate under the US Drug Price Competition and Patent Term Restoration Act and/or European, Japanese and other counterparts thereof. LICENSEE shall prepare all documents for such application, and UNIVERSITY shall execute such documents and take any other additional action as LICENSEE reasonably requests in connection therewith.

1.2 Patent Infringement.

(a) If LICENSEE learns of any substantial infringement of Patent Rights, LICENSEE shall so inform UNIVERSITY and provide UNIVERSITY with reasonable evidence of the infringement. Neither party shall notify a third party of the infringement of Patent Rights without the consent of the other party. Both parties shall use reasonable efforts and cooperation to terminate infringement without litigation.

(b) LICENSEE may request UNIVERSITY to take legal action against such third party for the infringement of Patent Rights. Such request shall be made in writing

and shall include reasonable evidence of such infringement and damages to LICENSEE. If the infringing activity has not abated ninety (90) days following LICENSEE's request, UNIVERSITY shall elect to or not to commence suit on its own account. UNIVERSITY shall give notice of its election in writing to LICENSEE by the end of the one-hundredth (100th) day after receiving notice of such request from LICENSEE. LICENSEE may thereafter bring suit for patent infringement in its own name (and in the name of UNIVERSITY if necessary) and at its own expense, if and only if UNIVERSITY elects not to commence suit and the infringement occurred in a jurisdiction where LICENSEE has an exclusive license under this Agreement. If LICENSEE elects to bring suit, UNIVERSITY may join that suit at its own expense.

(c) Recoveries from actions brought pursuant to Paragraph 5.2(b) shall belong to the party bringing suit except that in the event that LICENSEE brings suit for infringement of Patent Rights and an acceptable settlement is entered into or monetary damages are awarded in a final non-appealable judgment, UNIVERSITY shall be reimbursed for any amount which would have been due to UNIVERSITY under this Agreement if the products sold by the infringer actually had been sold by LICENSEE. Legal actions brought jointly by UNIVERSITY and LICENSEE and fully participated in by both shall be at the joint expense of the parties and all recoveries shall be shared jointly by them in proportion to the share of expense paid by each party.

(d) Each party shall cooperate with the other in litigation proceedings at the expense of the party bringing suit. Litigation shall be controlled by the party bringing the suit, except that UNIVERSITY may choose to be represented by counsel of its choice (at its expense) in any suit brought by LICENSEE.

1.3 Patent Marking. LICENSEE shall mark all Licensed Products made, used or sold under the terms of this Agreement, or their containers, in accordance with the applicable patent marking laws.

ARTICLE VI
GOVERNMENTAL MATTERS

1.1 Governmental Approval or Registration. If this Agreement or any associated transaction is required by the law of any nation to be either approved or registered with any governmental agency, LICENSEE shall assume all legal obligations to do so. LICENSEE shall notify UNIVERSITY if it becomes aware that this Agreement is subject to any government reporting or approval requirement. LICENSEE shall make all necessary filings and pay all costs including fees, penalties, and all other out-of-pocket costs associated with such reporting or approval process.

ARTICLE VII
TERMINATION OF THE AGREEMENT

1.1 Termination by UNIVERSITY.

(a) If LICENSEE fails to perform or violates any term of this Agreement, then UNIVERSITY may give written notice of default ("Notice of Default") to LICENSEE. If LICENSEE fails to cure the default within sixty (60) days of the Notice of Default with respect to the failure to make payments required under this Agreement or within one hundred twenty (120) days for any other breach, UNIVERSITY may terminate this Agreement and the license granted herein by a second written notice ("Notice of Termination") to LICENSEE. If a Notice of Termination is sent to LICENSEE, this Agreement shall automatically terminate on the effective date of that

notice. Termination shall not relieve LICENSEE of its obligation to pay any fees owed at the time of termination and shall not impair any accrued right of UNIVERSITY.

(b) UNIVERSITY shall have the right to terminate this Agreement by giving written notice, in the event of filing by LICENSEE of a petition of bankruptcy or insolvency or both, or in the event of an adjudication that LICENSEE is bankrupt or insolvent or both, or after filing by LICENSEE of any petition or pleading asking reorganization, readjustment or rearrangement of its business under any law relating to bankruptcy or insolvency, or upon or after appointment of a receiver for all or substantially all of the property of LICENSEE or upon or after the making of any assignment for the benefit of creditors or upon or after the institution of any proceedings for the liquidation or winding-up of LICENSEE's business or for the termination of its corporate charter, and this Agreement shall terminate upon the date specified in such written notice.

1.2 Termination by Licensee.

(a) LICENSEE shall have the right at any time and for any reason to terminate this Agreement upon a ninety (90) day written notice to UNIVERSITY. Said notice shall state LICENSEE's reason for terminating this Agreement.

(b) Any termination under Paragraph 7.2(a) shall not relieve LICENSEE of any obligation or liability accrued under this Agreement prior to termination or rescind any payment made to UNIVERSITY or action by LICENSEE prior to the time termination becomes effective. Termination shall not affect in any manner any rights of UNIVERSITY arising under this Agreement prior to termination.

1.3 Survival on Termination. The following Paragraphs and Articles shall survive the termination of this Agreement:

(a) Article 4 (REPORTS, RECORDS AND PAYMENTS);

(b) Paragraph 7.4 (Disposition of Licensed Products on Hand);

(c) Paragraph 8.2 (Indemnification);

(d) Article 9 (USE OF NAMES AND TRADEMARKS);

(e) Paragraph 10.2 hereof (Secrecy); and

(f) Paragraph 10.5 (Failure to Perform).

1.4 Disposition of Licensed Products on Hand. Upon termination of this Agreement, LICENSEE may dispose of all previously made or partially made Licensed Product within a period of one hundred and twenty (120) days of the effective date of such termination provided that the sale of such Licensed Product by LICENSEE, its Sublicensees, or Affiliates shall be subject to the terms of this Agreement, including but not limited to the rendering of reports and payment of royalties required under this Agreement.

ARTICLE VIII
LIMITED WARRANTY AND INDEMNIFICATION

1.1 Limited Warranty.

(a) UNIVERSITY warrants that it has the lawful right to grant this license, that Attachment A to this Agreement is a complete list of all patents and applications owned or controlled by UNIVERSITY pertaining to the Invention, and that it has good and sufficient title to the Licensed Patents to grant the licenses herein free and clear of the rightful claim of any third party.

(b) The license granted herein is provided "AS IS" and without WARRANTY OF MERCHANTABILITY or WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE or any other warranty, express or implied. UNIVERSITY makes no representation or warranty that the Licensed Product, Licensed Method or the use of Patent Rights will not infringe any other patent or other proprietary rights.

(c) In no event shall UNIVERSITY be liable for any incidental, special or consequential damages resulting from exercise of the license granted herein or the use of the Invention, Licensed Product, or Licensed Method.

(d) Nothing in this Agreement shall be construed as:

(1) a warranty or representation by UNIVERSITY as to the validity or scope of any Patent Rights;

(2) a warranty or representation that anything made, used, sold or otherwise disposed of under any license granted in this Agreement is or shall be free from infringement of patents of third parties;

(3) an obligation to bring or prosecute actions or suits against third parties for patent infringement except as provided in Paragraph 5.2 hereof;

(4) conferring by implication, estoppel or otherwise any license or rights under any patents of UNIVERSITY other than Patent Rights as defined in this Agreement, regardless of whether those patents are dominant or subordinate to Patent Rights;

(5) an obligation to furnish any know-how not provided in Patent Rights.

1.2 Indemnification.

(a) LICENSEE shall indemnify, hold harmless and defend UNIVERSITY, its officers, employees, and agents; the sponsors of the research that led to the Invention; and the inventors of the patents and patent applications in Patent Rights and their employers against any and all claims, suits, losses, damage, costs, fees, and expenses resulting from or arising out of exercise of this license or any sublicense. This indemnification shall include, but not be limited to, any product liability.

(b) LICENSEE, at its sole cost and expense, shall insure its activities in connection with the work under this Agreement and obtain, keep in force and maintain insurance or an equivalent program of self-insurance.

(c) UNIVERSITY shall notify LICENSEE in writing of any claim or suit brought against UNIVERSITY in respect of which UNIVERSITY intends to invoke the provisions of this Article. LICENSEE shall keep UNIVERSITY informed on a current basis of its defense of any claims under this Article.

ARTICLE IX
USE OF NAMES AND TRADEMARKS

1.1 Nothing contained in this Agreement confers any right to use in advertising, publicity, or other promotional activities any name, trade name, trademark, or other designation of either party hereto (including contraction, abbreviation or simulation of any of the foregoing).

1.2 UNIVERSITY may acknowledge the existence of this Agreement and the extent of the grant in Article 2 to third parties, but UNIVERSITY shall not disclose the financial terms of this Agreement to third parties, except where UNIVERSITY is required by law to do so.

ARTICLE X
MISCELLANEOUS PROVISIONS

1.1 Correspondence. Any notice or payment required to be given to either party under this Agreement shall be deemed to have been properly given and effective:

(a) on the date of delivery if delivered in person, or

(b) five (5) days after mailing if mailed by registered mail, postage paid, to the respective addresses given below, or to such other address as is designated by written notice given to the other party.

If sent to LICENSEE:

Viventia Bio, Inc.
147 Hamelin Street
Winnipeg MD, R3T 3Z1 (CANADA)
Attention: Mr. Stephen A. Hurly

If sent to UNIVERSITY:

University of Zurich
c/o Unitectra; Ref. UZ-03/064
Scheuchzerstrasse 21; CH-8006 Zurich (SWITZERLAND)

1.2 Secrecy.

(a) **"Confidential Information"** shall mean information relating to the Invention or activities hereunder disclosed by one party to the other during the term of this Agreement, which if disclosed in writing shall be marked "Confidential."

(b) The Receiving party of any such Confidential Information shall:

(1) use the Confidential Information for the sole purpose of performing under the terms of this Agreement;

(2) safeguard Confidential Information against disclosure to others with the same degree of care as it exercises with its own data of a similar nature;

(3) not disclose Confidential Information to others (except to its employees, agents or consultants who are bound to it by a like obligation of confidentiality) without the express written permission of the Disclosing party, , except that the Receiving party shall not be prevented from using or disclosing any of the Confidential Information that:

(i) it can demonstrate by written records was previously known to it;

(ii) is now, or becomes in the future, public knowledge other than through acts or omissions of it; or

(iii) is lawfully obtained by it from sources independent of Disclosing party.

(iv) is required to be disclosed by government authority; provided; however, that Receiving party has provided reasonable advance notice of the impending disclosure to Disclosing party and will disclose the Confidential Information to the extent necessary and to such authority only.

(c) The obligations of the Receiving party with respect to Confidential Information shall continue for a period ending five (5) years from the termination date of this Agreement.

1.3 Assignability. UNIVERSITY and LICENSEE each agree that their rights and obligations under this Agreement may not be transferred or assigned to a third party without the prior written consent of the other party thereto, such consent not to be unreasonably withheld. Notwithstanding the foregoing, in the event of a merger, consolidation or similar reorganization of either Party with or into another party, or in the event of a sale of all or substantially all of the assets of a Party or the business unit or product to which this Agreement pertains, this Agreement shall be assigned to or become the obligation and liability of the acquiring entity, subject to written notification of such acquisition or merger to the other Party. The terms and conditions of this Agreement shall be binding upon and inure to the benefit of the permitted successors and assigns of the Parties.

1.4 No Waiver. No waiver by either party of any breach or default of any covenant or agreement set forth in this Agreement shall be deemed a waiver as to any subsequent and/or similar breach or default.

1.5 Failure to Perform. In the event of a failure of performance due under this Agreement and if it becomes necessary for either party to undertake legal action against the other on account thereof, then the prevailing party shall be entitled to reasonable attorney's fees in addition to costs and necessary disbursements.

1.6 Governing Laws; Arbitration. THIS AGREEMENT SHALL BE INTERPRETED AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF SWITZERLAND, except that matters concerning the validity or infringement of any patent shall be governed by the national laws of the jurisdiction issuing such patent.

All disputes, differences or controversies arising out of or in connection with this Agreement, its interpretation, performance, or termination, which may arise between the Parties arising out of, or related to, this Agreement shall be amicably settled between the Parties. In case of failure of amicable settlement between the Parties, it shall be finally settled by binding arbitration conducted in accordance with the Rules of Concilliation and Arbitration of the International Chamber of Commerce (Paris, France) (the "ICC"). The arbitration panel shall be composed of three arbitrators, one of whom shall be selected by UNIVERSITY, one of whom shall be selected by LICENSEE and the third of whom shall be selected by the two so selected. If both or either of UNIVERSITY OR LICENSEE fails to select an arbitrator or arbitrators within

fourteen (14) days after receiving notice of commencement of arbitration or if the two arbitrators fail to select a third arbitrator within fourteen (14) days after their appointment, the ICC shall, in accordance with said rules, upon the request of both or either of the Parties to the arbitration, appoint the arbitrator or arbitrators required to complete the panel. The venue of arbitration shall be Zurich.

The Parties shall share the costs of the arbitration, including administrative and arbitrators' fees equally. Each Party shall bear its own costs and attorneys' and witnesses' fees; provided, however, that the prevailing Party, as determined by the arbitration panel, shall be entitled to an award against the other Party in the amount of the prevailing Party's costs and reasonable attorneys' fees. The arbitration award shall be final and each Party shall comply in good faith and submit itself to the jurisdiction of the appropriate courts in Zurich for the sole purpose of the entry of such arbitrator's award to render effective such arbitration decision.

1.7 Force Majeure. A party to this Agreement may be excused from any performance required herein if such performance is rendered impossible or unfeasible due to any catastrophe or other major event beyond its reasonable control, including, without limitation, war, riot, and insurrection; laws, proclamations, edicts, ordinances, or regulations; strikes, lockouts, or other serious labor disputes; and floods, fires, explosions, or other natural disasters. When such events have abated, the non-performing party's obligations herein shall resume.

1.8 Headings. The headings of the several sections are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.

1.9 Entire Agreement. This Agreement embodies the entire understanding of the parties and supersedes all previous communications, representations or understandings, either oral or written, between the parties relating to the subject matter hereof.

1.10 Amendments. No amendment or modification of this Agreement shall be valid or binding on the parties unless made in writing and signed on behalf of each party.

1.11 Severability. In the event that any of the provisions contained in this Agreement is held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Agreement, and this Agreement shall be construed as if the invalid, illegal, or unenforceable provisions had never been contained in it.

IN WITNESS WHEREOF, both UNIVERSITY and LICENSEE have executed this amended and restated Agreement, in duplicate originals, by their respective and duly authorized officers on 14 October, 2015.

UNIVERSITY

Date: October 14, 2015

By: **Prof. Dr. Andreas Pl✔ckthun** /s/ Dr. Andreas Pl✔ckthun

(Signature)

Date: October 14, 2015

By: **Prof. Dr. Christoph Hock** /s/ Dr. Christoph Hock

Vice President ***(Signature)***

LICENSEE
VIVENTIA BIO, INC.

Date: October 14, 2015

By: **Stephen A. Hurly** /s/ Stephen A. Hurly

President and CEO ***(Signature)***

Date: October 14, 2015

By: **Erick J. Lucera** /s/ Erick J. Lucera

Chief Financial Officer ***(Signature)***

Attachment A

[**]

Attachment B

Payments

[**]

Exhibit 31.1

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

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

1. I have reviewed this Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2022 of Sesen Bio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2022

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

Exhibit 31.2

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

I, Monica Forbes, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2022 of Sesen Bio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2022

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

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Sesen Bio, Inc. (the "Company") for the fiscal quarter ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 9, 2022

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

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Sesen Bio, Inc. (the "Company") for the fiscal quarter ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 9, 2022

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