# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 10-O

		FORM 10-Q	2		
(Mark On					
$\boxtimes$	QUARTERLY REPORT PURSUANT TO SECTION 13 O	R 15(d) OF THE S	SECURITIES EXCHA	NGE ACT OF 1934	
	For the quart	terly period ended OR	June 30, 2022		
	TRANSITION REPORT PURSUANT TO SECTION 13 O	R 15(d) OF THE S	SECURITIES EXCHA	NGE ACT OF 1934	
		tion period from _			
	Commiss	ion File Number:	001-36296		
		esen Bio, I of registrant as specifie			
	Delaware (State or other jurisdiction of			<b>26-2025616</b> (I.R.S. Employer	
	incorporation or organization)			Identification No.)	
	245 First Street, Suite 1800 Cambridge, MA (Address of principal executive offices)			<b>02142</b> (Zip Code)	
	(Address of principal executive offices)			(Zip Code)	
	Registrant's telephone n  (Former name, former address	Not applicable			
	(Former hane, former address	ss and former fiscar yea	m, it changed since hast repor	,	
Securiti	es registered pursuant to Section 12(b) of the Act:				_
	Title of each class	Trading Symbol(s)	Name of each exc	change on which registered	
	Common Stock, \$0.001 par value	SESN		q Stock Market LLC	1
during t	by check mark whether the registrant (1) has filed all report preceding 12 months (or for such shorter period that the nents for the past 90 days. Yes $\boxtimes$ No $\square$				
	by check mark whether the registrant has submitted electron S-T during the preceding 12 months (or for such shorter)				Rule 405 of
emergin	by check mark whether the registrant is a large accelerated growth company. See the definitions of "large acceleration" in Rule 12b-2 of the Exchange Act.				
	Large accelerated filer	Smaller	reporting company	$\boxtimes$	
	Accelerated filer  Non-accelerated filer	_	g growth company		
	erging growth company, indicate by check mark if the regis d financial accounting standards provided pursuant to Section			transition period for complying	with any new
	by check mark whether the registrant is a shell company (as		_	Act). Yes □ No ⊠	
There w	ere 199,463,645 shares of the registrant's common stock out	standing as of Aug	gust 1, 2022.		

# SESEN BIO, INC.

# Quarterly Report on Form 10-Q for the Quarterly Period Ended June 30, 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)

	Ju	ne 30, 2022	Decem	ber 31, 2021
Assets				
Current assets:				
Cash and cash equivalents	\$	72,090	\$	162,636
Short term marketable securities		69,454		_
Accounts receivables		73		21,011
Other receivables		14,046		3,482
Prepaid expenses and other current assets		757		18,476
Total current assets		156,420		205,605
Non-current assets:				
Restricted cash		30		20
Marketable securities		19,641		_
Property and equipment, net		30		43
Intangible assets		_		14,700
Goodwill		_		13,064
Long term prepaid expenses		_		7,192
Other assets		42		123
Total non-current assets	\$	19,743	\$	35,142
Total Assets	\$	176,163	\$	240,747
VIIII III III II II II II II II II II II				
Liabilities and Stockholders' Equity				
Current liabilities:				2052
Accounts payable	\$	1,667	\$	2,853
Accrued expenses		29,851		8,255
Other current liabilities		487		460
Total current liabilities		32,005		11,568
Non-current liabilities:				
Contingent consideration		1,800		52,000
Deferred tax liability		_		3,969
Deferred revenue		_		1,500
Total non-current liabilities		1,800		57,469
Total Liabilities		33,805		69,037
Stockholders' Equity:				
Preferred stock, \$0.001 par value per share; 5,000,000 shares authorized at June 30, 2022 and December 31, 2021; no s issued and outstanding at June 30, 2022 and December 31, 2021	shares	_		_
Common stock, \$0.001 par value per share; 400,000,000 shares authorized at June 30, 2022 and December 31, 2021; 199,463,645 shares issued and outstanding at June 30, 2022 and December 31, 2021		199		199
Additional paid-in capital		491,464		487,768
Other comprehensive loss		(281)		_
Accumulated deficit		(349,024)		(316,257)
Total Stockholders' Equity		142,358		171,710
	\$	176,163	\$	240,747

# SESEN BIO, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited; In thousands, except per share data)

		Three Mon Jun	nths i		Six Months Ended June 30,				
	2022			2021	2022			2021	
Revenue:									
License and related revenue	\$	_	\$	2,234	\$	_	\$	6,544	
Total revenue				2,234				6,544	
Operating expenses:									
Research and development		29,944		7,228		34,705		13,306	
General and administrative		15,589		6,805		24,564		12,098	
Intangibles impairment charge		27,764		_		27,764		_	
Change in fair value of contingent consideration		(37,300)		13,600		(50,200)		61,760	
Total operating expenses		35,997		27,633		36,833		87,164	
Loss from Operations	\$	(35,997)	\$	(25,399)	\$	(36,833)	\$	(80,620)	
Other income (expense), net		162		(43)		191		(46)	
Loss Before Taxes	\$	(35,835)	\$	(25,442)	\$	(36,642)	\$	(80,666)	
Benefit (provision) from income taxes		3,875		_		3,875		(288)	
Net Loss After Taxes	\$	(31,960)	\$	(25,442)	\$	(32,767)	\$	(80,954)	
								_	
Net loss attributable to common stockholders - basic and diluted	\$	(31,960)	\$	(25,442)	\$	(32,767)	\$	(80,954)	
Net loss per common share - basic and diluted	\$	(0.16)	\$	(0.15)	\$	(0.16)	\$	(0.49)	
Weighted-average common shares outstanding - basic and diluted	\$	199,464	\$	175,393	\$	199,464	\$	166,264	

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

Three Months Ended June 30, Six Months Ended June 30, 2022 2021 2022 2021 Net loss \$ 31,960 \$ 25,442 \$ 32,767 \$ 80,954 Unrealized loss on marketable securities (281)(281) Total comprehensive loss \$ 33,048 \$ \$ 80,954 32,241 \$ 25,442

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

	Common Stock		Additional Paid-in			Accumulated Other Comprehensive		Accumulated		Stockholders'		
	Shares		Amount		Capital		Loss Investments		Deficit		Equity	
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	
Net loss	_		_		_				(31,960)		(31,960)	
Share-based compensation	_		_		1,802		_		_		1,802	
Unrealized loss of investments	<u> </u>						(281)				(281)	
Balance at June 30, 2022	199,463,645	\$	199	\$	491,464	\$	(281)	\$	(349,024)	\$	142,358	

_	Common Stock		Additional Paid-in		Accumulated Other Comprehensive		Accumulated		Stockholders'			
	Shares		Amount		Capital		Loss Investments		Deficit		Equity	
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	
Net loss	_				_		_		(25,442)		(25,442)	
Share-based compensation	_		_		1,260		_		_		1,260	
Issuance of common stock under ATM Offering, net of issuance costs of \$2.0 million	16,482,152		16		64,245		_		_		64,261	
Balance at June 30, 2021	188,460,951	\$	188	\$	\$ 446,036	\$	_	\$	(396,875)	\$	49,349	

# SESEN BIO, INC. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited; In thousands)

Cir Months Ended

		Six Months Ended June 30,						
		2022	2021					
Cash Flows from Operating Activities:								
Net loss	\$	(32,767) \$	(80,954)					
Adjustments to reconcile net loss to net cash used in operating activities:								
Depreciation		13	64					
Share-based compensation		3,696	2,217					
Change in fair value of contingent consideration		(50,200)	61,760					
Intangibles impairment charge		27,764	_					
Changes in operating assets and liabilities:								
Accounts receivable (net)		20,939	(2,303)					
Other receivables		(10,565)	_					
Prepaid expenses and other current assets		17,719	(20,287)					
Long term prepaid expenses		7,192	_					
Unrealized loss on marketable securities		(281)	_					
Other assets		81	_					
Accounts payable		(1,186)	(1,875)					
Accrued expenses and other liabilities		17,654	1,262					
Deferred revenue		(1,500)	(1,500)					
Net cash used in operating activities		(1,441)	(41,616)					
Cash Flows from Investing Activities:								
Purchase of marketable securities		(89,095)	_					
Purchases of equipment		_	(49)					
Net cash used in investing activities		(89,095)	(49)					
Cash Flows from Financing Activities:								
Proceeds from issuance of common stock under ATM Offering, net of issuance costs		_	136,804					
Proceeds from exercises of stock options		_	39					
Proceeds from exercises of common stock warrants		_	469					
Net cash provided by financing activities		_	137,312					
Net (decrease) increase in cash, cash equivalents and restricted cash		(90,536)	95,647					
Cash, cash equivalents and restricted cash - beginning of period		162,656	55,409					
Cash, cash equivalents and restricted cash - end of period	<u>\$</u>	72,120 \$	151,056					
cass, tass equivalent and restrict that of period	<u> </u>	72,120	101,000					
Supplemental cash flow disclosure:								
Cash paid for amounts included in the measurement of lease liabilities	\$	86 \$	87					
Supplemental disclosure of non-cash investing activities:	•	•						
Purchase of equipment included in accrued expenses	\$	<b>—</b> \$	27					

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 focused on advancing targeted fusion protein therapeutics for the treatment of patients with cancer. The Company's most advanced product candidate, Vicineum<sup>TM</sup>, also known as VB4-845, is a locally-administered targeted fusion protein composed of an anti-epithelial cell adhesion molecule ("EpCAM") antibody fragment tethered to a truncated form of Pseudomonas exotoxin A for the treatment of non-muscle invasive bladder cancer ("NMIBC"). On July 15, 2022, the Company made the strategic decision to voluntarily pause further development of Vicineum in the United States. The decision was based on a thorough reassessment of Vicineum, which included the incremental development timeline and associated costs for an additional Phase 3 clinical trial, following its discussions with the FDA, which are further described below. The Company has turned its primary focus to the careful assessment of potential strategic alternatives with the goal of maximizing shareholder value, which it believes will be complete by the end of 2022. Additionally, the Company intends to seek a partner for the further development of Vicineum.

The Company has completed 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 would 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. On July 11, 2022, the Company participated in a Type B meeting with the FDA to discuss outstanding items related to the Company's proposed protocol and statistical analysis plan design elements for an 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 June 30, 2022, none of these individuals are active employees of the Company 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 six months ended June 30, 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 subsidiary, Viventia Bio USA Inc. 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 June 30, 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,
- <u>Level 2</u>: 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.
- <u>Level 3</u>: 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 June 30, 2022 and December 31, 2021 (in thousands):

				June 30, 2022				
				Fair Va	alue	Measurement	Bas	sed on
	Carrying Amount	Fair Value	(	Quoted Prices in Active Markets (Level 1)		Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs (Level 3)
Assets:								
Marketable securities:								
Money market funds (cash equivalents)	\$ 40,765	\$ 40,765	\$	40,765	\$	_	\$	_
Marketable securities	\$ 89,095	\$ 89,095	\$	_	\$	89,095	\$	_
Liabilities:								
Contingent consideration	\$ 1,800	\$ 1,800	\$	_	\$	_	\$	1,800

# December 31, 2021

			,					
				Fair V	alue	Measurement	Bas	ed on
	Carrying Amount	Fair Value	(	Quoted Prices in Active Markets (Level 1)		Significant Other Observable Inputs (Level 2)	1	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 six months ended June 30, 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 10.2% as of June 30, 2022 to 8.0% and 9.3% as of December 31, 2021. There have been no changes to the valuation methods utilized during the six months ended June 30, 2022.

On July 15, 2022, the Company made the strategic decision to voluntarily pause further development in the US of Vicineum. The decision was based on a thorough reassessment of Vicineum, which included the incremental development timeline and associated costs for an additional Phase 3 clinical trial for the treatment of NMIBC, following recent discussions with the FDA and the updated market data obtained through market research during the ongoing BCG shortage. Additionally, the Company intends to seek a partner for the further development of Vicineum. The Company expects that any partner who acquires Vicineum from the Company will be obligated to make any payments that become payable to the former shareholders of Viventia under the Share Purchase Agreement. Accordingly, as of June 30, 2022, the Company no longer expects to pay related milestone and earnout payments to the former shareholders of Viventia, with the exception of the potential 2% earnout payment related to the Greater China region since those territory rights have already been out-licensed.

Therefore, the balance as of June 30, 2022 relates to contingent consideration for projected net sales in the Greater China region as compared to the balance as of December 31, 2021 which was based upon projected world-wide net sales.

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 (in thousands).

Balance at December 31, 2021	\$	52,000
Change in fair value of contingent consideration		(50,200)
Balance at June 30, 2022	<b>\$</b>	1,800

The fair value of the Company's contingent consideration was 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 were determined using an earnout rate of 2% on all commercial net sales of Vicineum through December 2033. The discount rate applied to the 2% earnout was derived from the Company's weighted-average cost of capital, which has fluctuated from 9.3% as of December 31, 2021 to 10.2% as of June 30, 2022. As of December 31, 2021, the balance also reflected potential milestone payments which constitute debt-like obligations, and therefore a high-yield debt index rate was applied to the milestones in order to determine the estimated fair value. This index rate was 8.0% as of December 31, 2021. The decrease in the fair value of contingent consideration of \$50.2 million for the six months ended June 30, 2022 was driven by the Company's decision to voluntarily pause further development of Vicineum.

### 6. RECEIVABLES

The accounts receivable balance as of June 30, 2022 is \$0.1 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 June 30, 2022 is \$14.0 million compared to \$3.5 million as of December 31, 2021. The increase is driven by expected insurance recovery of \$13.0 million related to the preliminary settlements of the securities and derivative litigation. This was partially offset by the receipt of \$2.4 million for German value-added tax ("VAT") recovery in the first half of 2022, related to drug substance sent to Baxter in 2020 and 2019.

# 7. PREPAID EXPENSES

The prepaid expenses balance as of June 30, 2022 is \$0.8 million compared to \$25.7 million as of December 31, 2021. In light of the Company's decision to voluntarily pause further development of Vicineum, the Company evaluated prepaid balances and determined that the prepayments for the manufacturing of Vicineum, including consumables, had no future economic benefit or value. Pursuant to ASC Topic 730, Certain Nonrefundable Advance Payment, the Company expensed \$25.2 million of prepaids during the three months ended June 30, 2022.

# 8. INTANGIBLE ASSETS AND GOODWILL

#### Intangibles

Intangible assets on the Company's condensed consolidated balance sheets are the result of the Viventia Acquisition in September 2016. The following table sets forth the composition of intangible assets as of June 30, 2022 and December 31, 2021 (in thousands):

	June 30, 2022	December 31, 2021
IPR&D intangible assets:		
Vicineum European Union rights	<b>s</b> —	\$ 14,700
<b>Total Intangibles</b>	<u>s</u> —	\$ 14,700

The fair value of the acquired intangible assets for the European Union ("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 former 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 marketing authorization application ("MAA") to the European Medicines Agency (the "EMA") for Vysyneum<sup>TM</sup> for the treatment of BCG-unresponsive NMIBC in order to pause its plans to pursue regulatory approval of Vysyneum in the EU until there was 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 EU. 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 US 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 probability of success assumptions. This was primarily due to the fact that the EU asset was burdened with significantly less expense than the US asset, as the Company's strategic operating plan was 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.

During the second quarter of 2022, the Company observed an evolution of the current market treatment paradigm in NMIBC, with substantial uptake of intravesical chemotherapy (monotherapy and combination therapy) during the ongoing BCG shortage. The Company has also experienced a sustained decline in its share price and a resulting decrease in our market capitalization. On July 15, 2022 the Company made the strategic decision to voluntarily pause further development in the US of Vicineum and intends to seek a partner for the further development of Vicineum. The decision was based on a thorough reassessment of Vicineum, which included the incremental development timeline and associated costs for an additional Phase 3 clinical trial for the treatment of NMIBC, following recent discussions with the FDA and the updated market data obtained through market research during the ongoing BCG shortage. Management updated the discounted cash flow model using the market participant approach and considered preliminary terms of a potential partnering deal to conclude the fair value of EU asset. The Company concluded that the carrying value of the Company's intangible asset of Vicineum EU rights of \$14.7 million was fully impaired and written off as of June 30, 2022. The weighted average cost of capital used in the Company's most recent impairment test, which was 24.5%, was risk-adjusted to reflect the specific risk profile of the reporting unit. Management used considerable judgment to determine key assumptions, including projected revenue and appropriate discount rates, which are classified as level 3 in fair value measurement.

#### Goodwill

Goodwill on the Company's condensed consolidated balance sheets is the result of the Viventia Acquisition in September 2016. During the second quarter of 2022 the Company observed continued trends in the Company's market capitalization as compared to the carrying value of its single reporting unit as well as changes in certain assumptions in the fair value of the business including market share, length and cost of a clinical study, and time to potential market launch. The Company identified these changes as potential impairment indicators and performed a quantitative impairment analysis, in advance of the Company's typical annual assessment date of October 1. The Company reassessed the underlying assumptions used to develop its revenue projections, which were then used as significant inputs to determine the fair value of equity. Management updated its revenue forecast models based on further launch delays in both the US and outside the US ("OUS") regions. The Company also recently observed an evolution of the current treatment paradigm in NMIBC, with substantial uptake of intravesical chemotherapy (monotherapy and combination therapy) during the ongoing BCG shortage resulting in lower projected peak market share for Vicineum. Management also considered other factors including the preliminary valuations of strategic alternatives during the fair value assessment. As a result of the interim impairment test, the Company concluded that the carrying value of its goodwill of \$13.1 million was fully impaired as of June 30, 2022. The weighted average cost of capital used in the Company's most recent impairment test, which was 24.5%, was risk-adjusted to reflect the specific risk profile of the reporting unit. Management used considerable judgment to determine key assumptions, including projected revenue and appropriate discount rates, which are classified as level 3 in fair value measurement.

The following table sets forth a summary of the change in goodwill as of June 30, 2022 and December 31, 2021 (in thousands).

Balance at December 31, 2021	\$ 13,064
Impairment loss	(13,064)
Balance at June 30, 2022	\$ _

### 9. ACCRUED EXPENSES

The following table sets forth the composition of accrued expenses as of June 30, 2022 and December 31, 2021 (in thousands):

	Ju	ne 30, 2022	<b>December 31, 202</b> 1	1
Research and development	\$	1,847	\$ 1,84	1
Payroll-related expenses		3,099	2,96	7
Restructuring charge related		394	1,49	7
Professional fees		507	59	7
Legal expenses, including preliminary litigation settlement		22,477	1,34	4
Other		1,527		9
Total Accrued Expenses	\$	29,851	\$ 8,25	5

### 10. COMMITMENTS AND CONTINGENCIES

### Legal Proceedings

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

On August 19, 2021, August 31, 2021, and October 7, 2021, three substantially identical securities class action lawsuits captioned Bibb v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-07025, Cizek v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-07309, and Markman v. Sesen Bio, Inc. et al., Case No. 1:21-cv-08308 were filed against the Company and certain of its officers in the US District Court for the Southern District of New York. The three complaints 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. After the motion was fully briefed and before the court ruled on the motion, on June 3, 2022, the parties requested that the court hold any decision on the motion to dismiss in abeyance to provide the parties with an opportunity to engage in mediation. The parties engaged in mediation on June 30, 2022.

On September 20, 2021 and September 24, 2021, two substantially similar derivative lawsuits captioned Myers v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-11538 and D'Arcy v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-11577 were filed against the Company's board of directors and certain of its officers in the US District Court for the District of Massachusetts, with the Company named as a nominal defendant. On January 12, 2022, a third derivative complaint captioned Tang v. Sesen Bio, Inc., et al., was filed in Superior Court in Massachusetts against the Company's board of directors and certain of its officers (the "State Derivative Litigation"). 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. On May 18, 2022, the court entered a joint stipulation among the parties to stay the State Derivative Litigation until after a ruling on any motion to dismiss filed by defendants in the Securities Litigation.

The Company deemed the settlements of the Securities Litigation, the State Derivative Litigation, the Federal Derivative Litigation, and other potential related derivative claims, probable and amounts reasonably estimable as of June 30, 2022 and accrued \$21.6 million to litigation related liability.

The Company, its board of directors and the individual defendants continue to deny all allegations of any wrongdoing, but are seeking to settle the Securities Litigation, the State Derivative Litigation and the Federal Derivative Litigation to avoid the uncertainty, risk, expense and distraction of protracted litigation.

### **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.

### 11. 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. The minimum monthly rent under this lease is CAD \$18,100 (approximately \$14,000 at exchange rates in effect on June 30, 2022). In addition to rent expense, the Company expects to incur CAD \$18,200 per month related to operating expenses (approximately \$14,100 at exchange rates in effect on June 30, 2022). Operating lease cost under this lease, including the related operating costs, were \$83,000 and \$165,000 for the three and six months ended June 30, 2022, respectively, and \$84,000 and \$166,000 for the three and six months ended June 30, 2021, respectively.

The asset component of the Company's operating leases is recorded as operating lease right-of-use assets and reported within other assets on the Company's condensed consolidated balance sheets. The right of use asset total was \$41,700 as of June 30, 2022 and \$123,300 as of 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 \$41,700 as of June 30, 2022 and \$123,300 as of December 31, 2021. There was no long-term operating lease liability as of June 30, 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 are renewed on a month-to-month basis. The minimum monthly rent for these office spaces is \$2,200 and \$21,000, respectively, which is subject to change if and as the Company adds space to or deducts space from the leases.

# 12. 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 June 30, 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 Stock 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 and six months ended June 30, 2022. The Company raised \$136.8 million of net proceeds from the sale of 47.1 million shares of common stock at a weighted-average price of \$2.99 per share during the six months ended June 30, 2021. The Company raised \$64.3 million of net proceeds from the sale of 16.5 million shares of common stock at a weighted-average price of \$4.02 per share during the three months ended June 30, 2021. Share issuance costs, including sales agent commissions, related to the ATM Offering totaled \$2.0 million and \$4.2 million during the three and six months ended June 30, 2021, respectively.

# **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 June 30, 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 approximately 199 million shares were issued and outstanding as of June 30, 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 June 30, 2022 and December 31, 2021 (in thousands):

	June 30, 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	17,161	15,703
Restricted stock units	8,063	3,041
Shares available for grant under 2014 Stock Incentive Plan	3,076	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	230,263	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. The following table sets forth the Company's warrant activity for the three months ended June 30, 2022 (in thousands):

Issued	Exercise Price	Expiration	December 31, 2021	Issued	(Exercised)	(Cancelled)	June 30, 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

<sup>\*</sup>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.

# 13. EARNINGS (LOSS) PER SHARE

A net loss cannot be diluted. Therefore, when the Company is in a net loss position, basic and diluted loss per common share are the same. If the Company achieves profitability, the denominator of a diluted earnings per common share calculation includes both the weighted-average number of shares outstanding and the number of common stock equivalents, if the inclusion of such common stock equivalents would be dilutive. Dilutive common stock equivalents potentially include warrants, stock options and 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 June 30, 2022 and 2021 have been excluded from the denominator of the diluted loss per share of common stock outstanding calculation (in thousands):

	Three Month June 3		Six Months June 3	
	2022	2021	2022	2021
Warrants	199	1,394	199	1,394
Stock options	17,161	17,349	17,161	17,349
RSUs and PSUs	8,063	<u> </u>	8,063	_
Total	25,423	18,743	25,423	18,743

### 14. SHARE-BASED COMPENSATION

The following table sets forth the amount of share-based compensation expense recognized by the Company by line item on its Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2022 and 2021 (in thousands):

	Three Months Ended June 30,			Six Months Ended June 30,				
		2022		2021		2022		2021
Research and development	\$	473	\$	207	\$	975	\$	386
General and administrative		1,329		1,052		2,721		1,831
<b>Total Share Based Compensation</b>	\$	1,802	\$	1,259	\$	3,696	\$	2,217

#### 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 3.1 million shares of common stock available for issuance under the 2014 Plan as of June 30, 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 13.6 million stock options outstanding under the 2014 Plan as of June 30, 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 then-current base salary. The fair value of PSUs at the grant date was \$0.4 million. 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 June 30, 2022 achievement was deemed probable for only the cash management milestone, representing \$87,000, 20% of the PSU awards. Therefore, \$11,000 and \$33,000 have been expensed during the three and six months ended June 30, 2022, respectively and \$54,000 remains measured but unrecognized.

# 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 June 30, 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 June 30, 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 the 2009 Plan and inducement grants made outside of stockholder approved plans, for the six months ended June 30, 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	1,511	\$0.72		
Exercised	_	_		
Canceled or forfeited	(53)	1.20		
Outstanding at June 30, 2022	17,161	\$1.83	7.72	\$ 218
Exercisable at June 30, 2022	9,555	\$1.72	7.11	\$ 64

The Company recognized share-based compensation expense, related to stock options, of \$1.2 million and \$2.5 million for the three and six months ended June 30, 2022, respectively and \$1.3 million and \$2.2 million for the three and six months ended June 30, 2021, respectively. As of June 30, 2022, there was \$8.6 million of total unrecognized compensation cost related to unvested stock options which the Company expects to recognize over a weighted-average period of 2.36 years. The weighted-average grant-date fair value of stock options granted during the six months ended June 30, 2022 and 2021 were \$0.46 and \$2.17, respectively. No stock options were exercised during the six months ended June 30, 2022.

For the six months ended June 30, 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:

	June 30, 2022	June 30, 2021
Fair market value	\$0.72	\$3.34
Grant exercise price	\$0.72	\$3.34
Expected term (in years)	6.0	6.04
Risk-free interest rate	2.1%	0.9%
Expected volatility	71.8%	74.7%
Dividend yield	<u> </u>	<u>%</u>

#### Restricted Stock Units and Performance Stock Units

The following table sets forth a summary of the Company's RSU and PSU activity for the six months ended June 30, 2022:

	Restricted Stock Units (in thousands)	Weighted Average Grant Date Fair Value
Unvested at December 31, 2021	3,041	\$0.80
Granted RSU	4,161	\$0.68
Cancelled RSU	(143)	\$0.75
Granted PSU	1,004	\$0.67
Unvested at June 30, 2022	8,063	\$0.72

The Company did not grant any RSUs or PSUs during the six months ended June 30, 2021.

The share-based compensation expense related to RSUs and PSUs for the three and six months ended June 30, 2022 was \$0.6 million and \$1.2 million, respectively. There was no shared-based compensation expense related to RSUs and PSUs for the three and six months ended June 30, 2021. As of June 30, 2022, there was \$3.0 million of total unrecognized compensation cost related to unvested RSUs and PSUs.

# 15. EMPLOYEE BENEFIT PLANS

### 2014 Employee Stock Purchase Plan

The Company's 2014 Employee Stock Purchase Plan ("2014 ESPP") was adopted by its board of directors in December 2013 and subsequently approved by its stockholders in January 2014. The 2014 ESPP became effective immediately prior to the closing of the Company's IPO in February 2014 and established an initial reserve of 0.2 million shares of the Company's common stock for issuance to participating employees. At the Annual Meeting of the Company's stockholders in May 2021, the Company's stockholders approved an amendment to the 2014 ESPP that increased by 2.3 million the number of shares of common stock reserved for issuance under the 2014 ESPP. The purpose of the 2014 ESPP is to enhance employee interest in the success and progress of the Company by encouraging employee ownership of common stock of the Company. The 2014 ESPP provides employees with the opportunity to purchase shares of common stock at a 15% discount to the market price through payroll deductions or lump sum cash investments. The Company estimates the number of shares to be issued at the end of an offering period and recognizes expense over the requisite service period. Shares of the common stock issued and sold pursuant to the 2014 ESPP are shown on the condensed consolidated statements of changes in stockholders' equity (deficit). As of June 30, 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 during the six months ended June 30, 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 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 six months ended June 30, 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 six months ended June 30, 2022 and 2021, respectively.

# 16. INCOME TAXES

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

	Six Mont June	ded
	2022	2021
Country:		
United States	\$ (55,939)	\$ (21,210)
Canada	19,297	(59,456)
<b>Total Loss before Income Taxes</b>	\$ (36,642)	\$ (80,666)

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

	Six Mont Jun	ths End e 30,	ed
	 2022		2021
Current tax benefit (provision)			
Foreign	\$ 3,875	\$	(288)
Total current benefit (provision)	\$ 3,875	\$	(288)

The Company's deferred tax liability is comprised of the following:

		June 30	, 2022	December 31, 2021	
Deferred tax liabilities					
IPR&D		\$		\$	3,969
	Total deferred tax liabilities	\$	_	\$	3,969

For the six months ended June 30, 2022, the Company recorded a benefit from income taxes of \$3.9 million. In the second quarter of 2022, the Company determined that the fair value of the Vicineum EU rights was zero, which resulted in an impairment charge of \$14.7 million. In connection with this impairment charge, the Company reversed the associated deferred tax liability by \$4.0 million as an income tax benefit, partially offset by \$0.1 million income tax paid to foreign jurisdictions pursuant to the exclusive license agreement with Qilu Pharmaceutical Co., Ltd. ("Qilu") (the "Qilu License Agreement"). Please refer to Note 8, "Intangible Assets and Goodwill," for further information regarding the impairment charge. For the six months ended June 30, 2021, the Company recorded a provision for income taxes of \$0.3 million. This provision consisted of income taxes paid to foreign jurisdictions pursuant to the Qilu License Agreement.

# 17. LICENSE AGREEMENTS

# In-License Agreements

License Agreement with Zurich

The Company has a license agreement with the University of Zurich ("Zurich") which grants the Company exclusive license rights, with the right to sublicense, to make, have made, use and sell under certain patents primarily directed to the Company's targeting agent, including an EpCAM chimera and related immunoconjugates and methods of use and manufacture of the same (the "Zurich License Agreement"). These patents cover some key aspects of Vicineum. 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 June 30, 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 \$2.5 million at exchange rates in effect on June 30, 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 \$52,148 at exchange rates in effect as of June 30, 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) related to the submission of the MAA to the EMA for Vysyneum™ in the first quarter of 2021.

# 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. 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 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 previous periods. 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 Roche License Agreement and does not cure such breach within a specified cure period. Roche may terminate the Roche License Agreement following effectiveness by providing advance written notice to the Company or by providing written notice if the Company is debarred, disqualified, suspended, excluded, or otherwise declared ineligible from certain federal or state agencies or programs. The Company may terminate the Roche License Agreement if, prior to the first filing of a BLA for a 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.

Subsequent to June 30, 2022, the Company executed an asset purchase agreement with Roche pursuant to which Roche purchased all patent rights and know-how related to the monoclonal antibody EBI-031 and all other IL-6 antagonist monoclonal antibody technology owned by the Company for up to \$70 million. See further discussion in Note 19. "Subsequent Events".

# **OUS Business Development Partnership Agreements**

# Qilu License Agreement

On July 30, 2020, the Company and its wholly-owned subsidiary, Viventia Bio, Inc., entered into the Qilu License Agreement pursuant to which the Company granted Qilu an exclusive, sublicensable, royalty-bearing license, under certain intellectual property owned or exclusively licensed by the Company, to develop, manufacture and commercialize Vicineum (the "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 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 Qilu 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 within the stated timeline and was initially recorded as deferred revenue. During the second quarter of 2022, the Company changed assumptions in the clinical study design which resulted in longer clinical trial and further delay in regulatory approval in the MENA region. Therefore, the Company reclassed \$1.5 million of deferred revenue to short-term accrued liability as of June 30, 2022. 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 was recognized in the first quarter of 2021. 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 June 30, 2022, none of these additional amounts were reasonably certain to be achieved due to the nature and timing of the underlying activities.

Subsequent to June 30, 2022, the Company terminated the MENA License Agreement as a result of the Company's strategic decision to voluntarily pause further development of Vicineum in the US. See further discussion in Note 19. "Subsequent Events."

#### 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 June 30, 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 June 30, 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 June 30, 2022, none of these additional amounts were reasonably certain to be achieved due to the nature and timing of the underlying activities.

Subsequent to June 30, 2022, the Company terminated the EIP License Agreement as a result of the Company's strategic decision to voluntarily pause further development of Vicineum in the US. See further discussion in Note 19. "Subsequent Events."

#### 18. 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 "2021 Restructuring Plan").

The 2021 Restructuring Plan included a reduction in the Company's workforce by 18 positions (or approximately 35% of the Company's workforce as of the date of the 2021 Restructuring Plan), as well as additional cost-saving initiatives intended to preserve capital while the Company continues development of Vicineum. The following is a summary of accrued restructuring costs related to the 2021 Restructuring Plan, (in thousands):

Balance as of December 31, 2021	\$ 1,497
Cash payments	(1,103)
Balance at June 30, 2022	\$ 394

The Company expects that substantially all of the accrued restructuring costs as of June 30, 2022 will be paid in cash by the end of September 2022.

Subsequent to June 30, 2022, the Company approved a restructuring plan to reduce operating expenses and better align its workforce with the needs of its business following the decision to voluntarily pause further development of Vicineum in the US. See further discussion in Note 19. "Subsequent Events."

# 19. SUBSEQUENT EVENTS

# Vicineum

On July 11, 2022, the Company participated in a Type B meeting with the FDA to discuss outstanding items related to the Company's proposed protocol and statistical analysis plan design elements for an additional Phase 3 clinical trial for Vicineum for the treatment of NMIBC.

On July 15, 2022, the Company made the strategic decision to voluntarily pause further development of Vicineum in the US. The decision was based on a thorough reassessment of Vicineum, which included the incremental development timeline and associated costs for an additional Phase 3 clinical trial, following its discussions with the FDA. The Company has turned its primary focus to assessing potential strategic alternatives with the goal of maximizing shareholder value. Additionally, the Company intends to seek a partner for the further development of Vicineum.

In connection with our decision to voluntarily pause further development of Vicineum, we have commenced the process to wind down our manufacturing operations by terminating the Master Bioprocessing Services Agreement with Fujifilm Diosynth Biotechnologies U.S.A. and the Commercial Manufacturing and Supply Agreement with Baxter on July 17, 2022 and July 20, 2022, respectively. We requested that Fujifilm and Baxter cease all work under the respective agreements and refrain from incurring any additional costs or expenses. As a result of the termination, and in accordance with the terms of the Fujifilm MSA, we have the responsibility to pay Fujifilm for certain non-manufacturing stage services and current Good Manufacturing Practice batches of drug substance of Vicineum. The Company is in the process of assessing the estimated impact of the termination of the Fujifilm MSA and the Baxter CMSA.

On July 21, 2022, the Company terminated its Cooperative Research and Development Agreement with the National Cancer Institute for the development of Vicineum in combination with AstraZeneca's immune checkpoint inhibitor durvalumab for the treatment of BCG-unresponsive NMIBC.

# **OUS Business Development Partnerships**

In connection with the Company's decision to voluntarily pause further development of Vicineum in the US, the Company has commenced the process to wind down its OUS business development partnerships in MENA and Turkey by providing notice of termination for the MENA License Agreement and EIP License Agreement on July 20, 2022.

### 2022 Restructuring Plan

On July 15, 2022, the Company approved a restructuring plan to reduce operating expenses and better align its workforce with the needs of its business following the decision to pause further development of Vicineum in the US (the "2022 Restructuring Plan"). Execution of the 2022 Restructuring Plan is expected to be substantially complete by the end of the fourth quarter of 2022. The 2022 Restructuring Plan includes an incremental reduction in the Company's workforce as well as additional cost-saving initiatives intended to preserve capital while the Company continues to assess potential strategic alternatives with the goal of maximizing shareholder value and seek a potential partner for the further development of Vicineum. As of the filing of this Quarterly Report on Form 10-Q, the Company estimates that it will incur in the third and fourth quarters of 2022 severance and other employee-related costs of approximately \$8 million.

The Company also expects to incur one-time cash costs associated with the termination of certain contracts and all other activities under the 2022 Restructuring Plan, and is in the process of assessing the estimated impact.

# Sale of Legacy Technology to Roche

On July 15, 2022, the Company executed an asset purchase agreement (the "Roche Asset Purchase Agreement") with Roche pursuant to which Roche purchased all patent rights and know-how related to the monoclonal antibody EBI-031 and all other IL-6 antagonist monoclonal antibody technology owned by the Company for up to \$70 million. As a result of the Roche Asset Purchase Agreement, the Roche License Agreement was terminated resulting in no further diligence, milestone or royalty payment obligations under the Roche License Agreement. Pursuant to the Roche Asset Purchase Agreement, Roche made a \$40 million payment to the Company upon execution of the Roche Asset Purchase Agreement. The Roche Asset Purchase Agreement also provides that Roche will make an additional \$30 million payment to the Company upon Roche's initiation of a Phase 3 clinical trial with EBI-031 for a defined indication if initiated prior to December 31, 2026.

# **Securities and Derivative Litigation**

On June 30, 2022 and July 6, 2022, the Company and the plaintiffs in the Securities Litigation engaged in in-person mediation sessions in an attempt to resolve the litigation and continued to discuss a potential settlement over the following weeks. On July 19, 2022, the parties reached an agreement in principle to settle the Securities Litigation. Pursuant to that agreement, the Company and the individual defendants will pay or cause to be paid to members of the class who submit timely and valid proofs of claims. In exchange, the Lead Plaintiffs will dismiss the action and all class members who do not timely and validly opt-out of the settlement will provide broad customary releases to the Company and the individual defendants. On August 3, 2022, the parties entered into a Stipulation and Agreement of Settlement to settle the Securities Litigation, which is subject to court approval.

On July 6, 2022, the Company and the plaintiffs to the Federal Derivative Litigation and the State Derivative Litigation engaged in an in-person mediation session in an attempt to resolve the litigation, with settlement discussions continuing over the following days. On July 19, 2022, the parties reached an agreement in principle to settle the Federal Derivative Litigation, the State Derivative Litigation and other potential related derivative claims. Pursuant to that agreement, the individual defendants

will cause the Company to adopt certain enhancements to the Company's corporate governance policies and procedures. In exchange, the plaintiffs will dismiss the complaints and, on behalf of the Company, provide broad customary releases to the individual defendants. The agreement is subject to the execution of a definitive stipulation of settlement and, after notice to the Company's stockholders, court approval.

# Transfer to Nasdaq Capital Market

On July 26, 2022, the Company received approval from the Listing Qualifications Department of The Nasdaq Stock Market LLC ("Nasdaq") to transfer the listing of the Company's common stock from the Nasdaq Global Market to the Nasdaq Capital Market (the "Approval"). As a result of the Approval, the Company has been granted a second 180-day grace period, or until January 23, 2023, to regain compliance with the minimum bid price requirement.

As previously disclosed, on January 24, 2022, the Company received written notice from Nasdaq indicating that the Company was not in compliance with the \$1.00 minimum bid price requirement for continued listing on the Nasdaq Global Market, as set forth in Nasdaq Listing Rule 5450(a)(1). The Company was given until July 25, 2022, to regain compliance with the minimum bid price requirement. In response, the Company submitted an application to transfer the listing of its common stock from the Nasdaq Global Market to the Nasdaq Capital Market.

The Company's common stock was transferred to the Nasdaq Capital Market effective at the opening of business on July 28, 2022 and will continue to trade under the symbol "SESN". The Nasdaq Capital Market operates in substantially the same manner as the Nasdaq Global Market and requires that listed companies meet certain financial and liquidity requirements and comply with Nasdaq's corporate governance requirements.

To regain compliance with the minimum bid price requirement and qualify for continued listing on the Nasdaq Capital Market, the minimum bid price per share of the Company's common stock must be at least \$1.00 for at least ten consecutive business days during the second 180-day grace period. If the Company does not regain compliance during this second grace period, its common stock would be subject to delisting by Nasdaq. As part of its transfer application, the Company notified Nasdaq that if its stock price does not recover sufficiently during the second grace period, it would implement a reverse stock split, if necessary.

# 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 to continue to assess potential strategic alternatives with the goal of maximizing shareholder value;
- our intentions to seek a partner for the further development of Vicineum;
- the expected timing of implementing and completing our restructuring plan following the decision to pause further development of Vicineum in the US (the "2022 Restructuring Plan");
- the expected timing for incurring costs associated with the 2022 Restructuring Plan;
- our ability to preserve capital while we continue to assess potential strategic alternatives and seek a potential partner for the further development of Vicineum;
- the potential impact of the COVID-19 pandemic on our ability to identify and assess potential strategic alternatives and seek a partner for the further development of Vicineum;
- · our projected financial position;
- our ability to obtain and maintain intellectual property protection for our product candidates and our proprietary technology;
- · our beliefs regarding key advantages of our targeted fusion protein therapeutics ("TFPT") platform; and
- our expectations regarding the amount of future milestone payments pursuant to our Asset Purchase Agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (collectively, "Roche"), (the "Roche Asset Purchase Agreement") and any future milestone or royalty payments pursuant our exclusive license agreement with Qilu Pharmaceutical Co., Ltd. ("Qilu") for the development, manufacture and commercialization of Vicineum in China, Hong Kong, Macau and Taiwan ("Greater China") (the "Qilu License Agreement").

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 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;
- we may not be successful in identifying a partner for the further development of Vicineum;
- our exploration and evaluation of strategic alternatives may cause our stock price to fluctuate significantly;
- we may not be able to implement the 2022 Restructuring Plan as currently anticipated or within the timing currently anticipated;
- the workforce reduction in connection with the 2022 Restructuring Plan may have a negative impact on our business;
- our cost saving initiatives in connection with the 2022 Restructuring Plan may not be successful;

- we may have unanticipated difficulties with preserving capital or unanticipated difficulties in terminating certain contracts and arrangements in connection with the 2022 Restructuring Plan;
- we may incur unanticipated charges as a result of the 2022 Restructuring Plan;
- the risk that the respective courts may not approve any settlements agreed to by the parties to the ongoing securities litigation and the derivative litigation:
- 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 not meet the Nasdaq minimum bid price requirement during any compliance period or in the future; and
- such other factors described throughout Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations and in Part II, Item 1A. Risk Factors 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.

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 focused on advancing targeted fusion protein therapeutics for the treatment of patients with cancer.

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

On July 15, 2022, we made the strategic decision to voluntarily pause further development of Vicineum in the US. The decision was based on a thorough reassessment of Vicineum, which included the incremental development timeline and associated costs for an additional Phase 3 clinical trial, following our discussions with the United States Food and Drug Administration ("FDA"), which are further described below. We have turned our primary focus to assessing potential strategic alternatives with the goal of maximizing shareholder value. Additionally, we intend to seek a partner for the further development of Vicineum.

### **Recent Events**

Assessment of Potential Strategic Alternatives

On May 3, 2022, we announced that we 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 assessment process.

2022 Restructuring Plan

On July 15, 2022, we approved a restructuring plan to reduce operating expenses and better align our workforce with the needs of our business following the decision to pause further development of Vicineum in the US. Execution of the 2022 Restructuring Plan is expected to be substantially complete by the end of the fourth quarter of 2022. The 2022 Restructuring Plan includes an incremental reduction in our workforce as well as additional cost-saving initiatives intended to preserve capital while we continue to assess potential strategic alternatives with the goal of maximizing shareholder value and seek a potential partner for the further development of Vicineum. As of the filing of this Quarterly Report on Form 10-Q, we estimate that we will incur in the third and fourth quarters of 2022 severance and other employee-related costs of approximately \$8 million.

We also expect to incur one-time cash costs associated with the termination of certain contracts and all other activities under the 2022 Restructuring Plan, and are in the process of assessing the estimated impact.

Sale of Legacy Technology to Roche

On July 15, 2022, we executed an asset purchase agreement with Roche pursuant to which Roche purchased all patent rights and know-how related to the monoclonal antibody EBI-031 and all other IL-6 antagonist monoclonal antibody technology

owned by us for up to \$70 million. As a result of the Roche Asset Purchase Agreement, the exclusive license agreement between Roche and us was terminated resulting in no further diligence, milestone or royalty payment obligations under such license agreement. Pursuant to the Roche Asset Purchase Agreement, Roche made a \$40 million payment to us upon execution of the Roche Asset Purchase Agreement. The Roche Asset Purchase Agreement also provides that Roche will make an additional \$30 million payable to us upon Roche's initiation of a Phase 3 clinical trial with EBI-031 for a defined indication if initiated prior to December 31, 2026.

# 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 chemistry, manufacturing and controls ("CMC") issues pertaining to a recent pre-approval inspection and product quality. On August 20, 2021, we withdrew our marketing authorization application ("MAA") to the European Medicines Agency (the "EMA") for Vysyneum for the treatment of BCG-unresponsive NMIBC in order to pause our plans to pursue regulatory approval of Vysyneum in the EU 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 EU. In October 2021, the EMA issued its 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.

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

On July 15, 2022, we made the strategic decision to voluntarily pause further development of Vicineum in the US. The decision was based on a thorough reassessment of Vicineum, which included the incremental development timeline and associated costs for an additional Phase 3 clinical trial, following our discussions with the FDA. As a result of this decision, we no longer plan to pursue regulatory approval of Vicineum for NMIBC in the EU. We have turned our primary focus to assessing potential strategic alternatives with the goal of maximizing shareholder value. Additionally, we intend to seek a partner for the further development of Vicineum.

#### 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. In May 2022, we completed the follow-up phase of the VISTA Trial.

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%)

<sup>\*</sup>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%)

<sup>\*</sup>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%)

<sup>\*</sup>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.

**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 was 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 Diosynth Biotechnologies U.S.A., Inc. ("Fujifilm") (the "Fujifilm MSA") for the manufacturing process and technology transfer of Vicineum drug substance production.

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

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.

In connection with our decision to voluntarily pause further development of Vicineum, we have commenced the process to wind down our manufacturing operations by terminating the Fujifilm MSA and Baxter CMSA on July 17, 2022 and July 20, 2022, respectively. We requested that Fujifilm and Baxter cease all work under the respective agreements and refrain from incurring any additional costs or expenses. As a result of the termination, and in accordance with the terms of the Fujifilm MSA, we have the responsibility to pay Fujifilm for certain non-manufacturing stage services and current Good Manufacturing Practice batches of drug substance of Vicineum. We are in the process of assessing the estimated impact of the termination of the Fujifilm MSA and the Baxter CMSA.

# In-License Agreements

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

We have a License Agreement with Micromet AG ("Micromet"), now part of Amgen, Inc., which grants us nonexclusive rights, with certain sublicense rights, for know-how and patents allowing exploitation of certain single chain antibody products (the "Micromet License Agreement"). These patents cover some key aspects of Vicineum.

We have a license agreement with XOMA Ireland Limited ("XOMA") which grants us non-exclusive rights to certain XOMA patent rights and know-how related to certain expression technology, including plasmids, expression strains, plasmid maps and production systems (the "XOMA License Agreement"). These patents and related know-how cover some key aspects of Vicineum.

Notwithstanding our decision to voluntarily pause further development of Vicineum, we have not taken steps to terminate the above mentioned in-license agreements because our outside the United States ("OUS") business development partners have been granted sublicenses to the intellectual property licensed to us under these in-license agreements.

# **OUS Business Development Partnering**

In connection with our decision to voluntarily pause further development of Vicineum, we have commenced the process to wind down our OUS business development partnerships in the Middle East and North Africa region ("MENA") and Turkey by providing notice of termination for the MENA License Agreement and EIP License Agreement on July 20, 2022. In connection with the termination of our exclusive license agreement with our partner in MENA, we are required to refund the \$3 million upfront payment paid to us.

#### Greater China

On July 30, 2020, we and our wholly-owned subsidiary, Viventia Bio, Inc., entered into the Qilu License Agreement pursuant to which we granted Qilu an exclusive, sublicensable, royalty-bearing license, under certain intellectual property owned or exclusively licensed by us, to develop, manufacture and commercialize Vicineum for the treatment of 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.

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.

# **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 milestone payments and royalties in connection with 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 contract resource organizations ("CROs") and investigative sites that conduct our clinical trials;
- expenses associated with developing manufacturing capabilities;
- expenses associated with transferring manufacturing capabilities to contract manufacturing organizations ("CMOs") for commercial-scale production;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies;
- expenses associated with regulatory activities; and
- expenses associated with license milestone fees.

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

We allocate direct research and development expenses, consisting principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical trials, costs related to manufacturing or purchasing clinical trial materials and technology transfer and license milestone fees, to specific product programs. We do not allocate employee and contractor-related costs, costs associated with our platform and facility expenses, including depreciation or other indirect costs, to specific product programs because these costs may be deployed across multiple product programs under research and development and, as such, are separately classified. The table below provides research and development expenses incurred for Vicineum for the treatment of NMIBC and other expenses by category. We expect to significantly reduce our research and development expenses as we turn our primary focus to assessing potential strategic alternatives with the goal of maximizing shareholder value and seek a partner for the further development of Vicineum.

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

		nths Ended ne 30,	Six Months Ended June 30,		
	2022	2021	2022	2021	
Programs:					
Vicineum for the treatment of NMIBC	\$ 27,432	\$ 4,332	\$ 28,892	\$ 7,898	
Total direct program expenses	27,432	4,332	28,892	\$ 7,898	
Personnel and other expenses:					
Employee and contractor-related expenses	2,113	2,389	5,080	4,660	
Platform-related lab expenses	22	64	96	114	
Facility expenses	123	143	277	268	
Other expenses	254	300	360	366	
Total personnel and other expenses	2,512	2,896	5,813	5,408	
<b>Total Research and Development</b>	\$ 29,944	\$ 7,228	\$ 34,705	\$ 13,306	

### 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, estimated payments to settle litigation, insurance, investment banking fees, patent, consulting and accounting services, and pre-commercial United States market research. Our general and administrative expenses may increase due to increases in professional and advisory fees as we assess potential strategic alternatives.

# 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 June 30, 2022 and 2021

	Three Months Ended June 30,			Increase/(Decrease)					
		2022		2021		Dollars	Percentage		
		(in thousands, exce					ept percentages)		
Revenue:									
License and related revenue	\$	_	\$	2,234	\$	(2,234)	(100)%		
Total revenue		_		2,234		(2,234)	(100)%		
Operating expenses:									
Research and development	\$	29,944	\$	7,228	\$	22,716	314 %		
General and administrative		15,589		6,805		8,784	129 %		
Intangibles impairment charge		27,764		_		27,764	_		
Change in fair value of contingent consideration		(37,300)		13,600		(50,900)	(374) %		
Total operating expenses		35,997		27,633		8,364	30 %		
Loss from Operations		(35,997)		(25,399)		(10,598)	42 %		
Other income (expense):									
Other income (expense), net		162		(43)		205	(477)%		
Loss Before Taxes	\$	(35,835)	\$	(25,442)	\$	(10,393)	41 %		
Benefit from income taxes		3,875				3,875	_		
Net Loss After Taxes	\$	(31,960)	\$	(25,442)	\$	(6,518)	26 %		

#### License Revenue

We did not record any revenue for the three months ended June 30, 2022. Revenue for the three months ended June 30, 2021 was \$2.2 million, which was due to clinical supply revenue resulting from the delivery of drug product to Qilu, our OUS business development partner for Greater China and license revenue for additional purchase price due to the recovery of VAT by Oilu.

# Research and Development

Research and development expenses were \$29.9 million for the three months ended June 30, 2022, compared to \$7.2 million for the three months ended June 30, 2021. The increase of \$22.7 million was primarily due to the expense of prepaid balances related to consumables and manufacturing reservations as the balances were evaluated and deemed to have no future value (\$25.2 million). This increase was partially offset by lower costs associated with manufacturing (\$2.5 million).

# General and Administrative

General and administrative expenses were \$15.6 million for the three months ended June 30, 2022, compared to \$6.8 million for the three months ended June 30, 2021. The increase of \$8.8 million was primarily due to an increase in legal expense (\$10.3 million). This increase was driven by the preliminary settlements of the securities and derivative litigation net of expected insurance recovery (\$8.6 million), related legal fees (\$0.9 million), legal fees related to the internal review (\$0.3 million) and other legal expenses (\$0.5 million). This increase was partially offset by a decrease in marketing and commercial expenses, which were incurred in the second quarter of 2021 in preparation for potential commercial launch but were discontinued as a result of the Complete Response Letter received in August 2021 (\$1.5 million).

# Change in Fair Value of Contingent Consideration

The non-cash change in fair value of contingent consideration was income of \$37.3 million for the three months ended June 30, 2022, compared to a loss of \$13.6 million for the three months ended June 30, 2021. The decrease in the fair value of contingent consideration of \$37.3 million for the three months ended June 30, 2022 was driven by our strategic decision to

voluntarily pause further development of Vicineum. The decision was based on a thorough reassessment of Vicineum, which included the incremental development timeline and associated costs for an additional Phase 3 clinical trial for the treatment of NMIBC, following recent discussions with the FDA and the updated market data obtained through market research during the ongoing BCG shortage. We intend to seek a partner for the further development of Vicineum. We expect that any partner who acquires Vicineum from us will be obligated to make any payments to the former shareholders of Viventia under the Share Purchase Agreement.

The change in fair value of contingent consideration was a loss of \$13.6 million for the three months ended June 30, 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.

#### Benefit (Provision) from Income Taxes

For the three months ended June 30, 2022, we recorded a benefit from income taxes of \$3.9 million. In the second quarter of 2022, we determined that the fair value of the Vicineum EU rights was zero, which resulted in an impairment charge of \$14.7 million. In connection with this impairment charge, in the second quarter of 2022, we wrote-down the associated deferred tax liability by \$4.0 million as a benefit, partially offset by \$0.1 million income tax paid to foreign jurisdictions pursuant to the Qilu License Agreement. Please refer to Note 8, "Intangible Assets and Goodwill," for further information regarding the impairment charge. No provision for income taxes was recorded for the three months ended June 30, 2021.

#### Net loss

For the three months ended June 30, 2022, net loss was \$32.0 million, compared to net loss of \$25.4 million for the three months ended June 30, 2021. The change was primarily attributable to increases in R&D and G&A expense (\$31.5 million), primarily driven by the reduction of prepaid balances related to consumables and manufacturing reservations and the preliminary settlements of the securities and derivative litigation. Additionally, license and related revenue recognized decreased (\$2.2 million). This was partially offset by favorable changes in non-cash related expenses of \$27.0 million (including tax benefit).

### **Our Results of Operations**

#### Comparison of the six months ended June 30, 2022 and 2021

	Six Months Ended June 30,				Increase/(Decrease)			
		2022		2021		Dollars	Percentage	
		(in thousands, except percentages)						
Revenue:								
License and related revenue	\$		\$	6,544	\$	(6,544)	(100)%	
Total revenue		_		6,544		(6,544)	(100)%	
Operating expenses:								
Research and development	\$	34,705	\$	13,306	\$	21,399	161 %	
General and administrative		24,564		12,098		12,466	103 %	
Restructuring charge		_		_		_	_	
Intangibles impairment charge		27,764		_		27,764	_	
Change in fair value of contingent consideration		(50,200)		61,760		(111,960)	(181)%	
Total operating expenses		36,833		87,164		(50,331)	(58) %	
Loss from Operations		(36,833)		(80,620)		43,787	(54) %	
Other income (expense), net		191		(46)		237	(515)%	
Loss Before Taxes		(36,642)		(80,666)		44,024	(55)%	
Benefit (provision) from income taxes		3,875		(288)		4,163	(1,445)%	
Net Loss After Taxes		(32,767)	\$	(80,954)	\$	48,187	(60)%	

#### License Revenue

We did not record any revenue for the six months ended June 30, 2022. Revenue for the six months ended June 30, 2021 was \$6.5 million, which was due to achieving the IND milestone in China pursuant to the Qilu License Agreement, clinical supply revenue resulting from the delivery of drug product to Qilu, our OUS partner for Greater China, and license revenue for additional purchase price due to the recovery of VAT by Qilu.

## Research and Development

Research and development expenses were \$34.7 million for the six months ended June 30, 2022, compared to \$13.3 million for the six months ended June 30, 2021. The increase of \$21.4 million was primarily due to the expense of prepaid balances related to consumables and manufacturing reservations as the balances were deemed to have no future value (\$25.2 million). This increase was partially offset by lower costs associated with manufacturing (\$3.7 million).

### General and Administrative

General and administrative expenses were \$24.6 million for the six months ended June 30, 2022, compared to \$12.1 million for the six months ended June 30, 2021. The increase of \$12.5 million was primarily due to an increase in legal expense (\$13.3 million) driven by the preliminary settlements of the securities and derivative litigation net of expected insurance recovery (\$8.6 million), related legal fees (\$1.2 million), legal fees related to the internal review (\$3.2 million) and other legal expenses (\$0.3 million). In addition, employee-related compensation, primarily driven by increased headcount and the retention program implemented in the fourth quarter of 2021 (\$1.2 million) and increased insurance expense (\$0.3 million). This was partially offset by decreases in marketing and commercial expenses (\$1.7 million) and consultant fees (\$0.9 million), which were incurred during the first half of 2021 in preparation for potential commercial launch but were discontinued as a result of the Complete Response Letter received in August 2021 and other general expenses (\$0.1 million).

#### Change in Fair Value of Contingent Consideration

The non-cash change in fair value of contingent consideration was income of \$50.2 million for the six months ended June 30, 2022, compared to a loss of \$61.8 million for the six months ended June 30, 2021. The decrease in the fair value of contingent consideration of \$50.2 million for the six months ended June 30, 2022 was driven by our strategic decision to voluntarily pause further development of Vicineum. The decision was based on a thorough reassessment of Vicineum, which included the incremental development timeline and associated costs for an additional Phase 3 clinical trial for the treatment of NMIBC, following recent discussions with the FDA and the updated market data obtained through market research during the ongoing BCG shortage. We intend to seek a partner for the further development of Vicineum. We expect that any partner who acquires Vicineum from us will be obligated to make any payments to the former shareholders of Viventia under the Share Purchase Agreement

The change in fair value of contingent consideration was a loss of \$61.8 million for the six months ended June 30, 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

For the six months ended June 30, 2022, we recorded a benefit from income taxes of \$3.9 million. In the second quarter of 2022, we determined that the fair value of the Vicineum EU rights was zero, which resulted in an impairment charge of \$14.7 million. In connection with this impairment charge, in the second quarter of 2022, we wrote-down the associated deferred tax liability by \$4.0 million as a benefit, partially offset by \$0.1 million income tax paid to foreign jurisdictions pursuant to the Qilu License Agreement. Please refer to Note 8, "Intangible Assets and Goodwill," for further information regarding the impairment charge. For the six months ended June 30, 2021, we recorded a provision for income taxes of \$0.3 million. This provision consisted of income taxes paid to foreign jurisdictions pursuant to the Qilu License Agreement.

#### Net Loss

For the six months ended June 30, 2022 net loss was \$32.8 million, compared to net loss of \$81.0 million, for the six months ended June 30, 2021. The decrease of \$48.2 million was primarily due to decreases in operating expense (\$50.3 million) and the tax provision (\$4.2 million) partially offset by a decrease in license and related revenue recognized (\$6.5 million). The decrease in operating expense (\$50.3 million) was driven by non-cash adjustments (\$84.2 million), partially offset by a \$33.9 million increase in expense. This increase was primarily due to the reduction of our prepaid balances related to consumables and manufacturing reservations and the preliminary settlements of the securities and derivative litigation.

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

# Overview

As of June 30, 2022, we had cash, cash equivalents and marketable securities of \$161.2 million, net working capital of \$124.4 million and an accumulated deficit of \$349.0 million. We incurred negative cash flows from operating activities of \$1.4 million for the six months ended June 30, 2022, compared to negative cash flows of \$41.6 million for the six months ended June 30, 2021. We believe that, based on our current operating plans and financial forecasts, our cash, cash equivalents and marketable securities of \$161.2 million as of June 30, 2022, are sufficient to fund our current operating plan for at least twelve months from the date of this Form 10-Q filing, August 8, 2022.

Since our inception, we have received no revenue from sales of our products, and we anticipate that operating losses will continue for the foreseeable future as we continue to assess any potential 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 June 30, 2022. Sales of common stock under the Sale Agreement are made by any method that is deemed to be an ATM offering as defined in Rule 415(a)(4) of the Securities Act of 1933, including but not limited to sales made directly on or through the Nasdaq Stock Market or any other existing trading market for our common stock. We may sell shares of our common stock efficiently from time to time but have no obligation to sell any of our common stock and may at any time suspend offers under the Sale Agreement or terminate the Sale Agreement. Subject to the terms and conditions of the Sale Agreement, Jefferies will use its commercially

reasonable efforts to sell common stock from time to time, as the sales agent, based upon our instructions, which include a prohibition on sales below a minimum price set by us from time to time. We have provided Jefferies with customary indemnification rights, and Jefferies is entitled to a commission at a fixed rate equal to 3.0% of the gross proceeds for each sale of common stock under the Sale Agreement. We did not sell any shares of common stock pursuant to the Sale Agreement during the six months ended June 30, 2022. We raised \$136.8 million of net proceeds from the sale of 47.1 million shares of common stock at a weighted-average price of \$2.99 per share during the six months ended June 30, 2021, including \$64.3 million of net proceeds from the sale of 16.5 million shares of common stock at a weighted-average price of \$4.02 per share during the three months ended June 30, 2021. Share issue costs, including sales agent commissions, related to the ATM Offering totaled \$2.0 million and \$4.2 million for the three and six months ended June 30, 2021, respectively.

# **Funding Requirements**

Our future success is dependent on our ability to identify and ultimately consummate a strategic transaction. 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 assessment process.

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

We will incur substantial expenses if and as we:

- address our ongoing securities litigation and derivative litigation;
- maintain, expand and protect our intellectual property portfolio;
- reduce our personnel and incur related severance and employee-related costs;
- wind down and dispose of the equipment and physical infrastructure that had been used to support our research and development activities;
- terminate contracts with our CMOs;
- terminate our property leases in Winnipeg, Manitoba, Cambridge, Massachusetts and Philadelphia, Pennsylvania;
- · restore our Winnipeg manufacturing facility to the state in which it was originally leased; and
- explore, evaluate and pursue any strategic alternatives in connection with the review process we have initiated.

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

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

Until such time, if ever, as we can generate substantial revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, or government or other third-party funding To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include liens or other restrictive covenants limiting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our assessment of strategic alternatives. If we do not successfully consummate a strategic alternative, our board of directors may decide to pursue a dissolution and liquidation of our company.

# Contractual and Other Obligations

For information related to our cash requirements from known contractual and other obligations, see the description of Contingent Consideration in Note 5 "Fair Value Measurement and Financial Instruments," as well as the description of our leases in Note 11 "Leases", and the description of our license agreement and collaborations in Note 17, "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 six months ended June 30, 2022 and 2021 (in thousands):

	Six Months Ended June 30,			
		2022		2021
Net Cash Used in Operating Activities	\$	(1,441)	\$	(41,616)
Net Cash Used in Investing Activities		(89,095)		(49)
Net Cash Provided by Financing Activities		_		137,312
Net (Decrease) Increase in Cash, Cash Equivalents and Restricted Cash	\$	(90,536)	\$	95,647

#### Net Cash Used in Operating Activities

Net cash used in operating activities was \$1.4 million for the six months ended June 30, 2022 and consisted primarily of a net loss of \$32.8 million, adjusted for non-cash items including, a decrease in the fair value of contingent consideration (\$50.2 million), intangible impairment charge (\$27.8 million), share-based compensation (\$3.7 million), and a net increase in operating assets and liabilities (\$50.1 million).

Net cash used in operating activities was \$41.6 million for the six months ended June 30, 2021 and consisted primarily of a net loss of \$81.0 million, which includes \$6.5 million of revenue recognized pursuant to certain of our out-license agreements, adjusted for non-cash items, including share-based compensation (\$2.2 million), an increase in the fair value of contingent consideration (\$61.8 million) and a net decrease in operating assets and liabilities of (\$24.7 million).

#### Net Cash Used in Investing activities

Net cash used in investing activities was \$89.1 million for the six months ended June 30, 2022 and consisted of marketable security purchases.

Net cash used in investing activities consisted of de minimis purchases and sales or property and equipment during the six months ended June 30, 2021.

# Net Cash Provided by Financing activities

Net cash provided by financing activities was zero for the six months ended June 30, 2022.

Net cash provided by financing activities was \$137.3 million for the six months ended June 30, 2021 and consisted primarily of \$136.8 million net proceeds from the sale of common stock under the ATM Offering.

# **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 IPR&D worldwide product rights to Vicineum as a result of the acquisition of Viventia in 2016. IPR&D assets acquired in a business combination are considered indefinite-lived until the completion or abandonment of the associated research and development efforts.

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

or changes in circumstances have occurred which could indicate that the carrying value of our intangible assets was not recoverable. If an impairment indicator is identified, an interim impairment assessment is performed.

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

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

### **Contingent Consideration**

Contingent consideration on our 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 earnout payments 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.

The estimated fair value of our contingent consideration was determined using probabilities of successful achievement of regulatory milestones and commercial sales, the period in which these milestones and sales were expected to be achieved through 2033, the level of commercial sales of Vicineum forecasted for the US, Europe, Japan, China and other potential markets. Earnouts were determined using an earnout rate of 2% on all commercial net sales of Vicineum through December

2033. The discount rate applied to the 2% earnout was derived from our estimated weighted-average cost of capital, which has fluctuated from 9.3% as of December 31, 2021 to 10.2% as of June 30, 2022. Milestone payments constitute debt-like obligations, and therefore a high-yield debt index rate was applied to the milestones in order to determine the estimated fair value. This index rate was 8.0% as of December 31, 2021.

On July 15, 2022, we made the strategic decision to voluntarily pause further development in the US of Vicineum. The decision was based on a thorough reassessment of Vicineum, which included the incremental development timeline and associated costs for an additional Phase 3 clinical trial for the treatment of NMIBC, following recent discussions with the FDA and the updated market data obtained through market research during the ongoing BCG shortage. Additionally, we intend to seek a partner for the further development of Vicineum. We expect any partner who acquires Vicineum from us will be obligated to make any payments to the former shareholders of Viventia under the Share Purchase Agreement. Accordingly, as of June 30, 2022, we no longer expect to pay related milestone and earnout payments, with the exception of the potential 2% earnout payment related to the Greater China region since those territory rights have already been out-licensed. Therefore, the June 30, 2022 balance relates to contingent consideration related to projected net sales in the Greater China region as compared to the December 31, 2021 balance which was based upon projected world-wide net sales.

#### 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. As of June 30, 2022, we reduced our deferred tax liabilities by \$4.0 million as a result of intangibles impairment charge, driven by the decision to pause the development of Vicineum.

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 June 30, 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.

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

# 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 principal 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 June 30, 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 June 30, 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. After the motion was fully briefed and before the court ruled on the motion, on June 3, 2022, the parties requested that the court hold any decision on the motion to dismiss in abeyance to provide the parties with an opportunity to engage in mediation. On June 30, 2022 and July 6, 2022, the Company and the plaintiffs in the Securities Litigation engaged in in-person mediation sessions in an attempt to resolve the litigation and continued to discuss a potential settlement over the following weeks. On July 19, 2022, the parties reached an agreement in principle to settle the Securities Litigation. Pursuant to that agreement, the Company and the individual defendants will pay or cause to be paid to members of the class who submit timely and valid proofs of claims. In exchange, the Lead Plaintiffs will dismiss the action and all class members who do not timely and validly opt-out of the settlement will provide broad customary releases to the Company and the individual defendants. On August 3, 2022, the parties entered into a Stipulation and Agreement of Settlement to settle the Securities Litigation, which is subject to court approval.

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 (the "State Securities Litigation"). 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. On May 18, 2022, the court entered a joint stipulation among the parties to stay the State Derivative Litigation until after a ruling on any motion to dismiss filed by defendants in the Securities Litigation. On July 6, 2022, the Company and the plaintiffs to the Federal Derivative Litigation and the State Derivative Litigation engaged in an in-person mediation session in an attempt to resolve the litigation, with settlement discussions continuing over the following days. On July 19, 2002, the parties reached an agreement in principle to settle the Federal Derivative Litigation, the State Derivative Litigation and other potential related derivative claims. Pursuant to that agreement, the individual defendants will cause the Company to adopt certain enhancements to the Company's corporate governance policies and procedures. In exchange, plaintiffs will dismiss the complaints and, on behalf of the Company, provide broad customary releases to the individual defendants. The agreement is subject to the execution of a definitive stipulation of settlement and, after notice to the Company's stockholders, court approval.

The Company, its board of directors and the individual defendants continue to deny all allegations of any wrongdoing, but are seeking to settle the Securities Litigation, the State Derivative Litigation and the Federal Derivative Litigation to avoid the uncertainty, risk, expense and distraction of protracted litigation.

#### Item 1A. Risk Factors.

During the six months ended June 30, 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 financial 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 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 assessment process, which we believe will be complete by the end of 2022. On July 15, 2022, we made the strategic decision to voluntarily pause further development in the US of Vicineum. This decision enables us to conserve cash while we continue to assess potential strategic alternatives. Additionally, we intend to seek a partner for the further development of Vicineum.

There can be no assurance any transaction will result from the Company's evaluation of strategic alternatives. 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, obtaining stockholder approval 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 may involve the dedication of significant resources and may require us to incur significant costs and expenses. It could 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 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 within the anticipated timing or at all.

If we do not successfully complete a strategic transaction, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no guarantee that the process to identify a strategic transaction will result in a successfully completed transaction. If no transaction is completed, our board of directors may decide that it is in the best interest of our stockholders to dissolve our company and liquidate our assets. In that event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as we fund our operations and evaluate our strategic alternatives. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution of our company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of our company. If a dissolution and liquidation were pursued, our board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a dissolution, liquidation or winding up of our company.

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

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

On January 24, 2022, we received notice (the "Notice") from the Nasdaq Stock Market LLC ("Nasdaq") that we were not currently in compliance with the \$1.00 minimum bid price requirement for continued listing on the Nasdaq Global Market, as set forth in Nasdaq Listing Rule 5450(a)(1). The Notice indicated that, consistent with Nasdaq Listing Rule 5810(c)(3)(A), we

had 180 calendar days, or until July 25, 2022, to regain compliance with the minimum bid price requirement by having the closing bid price of our common stock meet or exceed \$1.00 per share for at least ten consecutive business days. On July 26, 2022, we received approval from the Listing Qualifications Department of Nasdaq to transfer the listing of our common stock from the Nasdaq Global Market to the Nasdaq Capital Market. As a result, we were granted a second 180-day grace period, or until January 23, 2023, to regain compliance with the minimum bid price requirement.

If we do not regain compliance by January 23, 2023, we will receive notification from Nasdaq that our common stock is subject to delisting. At that time, we may then appeal the delisting determination to a Nasdaq hearings panel. Such notification will have no immediate effect on our listing on the Nasdaq Capital Market, nor will it have an immediate effect on the trading of our common stock pending such hearing. There can be no assurance, however, that we will be able to regain compliance with Nasdaq's minimum bid price requirement, there can be no assurance that we will be able to maintain compliance with the continued listing requirements for the Nasdaq Capital Market or that our common stock will not be delisted from the Nasdaq Capital Market in the future. In addition, we may be unable to meet other applicable listing requirements of the Nasdaq Capital Market, including maintaining minimum levels of stockholders' equity or market values of our common stock in which case, our common stock could be delisted notwithstanding our ability to demonstrate compliance with the minimum bid price requirement.

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

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

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

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

On August 30, 2021, we approved a restructuring plan to reduce operating expenses and better align our workforce with the needs of our business following receipt of the CRL from the FDA regarding our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC (the "2021 Restructuring Plan"). On July 15, 2022, we approved a restructuring plan to reduce operating expenses and better align our workforce with the needs of our business following our decision to pause further development of Vicineum in the US (the "2022 Restructuring Plan"). Execution of the 2021 Restructuring Plan was substantially completed by the end of 2021. Execution of the 2022 Restructuring Plan is expected to be substantially completed by the end of 2022. The 2022 Restructuring Plan includes an incremental reduction in the Company's workforce as well as additional cost-saving initiatives intended to preserve capital while the Company continues to assess potential strategic alternatives with the goal of maximizing shareholder value and seek a potential partner for the further development of Vicineum. As of the filing of this Quarterly Report on Form 10-Q, the Company estimates that it will incur in the third and fourth quarters of 2022 severance and other employee-related costs of approximately \$8 million.

The Company also expects to incur one-time cash costs associated with the termination of certain contracts and all other activities under the 2022 Restructuring Plan, and is in the process of assessing the estimated impact.

We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. For example, we may incur unanticipated charges not currently contemplated as a result of the restructuring plans. If we are unable to realize the expected operational cost savings from the restructuring, our operating results and financial condition would be adversely affected.

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

We did not issue any unregistered equity securities during the six months ended June 30, 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 <u>No.</u>	Description
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 (File 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 (File 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).

- 31.1\* <u>Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
- 31.2\* Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1\*\* Certification of the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2\*\* Certification of the Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101\* Interactive Data File (Form 10-Q for the Quarterly Period ended June 30, 2022 filed in XBRL). The financial information contained in the XBRL-related documents is "unaudited" and "unreviewed." The instance document does not appear in the interactive file because its XBRL tags are embedded within the Inline XBRL document.
- 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.

# **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: August 8, 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: August 8, 2022 By: /s/ Monica Forbes

Name: Monica Forbes

Title: Chief Financial Officer

(Principal Financial Officer)