# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 10-O

		OKWI 10-V	Z		
(Mark O					
×	QUARTERLY REPORT PURSUANT TO SECTION 13 OR	15(d) OF THE	SECUDITIES EVOUA	NGE ACT OF 1024	
				INGE ACT OF 1954	
	For the quarterry	OR	eptember 30, 2022		
	TRANSITION REPORT PURSUANT TO SECTION 13 OR	15(d) OF THE	SECURITIES EXCHA	ANGE ACT OF 1934	
	For the transiti	on period from	to		
	Commissio	on File Number:	001-36296		
		sen Bio, I			
	Delaware			26-2025616	
	(State or other jurisdiction of			(I.R.S. Employer	
	incorporation or organization)			Identification No.)	
	245 First Street, Suite 1800			02142	
	Cambridge, MA (Address of principal executive offices)			<b>02142</b> (Zip Code)	
	Registrant's telephone nu	mber including	area code (617) 444-85	550	
	•	Not applicable			
	(Former name, former address	and former fiscal ye	ear, if changed since last repo	ort)	
Securit	ies registered pursuant to Section 12(b) of the Act:				
	Title of each class	Trading Symbol(s)	Name of each ex	change on which registered	
	Common Stock, \$0.001 par value	SESN		nq Stock Market LLC	L
during require Indicate	e by check mark whether the registrant (1) has filed all report the preceding 12 months (or for such shorter period that the ments for the past 90 days. Yes ⊠ No □ e by check mark whether the registrant has submitted electro tion S-T during the preceding 12 months (or for such shorter p	registrant was	required to file such re teractive Data File req	ports), and (2) has been subject to uired to be submitted pursuant to	o such filing
Indicate	e by check mark whether the registrant is a large accelerated ng growth company. See the definitions of "large accelerating" in Rule 12b-2 of the Exchange Act.	filer, an acceler	ated filer, a non-accele	rated filer, a smaller reporting cor	
	Large accelerated filer	Smalle	reporting company	$\boxtimes$	
	Accelerated filer □ Non-accelerated filer □	Emergi	ng growth company		
	nerging growth company, indicate by check mark if the registred financial accounting standards provided pursuant to Section			d transition period for complying v	vith any new
Indicate	e by check mark whether the registrant is a shell company (as	defined in Rule	12b-2 of the Exchange	Act). Yes □ No ⊠	
There v	were 202,757,012 shares of the registrant's common stock outst	anding as of Oc	tober 31, 2022.		
		<u> </u>			

## SESEN BIO, INC.

## Quarterly Report on Form 10-Q for the Quarterly Period Ended September 30, 2022

## **Table of Contents**

		Page
	PART I - FINANCIAL INFORMATION	
tem 1.	Financial Statements.	
	Condensed Consolidated Balance Sheets as of September 30, 2022 and December 31, 2021	<u>1</u>
	Condensed Consolidated Statements of Income (Operations) for the Three and Nine Months Ended September 30, 2022 and 2021	<u>2</u>
	Condensed Consolidated Statements of Comprehensive Income (Loss) for the Three and Nine Months Ended September 30, 2022 and 2021	<u>3</u>
	Condensed Consolidated Statements of Changes in Stockholders' Equity for the Three and Nine Months Ended September 30, 2022 and 2021	<u>4</u>
	Condensed Consolidated Statements of Cash Flows for the Three and Nine Months Ended September 30, 2022 and 2021	<u>6</u>
	Notes to Condensed Consolidated Financial Statements	<u>7</u>
tem 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations.	<u>27</u>
tem 3.	Quantitative and Qualitative Disclosures About Market Risk.	<u>46</u>
tem 4.	Controls and Procedures.	<u>46</u>
	PART II - OTHER INFORMATION	
tem 1.	Legal Proceedings.	<u>47</u>
tem 1A.	Risk Factors.	<u>48</u>
tem 2.	Unregistered Sales of Equity Securities and Use of Proceeds.	<u>55</u>
tem 3.	Defaults Upon Senior Securities.	<u>55</u>
tem 4.	Mine Safety Disclosures.	<u>55</u>
tem 5.	Other Information.	<u>55</u> <u>56</u>
tem 6.	Exhibits.	<u>56</u>

**SIGNATURES** 

### PART I - FINANCIAL INFORMATION

### Item 1. Financial Statements

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

	Septen	nber 30, 2022	December 31, 2021		
Assets					
Current assets:		<b>51.105</b>		1.00.000	
Cash and cash equivalents	\$	71,107	\$	162,636	
Short term marketable securities		106,427		21.011	
Accounts receivables		11207		21,011	
Other receivables		14,297		3,482	
Prepaid expenses and other current assets		527		18,476	
Total current assets		192,358		205,605	
Non-current assets:					
Restricted cash		30		20	
Marketable securities		7,336		_	
Property and equipment, net		_		43	
Intangible assets		_		14,700	
Goodwill		_		13,064	
Long term prepaid expenses		_		7,192	
Other assets		_		123	
Total non-current assets		7,366	-	35,142	
Total Assets	\$	199,724	\$	240,747	
Liabilities and Stockholders' Equity Current liabilities:					
Accounts payable	\$	514	\$	2,853	
Accrued expenses		33,800		8,255	
Other current liabilities		381		460	
Total current liabilities		34,695		11,568	
Non-current liabilities:					
Contingent consideration		_		52,000	
Deferred tax liability		_		3,969	
Deferred revenue		<u>_</u>		1,500	
Total non-current liabilities			_	57,469	
Total Liabilities	_	34,695	_	69,037	
Stockholders' Equity:					
Preferred stock, \$0.001 par value per share; 5,000,000 shares authorized at September 30, 2022 and December 31, 2021; no shares issued and outstanding at September 30, 2022 and December 31, 2021	1	_		_	
Common stock, \$0.001 par value per share; 400,000,000 shares authorized at September 30, 2022 and December 31, 2021; 202,757,012 and 199,463,645 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	,	202		199	
Additional paid-in capital		493,629		487,768	
Other comprehensive loss		(235)		_	
Accumulated deficit		(328,567)		(316,257)	
Total Stockholders' Equity		165,029		171,710	

# SESEN BIO, INC. CONDENSED CONSOLIDATED STATEMENTS OF INCOME (OPERATIONS)

(Unaudited; In thousands, except per share data)

	Three Mo Septen		Nine Mon Septen			
	2022		2021	2022		2021
Revenue:						
License and related revenue	\$ 40,000	\$	_	\$ 40,000	\$	6,544
Total revenue	 40,000			40,000		6,544
Operating expenses:						
Research and development	2,931		4,967	37,636		18,273
General and administrative	8,141		8,699	32,705		20,797
Restructuring charge	10,947		5,522	10,947		5,522
Intangibles impairment charge	´ _		31,700	27,764		31,700
Change in fair value of contingent consideration	(1,800)		(114,000)	(52,000)		(52,240)
Total operating expenses	20,219		(63,112)	57,052		24,052
Income (Loss) from Operations	\$ 19,781	\$	63,112	\$ (17,052)	\$	(17,508)
Other income (expense), net	676		1	867		(45)
Income (Loss) Before Taxes	\$ 20,457	\$	63,113	\$ (16,185)	\$	(17,553)
Benefit from income taxes	_		8,561	3,875		8,273
Net Income (Loss) After Taxes	\$ 20,457	\$	71,674	\$ (12,310)	\$	(9,280)
Net income (loss) attributable to common stockholders - basic	\$ 20,442	\$	71,622	\$ (12,310)	\$	(9,280)
Net income (loss) attributable to common stockholders - diluted	\$ 20,442	\$	71,623	\$ (12,310)	\$	(9,280)
Net income (loss) per common share - basic	\$ 0.10	\$	0.36	\$ (0.06)	\$	(0.05)
Weighted-average common shares outstanding - basic	200,464		196,778	199,801		176,547
Net income (loss) per common share - diluted	\$ 0.10	\$	0.36	\$ (0.06)	\$	(0.05)
Weighted-average common shares outstanding - diluted	200,947		201,017	199,801		176,547

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

		Three Mor Septem		Nine Months Ended September 30,				
	2022		2021		2022		2021	
Net income (loss)	\$	20,457	\$	71,674	\$	(12,310)	\$	(9,280)
Unrealized (gain) loss on marketable securities		(46)		_		235		_
Total comprehensive income (loss)	\$	20,503	\$	71,674	\$	(12,545)	\$	(9,280)

# 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	A	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							(281)				(281)	
Balance at June 30, 2022	199,463,645	\$	199	\$	491,464	\$	(281)	\$	(349,024)	\$	142,358	
Net income			_		_		_		20,457		20,457	
Share-based compensation	3,293,367		3		2,165		_		_		2,168	
Unrealized gain of investments	_		_		_		46		_		46	
Balance at September 30, 2022	202,757,012	\$	202	\$	493,629	\$	(235)	\$	(328,567)	\$	165,029	

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

	Common	Stock		Additional Paid-in	Accum	ulated	Ç.	tockholders'
	Shares Amount		Capital	Deficit		3	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
Net income	_				·	71,674		71,674
Share-based compensation	_		_	1,168		_		1,168
Exercises of stock options	3,000		_	3		_		3
Exercises of common stock warrants	1,195,219		1	656		_		657
Issuance of common stock under ATM Offering, net of issuance costs of \$1.2 million	9,804,475		10	38,147		_		38,157
Balance at September 30, 2021	199,463,645	\$	199	\$ 486,010	\$ (	325,201)	\$	161,008

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

Nine Months Ended September 30, 2022 2021 **Cash Flows from Operating Activities:** Net loss \$ (12,310) \$ (9,280)Adjustments to reconcile net loss to net cash used in operating activities: Depreciation 13 74 Share-based compensation 5,864 3,386 Change in fair value of contingent consideration (52,000)(52,240)Intangibles impairment charge 27,764 31,700 Changes in operating assets and liabilities: Accounts receivable (net) 21,012 (1,107)Other receivables (10,816)Prepaid expenses and other current assets 17,949 (23,665)Long term prepaid expenses 7,192 Unrealized loss on marketable securities (235)Other assets 123 807 Accounts payable (2,339)Accrued expenses and other liabilities 21,497 (4,453)Deferred revenue (1,500)(1,500)Net cash provided by (used in) operating activities 22,214 (56, 278)**Cash Flows from Investing Activities:** Purchase of marketable securities (113,763)Disposal (purchase) of equipment 30 (4) Net cash used in investing activities (113,733)(4) **Cash Flows from Financing Activities:** Proceeds from issuance of common stock under ATM Offering, net of 174,961 issuance costs Proceeds from exercises of stock options 42 Proceeds from exercises of common stock warrants 1,126 Net cash provided by financing activities 176,129 Net (decrease) increase in cash, cash equivalents and restricted cash (91,519)119,847 Cash, cash equivalents and restricted cash - beginning of period 55,409 162,656 175,256 Cash, cash equivalents and restricted cash - end of period 71,137 Supplemental cash flow disclosure: Cash paid for amounts included in the measurement of lease liabilities 131 \$ 127 \$

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

#### 1. DESCRIPTION OF BUSINESS

Sesen Bio, Inc. ("Sesen Bio" or the "Company"), a Delaware corporation formed in February 2008, is a late-stage clinical company 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 following recent discussions with the United States Food and Drug Administration ("FDA"), which had implications on the size, timeline and costs of an additional Phase 3 clinical trial, which the FDA previously confirmed would be required for a potential resubmission of a biologics license application ("BLA") for Vicineum for the treatment of NMIBC. The Company continues to believe that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with a larger infrastructure, and as such, intends to seek a partner that can execute further development to realize the full potential of Vicineum. As a result of this decision, the Company has turned its primary focus to the careful assessment of potential strategic alternatives with the goal of maximizing shareholder value.

### Anticipated Merger with CARISMA Therapeutics Inc.

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

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

#### Viventia Acquisition

In September 2016, the Company entered into a Share Purchase Agreement with Viventia Bio, Inc., a corporation incorporated under the laws of the Province of Ontario, Canada ("Viventia"), the shareholders of Viventia named therein (the "Selling Shareholders") and, solely in its capacity as seller representative, Clairmark Investments Ltd., a corporation incorporated under the laws of the Province of Ontario, Canada (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 September 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 nine months ended September 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 subsidiaries Viventia and Seahawk Merger Sub, Inc. 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 September 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:

- <u>Level 1</u>: 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 September 30, 2022 and December 31, 2021 (in thousands):

				September 30, 2022								
		Bas	Based on									
	Carrying Amount		Fair Value		Quoted Prices in Active Markets (Level 1)		Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs (Level 3)			
Assets:												
Marketable securities:												
Money market funds (cash equivalents)	\$ 11,450	\$	11,450	\$	11,450	\$	_	\$	_			
Marketable securities	\$ 113,763	\$	113,763	\$	_	\$	113,763	\$	_			
Liabilities:												
Contingent consideration	\$ _	\$	_	\$	_	\$	_	\$	_			

#### December 31, 2021

	<u>-</u>					Fair Value Measurement Based 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 asset or liability transfers between fair value levels during the nine months ended September 30, 2022 and the year ended December 31, 2021.

#### **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.

On July 15, 2022, the Company made the strategic decision to voluntarily pause further development of Vicineum in the United States. The decision was based on a thorough reassessment of Vicineum following recent discussions with the FDA, which had implications on the size, timeline and costs of an additional Phase 3 clinical trial for the treatment of NMIBC. The Company continues to believe that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with a larger infrastructure, and as such intends to seek a partner for the further development of Vicineum. Additionally, 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 bacillus Calmette-Guérin ("BCG") shortage. Accordingly, during the second quarter of 2022, the Company concluded that it no longer expected to pay related milestone and earnout payments to the former shareholders of Viventia, with the exception of the potential 2% earnout payment related to the Greater China region since those territory rights had been out-licensed pursuant to the exclusive license agreement with Qilu Pharmaceutical Co., Ltd. ("Qilu") (the "Qilu License Agreement") (as further described in Note 17. "License Agreements" below). As of June 30, 2022, Qilu held the exclusive license to develop Vicineum in the Greater China region, and accordingly, the \$1.8 million estimated earnout payment in the Greater China region remained as long-term contingent consideration as of June 30, 2022.

The Company and Qilu are in the process of negotiating a termination of the Qilu License Agreement. Upon the termination of the Qilu License Agreement, the Company will regain the rights to develop, manufacture and commercialize Vicineum in Greater China. However, the Company does not plan to develop or commercialize Vicineum in that region or any other, as it is pursuing the Merger with Carisma. The Company is also seeking to sell or out-license Vicineum and all the related obligations related to Vicineum. The Company expects that any partner who acquires or licenses Vicineum from the Company will be obligated to make any payments, including those related to sales in the Greater China region (if any), that become payable to the former shareholders of Viventia under the Share Purchase Agreement. If a sale or license of Vicineum has not occurred at the time the Merger is completed, Carisma has indicated it may continue to seek a sale or license of Vicineum and has no plans to develop Vicineum. Accordingly, as of September 30, 2022, the Company concluded that it no longer expects to owe any

future earnout payments related to the Greater China region and reduced its remaining \$1.8 million of contingent consideration liabilities to zero as of September 30, 2022.

The contingent consideration balance as of December 31, 2021 was \$52.0 million which was based upon projected world-wide net sales. 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 8.0% to 9.3% as of December 31, 2021.

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	(52,000)
Balance at September 30, 2022	\$ _

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 was 9.3% as of December 31, 2021. 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 \$52.0 million for the nine months ended September 30, 2022 was driven by the Company's decision to voluntarily pause further development of Vicineum in the United States and seek a partner to acquire or license the asset and assume all associated liabilities.

#### 6. RECEIVABLES

The accounts receivable balance as of December 31, 2021 was \$21.0 million, comprised primarily of a \$20 million milestone achieved in December 2021 due to F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (collectively, "Roche") initiating a Phase II clinical trial in the fourth quarter of 2021. In January 2022 the payment of \$20 million was received. Additionally, in June 2021, the Qilu License Agreement was recognized by Shandong Province, Bureau of Science and Technology as a "Technology Transfer". As such, the Company recorded \$0.9 million of revenue and accounts receivable for the additional purchase price resulting from Qilu's obligation to pay the Company an amount equal to its recovery of value-added tax ("VAT"). The accounts receivable balance as of September 30, 2022 was zero.

The other receivables balance as of September 30, 2022 was \$14.3 million compared to \$3.5 million as of December 31, 2021. The increase of \$10.8 million was primarily driven by expected insurance recovery of \$13.4 million related to the preliminary settlements of the Securities Litigation and Derivative Litigation (as defined in Note 10. "Commitments and Contingencies" below). This amount was partially offset by the receipt of \$2.4 million for German VAT recovery in the first half of 2022, related to drug substance sent to Baxter in 2020 and 2019 and other individually immaterial changes of \$0.2 million.

#### 7. PREPAID EXPENSES

The prepaid expenses balance as of September 30, 2022 was \$0.5 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 in the United States, 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 prepayments during the second quarter of 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 September 30, 2022 and December 31, 2021 (in thousands):

	<b>September 30, 2022</b>	December 31, 2021
IPR&D intangible assets:		
Vicineum European Union rights	\$	- \$ 14,700
Total Intangibles	\$	<b>\$</b> 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.

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. On July 15, 2022, the Company made the strategic decision to voluntarily pause further development of Vicineum in the United States. The decision was based on a thorough reassessment of Vicineum following recent discussions with the FDA, which had implications on the size, timeline and costs of an additional Phase 3 clinical trial for the treatment of NMIBC. Management updated the discounted cash flow model using the market participant approach and considered preliminary terms of a potential partnering deal to conclude the fair value of the Company's intangible asset of Vicineum EU rights. 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 was reduced to zero in the second quarter of 2022.

#### 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, size, length and cost of a clinical trial, and time to potential market launch. The Company identified these changes as potential impairment indicators and performed a quantitative impairment analysis, in advance of the Company's typical annual assessment date of October 1 and concluded that the carrying value of its goodwill of \$13.1 million was fully impaired and was reduced to zero in the second quarter of 2022.

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

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

#### 9. ACCRUED EXPENSES

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

	Septen	nber 30, 2022	Decem	ber 31, 2021
Research and development	\$	1,242	\$	1,841
Payroll-related expenses		2,043		2,967
Restructuring charge related		6,365		1,497
Professional fees		381		597
Legal expenses, including preliminary litigation settlement		23,720		1,344
Other		49		9
Total Accrued Expenses	\$	33,800	\$	8,255

#### 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 (collectively, the "Lead Plaintiffs") collectively as the lead plaintiffs under the Private Securities Litigation Reform Act. On November 1, 2021, two stockholders filed motions to reconsider asking the court to appoint a different lead plaintiff. On November 24, 2021, defendants filed a motion to transfer venue to the US District Court for the District of Massachusetts. That motion was fully briefed as of December 13, 2021, but the court has not ruled on that motion. On December 6, 2021, the Lead Plaintiffs filed an amended class action complaint (the "Amended Complaint"). The Amended Complaint 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, and that motion was fully briefed on May 6, 2022. On June 3, 2022, before the court ruled on the motion to dismiss, the parties requested that the court hold any decision on the motion to dismiss in abeyance to provide the parties with an opportunity to engage in mediation. On June 30, 2022 and July 6, 2022, the Company and the plaintiffs engaged in mediation sessions in an attempt to resolve the Securities Litigation and continued to discuss a potential settlement over the following weeks. On July 19, 2022, the parties reached an agreement in principle to settle the Securities Litigation. Pursuant to that agreement, the Company and the individual defendants will pay or cause to be paid to members of the class who submit timely and valid proofs of claims. In exchange, the Lead Plaintiffs will dismiss the action and all class members who do not timely and validly opt-out of the settlement will provide broad customary releases to the Company and the individual defendants. On August 3, 2022, the parties entered into a Stipulation and Agreement of Settlement to settle the Securities Litigation, which was filed with the court on August 17, 2022. The Stipulation and Agreement of Settlement related to the Securities Litigation provides for a settlement payment of \$21.0 million to the class and the dismissal of all claims against the Company and the other defendants. The settlement payment is being funded by the Company and its insurance carriers. On September 1, 2022, the US District Court for the Southern District of New York issued an order denying the motions to appoint a different lead plaintiff. On September 28, 2022, the court issued an order granting preliminary approval of the proposed settlement of the Securities Litigation. The court has set a final settlement approval hearing for January 23, 2023 at 10:00 a.m. local time.

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 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. On July 6, 2022, the Company and the plaintiffs to the Federal Derivative Litigation and the State Derivative Litigation engaged in mediation in an attempt to resolve the litigation, with settlement discussions continuing over the following days. On July 19, 2002, the parties reached an agreement in principle to settle the Federal Derivative Litigation, the State Derivative Litigation and other potential related derivative claims (collectively, the "Derivative Litigation"). Pursuant to that agreement, the individual defendants will cause the Company to adopt certain enhancements to its corporate governance policies and procedures. In exchange, plaintiffs will dismiss the Derivative Litigation and, on behalf of the Company, provide broad customary releases to the individual defendants. On August 22, 2002, the parties entered into a Stipulation of Settlement to settle the Derivative Litigation, which was filed with the court on August 30, 2022. The Stipulation of Settlement related to the Derivative Litigation confirms that the Company previously adopted certain corporate governance enhancements in response to, among other things, the filing of the Derivative Litigation, and that, subject to final court approval, the Company will adopt additional corporate governance enhancements. The Stipulation of Settlement also provides for a \$0.6 million payment for plaintiffs' attorneys fees due to the benefits the corporate governance enhancements are intended to provide to the Company. The payment of plaintiffs' attorneys fees due to the Derivative Litigation. The court has set a final settlement approval hearing for November 8, 2022 at 2:00 p.m. local time.

During the second quarter of 2022, the Company deemed the settlements of the Securities Litigation and the Derivative Litigation probable and amounts reasonably estimable and recorded \$21.6 million to litigation related liability. During the third quarter of 2022, the Company paid \$0.6 million to be held in escrow for the plaintiffs' attorneys fees and \$21.0 million remains as a litigation related liability as of September 30, 2022.

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 and the Derivative Litigation to avoid the uncertainty, risk, expense and distraction of protracted litigation.

Subsequent to September 30, 2022, on October 21, 2022, the Company received two separate letters and on November 4, 2022, the Company received one letter from purported stockholders demanding that the Company amend the Registration Statement filed with the SEC on October 14, 2022 (the "Registration Statement") to provide additional disclosures that such stockholders allege were improperly omitted from the Registration Statement, including information regarding the financial projections for Carisma, the financial analyses performed by the Company's financial advisor in support of its fairness opinion, and the background and process leading to the execution of the Merger Agreement. The Company believes that these demands are without merit and intends to vigorously defend against them. See discussion in Note 19. "Subsequent Events."

#### **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.

#### Termination Fees associated with the Anticipated Merger with Carisma

The Merger Agreement contains certain termination rights of each of the Company and Carisma. Upon termination of the Merger Agreement under specified circumstances, the Company may be required to pay Carisma a termination fee of \$7.6 million and/or reimburse Carisma's expenses up to a maximum of \$1.75 million, and Carisma may be required to pay the Company a termination fee of \$5.49 million and/or reimburse the Company expenses up to a maximum of \$1.75 million. At this time, no assessment can be made as to the likely outcome or whether the outcome will be material to the Company

#### 11. LEASES

During the third quarter of 2022, the Company entered into a Lease Termination Agreement (the "Lease Termination Agreement") pursuant to which the Company terminated its operating lease agreement for its 31,000 square foot facility in Winnipeg, Manitoba which consists of manufacturing, laboratory, warehouse, and office space and agreed to end the lease by September 30, 2022. As part of the execution of the Lease Termination Agreement, the Company paid the landlord the all-inclusive sum of CAD \$1.2 million (USD \$0.9 million). Operating lease costs under this lease, including the related operating costs, were \$81,000 and \$245,000 for the three and nine months ended September 30, 2022, respectively, and \$79,000 and \$245,000 for the three and nine months ended September 30, 2021, respectively.

The right of use asset total was zero as of September 30, 2022 and \$123,300 as of December 31, 2021. As of December 31, 2021, the asset component of the Company's operating leases was recorded as operating lease right-of-use assets and reported within other assets on the Company's condensed consolidated balance sheets. The short-term lease liability was zero as of September 30, 2022 and \$123,300 as of December 31, 2021. As of December 31, 2021, the short-term lease liability was recorded in other current liabilities on the Company's condensed consolidated balance sheets. There was no long-term operating

lease liability as of September 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 Company intends to terminate both leases in connection with the closing of the anticipated Merger with Carisma. The short-term lease in Philadelphia is renewed on a month-to-month basis. The short-term lease in Cambridge ends in June 2023. The minimum monthly rent for these office spaces is \$2,500 and \$17,200, 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 September 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 nine months ended September 30, 2022. The Company raised \$175.0 million of net proceeds from the sale of 56.9 million shares of common stock at a weighted-average price of \$3.17 per share during the nine months ended September 30, 2021. The Company raised \$38.2 million of net proceeds from the sale of 9.8 million shares of common stock at a weighted-average price of \$4.01 per share during the three months ended September 30, 2021. Share issuance costs, including sales agent commissions, related to the ATM Offering totaled \$1.2 million and \$5.4 million during the three and nine months ended September 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 September 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 203 million and 199 million shares were issued and outstanding as of September 30, 2022 and December 31, 2021, respectively. In addition, the Company had reserved for issuance the following amounts of shares of its common stock for the purposes described below as of September 30, 2022 and December 31, 2021 (in thousands):

	September 30, 2022	December 31, 2021
Shares of common stock issued	202,757	199,464
Shares of common stock reserved for issuance for:		
Warrants	199	199
Stock options	16,202	15,703
Restricted stock units	4,695	3,041
Shares available for grant under 2014 Stock Incentive Plan	3,725	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	229,878	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, other than the CVR (as further described in Note 17. "License Agreements" below) and any special cash dividend that the Company may pay to its stockholders in connection with the consummation of the Merger.

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 September 30, 2022 (in thousands):

Issued	Exercise Price	Expiration	December 31, 2021	Issued	(Exercised)	(Cancelled)	September 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.

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

For periods with net income, diluted net earnings per share is calculated by either (i) adjusting the weighted-average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period as determined using the treasury stock method or (ii) the two-class method considering common stock equivalents, whichever is more dilutive. The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. Accordingly, the Company applied the two-class method to calculate basic and diluted net earnings per share of common stock for the three months ended September 30, 2022 and September 30, 2021.

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

The following table illustrates the determination of earnings (loss) per share for each period presented:

	Three Months Ended September 30,				Nine Mon Septen			
		2022		2021		2022		2021
		(iı	n th	ousands, excep	t pe	r share amount	ts)	
Basic Earnings (Loss) Per Share:								
Numerator:								
Net income (loss)	\$	20,457	\$	71,674	\$	(12,310)	\$	(9,280)
Less: Income attributable to participating securities - basic		(15)	_	(52)				
Net income (loss) attributable to common stockholders - basic	\$	20,442	\$	71,622	\$	(12,310)	\$	(9,280)
Denominator:								
Weighted average common shares outstanding - basic		200,464		196,778		199,801		176,547
Net income (loss) per share applicable to common stockholders - basic	\$	0.10	\$	0.36	\$	(0.06)	\$	(0.05)
Dilutive Earnings (Loss) Per Share:								
Numerator:								
Net income (loss)	\$	20,457	\$	71,674	\$	(12,310)	\$	(9,280)
Less: Income attributable to participating securities - diluted		(15)		(51)				
Net income (loss) attributable to common stockholders - diluted	\$	20,442	\$	71,623	\$	(12,310)	\$	(9,280)
Denominator:								
Weighted average shares outstanding		200,464		196,778		199,801		176,547
Dilutive impact from:								
Stock options and employee stock purchase plan		20		4,239				
Restricted stock units & performance based stock units		463		4,239				_
Weighted average common shares outstanding - diluted		200,947		201,017		199,801		176,547
	•		\$		<u>c</u>		•	
Net income (loss) per share applicable to common stockholders - diluted	\$	0.10	Э	0.36	\$	(0.06)	Э	(0.05)

The following potentially dilutive securities outstanding as of September 30, 2022 and 2021 have been excluded from the denominator of the diluted loss per share of common stock outstanding calculation (in thousands):

		Three Months Ended September 30,		ns Ended per 30,
	2022	2021	2022	2021
Warrants	55	55	199	199
Stock options	16,182	11,273	16,202	15,511
RSUs and PSUs	4,232	<u> </u>	4,695	_
Total	20,469	11,328	21,096	15,710

#### 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 nine months ended September 30, 2022 and 2021 (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,				
		2022		2021		2022		2021
Research and development	\$	863	\$	152	\$	1,838	\$	536
General and administrative		1,305		1,016		4,026		2,849
<b>Total Share Based Compensation</b>	\$	2,168	\$	1,168	\$	5,864	\$	3,385

#### 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 3.7 million shares of common stock available for issuance under the 2014 Plan as of September 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 13.0 million stock options outstanding under the 2014 Plan as of September 30, 2022.

On September 9, 2021, the Company's board of directors and the compensation committee of the board of directors (the "Compensation Committee") approved a retention program for all then-current employees, except for the Chief Executive Officer, pursuant to which the Company will provide certain incentives designed to retain such employees (the "2021 Retention Program"). Pursuant to the 2021 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 vested in full on September 30, 2022, subject to continued employment through September 30, 2022. Each RSU represents a contingent right to receive one share of the Company's common stock.

Also pursuant to the 2021 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 September 30, 2022, achievement was deemed probable for only the cash management milestone, representing \$87,000, 20% of the PSU awards. Therefore, \$11,000 and \$44,000 have been expensed during the three and nine months ended September 30, 2022, respectively and \$43,000 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 September 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 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 3.1 million stock options outstanding which were granted as employment inducement awards outside of the 2014 Plan as of September 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 nine months ended September 30, 2022:

	Number of Shares under Option (in thousands)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value n thousands)
Outstanding at December 31, 2021	15,703	\$1.93	8.03	\$ 82
Granted	1,510	\$0.72		
Exercised	_	_		
Canceled or forfeited	(1,011)	2.10		
Outstanding at September 30, 2022	16,202	\$1.81	7.41	DM
Exercisable at September 30, 2022	10,494	\$1.72	6.94	DM

The Company recognized share-based compensation expense, related to stock options, of \$1.0 million and \$3.5 million for the three and nine months ended September 30, 2022, respectively and \$1.2 million and \$3.4 million for the three and nine months ended September 30, 2021, respectively. As of September 30, 2022, there was \$6.4 million of total unrecognized compensation cost related to unvested stock options which the Company expects to recognize over a weighted-average period of 2.09 years. The weighted-average grant-date fair value of stock options granted during the nine months ended September 30, 2022 and 2021 were \$0.46 and \$2.20, respectively. No stock options were exercised during the nine months ended September 30, 2022.

For the nine months ended September 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:

	<b>September 30, 2022</b>	<b>September 30, 2021</b>
Fair market value	\$0.72	\$3.40
Grant exercise price	\$0.72	\$3.40
Expected term (in years)	6.0	6.03
Risk-free interest rate	2.1%	0.9%
Expected volatility	71.8%	74.6%
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 nine months ended September 30, 2022:

	Restricted Stock Units (in thousands)	Weighted Average Grant Date Fair Value
Unvested at December 31, 2021	3,041	\$0.80
Granted RSU	4,160	\$0.68
Cancelled RSU	(217)	\$0.75
Released RSU	(3,293)	\$0.76
Granted PSU	1,004	\$0.67
Unvested at September 30, 2022	4,695	\$0.68

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

The share-based compensation expense related to RSUs and PSUs for the three and nine months ended September 30, 2022 was \$1.2 million and \$2.4 million, respectively. There was no shared-based compensation expense related to RSUs and PSUs for the three and nine months ended September 30, 2021. As of September 30, 2022, there was \$1.8 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 September 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 nine months ended September 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. 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 nine months ended September 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 nine months ended September 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):

	Nine Months Ended September 30,				
	2022		2021		
Country:					
United States	\$ (32,083)	\$	(38,864)		
Canada	15,898		21,311		
Total loss before income taxes	\$ (16,185)	\$	(17,553)		

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

	Nine Months Ended September 30,				
	 2022		2021		
Current tax benefit (provision)					
Federal	\$ _	\$	8,559		
State	_		_		
Foreign	3,875		(286)		
Total current benefit	\$ 3,875	\$	8,273		

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

	September 30, 2	2022	<b>December 31, 2021</b>
Deferred tax liabilities			
IPR&D	\$	<u> </u>	(3,969)
Total deferred tax liabilities	\$		(3,969)

For the nine months ended September 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 Qilu License Agreement.

During the nine months ended September 30, 2021, the Company recorded a benefit from income taxes of \$8.3 million. In the third quarter of 2021, the Company determined that the fair value of the Vicineum US rights was zero, which resulted in an impairment charge of \$31.7 million. In connection with this impairment charge, in the third quarter of 2021, the Company wrote-down the associated deferred tax liability by \$8.6 million as a benefit.

#### 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 Complete Response Letter ("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, as of September 30, 2022, 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 September 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 \$2.4 million at exchange rates in effect on September 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 \$48,987 at exchange rates in effect as of September 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 (\$0.6 million) related to the submission of marketing authorization application (the "MAA") to the European Medicines Agency (the "EMA") for Vysyneum<sup>TM</sup> in the first quarter of 2021. Vysyneum is the proprietary brand name that was conditionally approved by the EMA for oportuzumab monatox in the EU.

#### 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 was required to continue developing, at its cost, EBI-031 and any other product made from the Roche Licensed Intellectual Property that contains an IL-6 antagonist monoclonal antibody and pursue ongoing patent prosecution, at its cost. For additional information regarding the Roche License Agreement, see Note 17. "License Agreements" in the Notes to Condensed Consolidated Financial Statements in the Company's Quarterly Report on Form 10-O for the quarter ended June 30, 2022.

On July 15, 2022, the Company entered into an asset purchase agreement with Roche (the "Roche Asset Purchase Agreement") pursuant to which Roche purchased all patent rights and know-how related to the monoclonal antibody EBI-031 and all other IL-6 antagonist monoclonal antibody technology owned by the Company for up to \$70 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, which was recorded as license

revenue in the third quarter of 2022. The Roche Asset Purchase Agreement also provides that Roche will make an additional \$30 million payment to the Company upon Roche's initiation of a Phase 3 clinical trial with EBI-031 for a defined indication if initiated prior to December 31, 2026. Pursuant to ASC 606, the variable consideration of \$30 million is constrained. Therefore, the amount was not recorded as revenue during the third quarter of 2022.

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

#### **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 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 Licensed Product 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 Oilu

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 Topic 606, *Revenue*. 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 Bio an amount equal to its recovery of VAT.

#### **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 Middle East and North Africa region ("MENA") (the "MENA License Agreement"). 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.

On July 20, 2022, the Company provided notice of termination of the MENA License Agreement as a result of the Company's strategic decision to voluntarily pause further development of Vicineum in the US.

#### 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 was 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 would be eligible to receive additional regulatory and commercial milestone payments of \$2.0 million and also to receive a 30% royalty on net sales in Turkey and Northern Cyprus.

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

#### 18. RESTRUCTURING AND RELATED ACTIVITIES

On July 15, 2022, the Company approved a restructuring plan to reduce operating expenses and better align its workforce with the needs of its business following the decision to voluntarily pause further development of Vicineum in the US (the "2022 Restructuring Plan"). Execution of the 2022 Restructuring Plan is expected to be substantially completed in connection with the closing of the Merger with Carisma, which is expected to occur approximately two to three months from the date of this form 10-Q filing, November 7, 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 during the pendency of the Merger with Carisma and while the Company seeks a potential partner for the further development of Vicineum.

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

2022 Restructuring Plan

Severance and benefits costs	\$ 6,944
Contract termination and other associated costs	4,003
Total restructurings costs	 10,947
Cash payments	(4,582)
Balance at September 30, 2022	\$ 6,365

Restructuring costs related to the Restructuring Plan were recorded in operating expenses in the Company's Condensed Consolidated Statements of Income (Operations) and Comprehensive Income (Loss) in the three months ended September 30, 2022. The Company expects that substantially all of the accrued restructuring costs as of September 30, 2022 will be paid in cash in connection with the closing of the Merger with Carisma, which is expected to occur approximately two to three months from the date of this form 10-Q filing, November 7, 2022.

#### 19. SUBSEQUENT EVENTS

On October 21, 2022, the Company received two separate letters and on November 4, 2022, the Company received one letter from purported stockholders demanding that the Company amend the Registration Statement filed with the SEC on October 14, 2022 to provide additional disclosures that such stockholders allege were improperly omitted from the Registration Statement, including information regarding the financial projections for Carisma, the financial analyses performed by the Company's financial advisor in support of its fairness opinion, and the background and process leading to the execution of the Merger Agreement. The Company believes that these demands are without merit and intends to vigorously defend against them. At this time, no assessment can be made as to the likely outcome or whether the outcome will be material to the Company.

#### 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 proposed merger with CARISMA Therapeutics Inc. ("Carisma"), the impact of the COVID-19 pandemic, business strategy, current and prospective products, product approvals, research and development costs, current and prospective collaborations, timing and likelihood of success, plans and objectives of management for future operations and future results of current and anticipated products, are forward-looking statements.

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 ability to complete, on a timely basis or at all, the proposed merger with Carisma announced on September 21, 2022, pursuant to the terms and conditions of the Merger Agreement (as defined below);
- the receipt of any potential future payments to our stockholders under the CVR Agreement (as defined below);
- the strategy or future operations of the combined company following the closing of the proposed merger with Carisma.
- advancement of the combined company's product candidates and product pipeline, clinical development of the combined company's product candidates, including expectations regarding timing of initiation and results of clinical trials of the combined company;
- our 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 voluntarily 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 during the pendency of the proposed merger with Carisma and while we seek a potential partner for the further development of Vicineum;
- the potential impact of the COVID-19 pandemic on our ability to consummate the proposed merger with Carisma and seek a partner for the further development of Vicineum;
- our projected financial position;
- our ability to 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").

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:

• the risk that the conditions to the closing of the proposed merger with Carisma are not satisfied, including the failure to obtain stockholder approval of matters related to the proposed merger in a timely manner or at all;

- uncertainties as to the timing of the consummation of the proposed merger with Carisma and the ability of each of us and Carisma to consummate the proposed merger, including Carisma's completion the Carisma Pre-Closing Financing (as defined below);
- risks related to our ability to correctly estimate our expected net cash at closing and our ability to correctly estimate and manage our respective operating expenses and expenses associated with the proposed merger;
- risks related to our continued listing on The Nasdaq Stock Market ('Nasdaq") until closing of the proposed merger;
- the risk that as a result of adjustments to the exchange ratio, as defined in the Merger Agreement, our stockholders could own less of the combined company than is currently anticipated;
- the risk that the conditions to payment under the CVR Agreement will not be met and may never deliver any value to our stockholders;
- risks associated with the possible failure to realize certain anticipated benefits of the proposed merger, including with respect to future financial and operating results;
- uncertainties regarding the impact any delay in the closing of the proposed merger would have on the anticipated cash resources of the combined company upon closing of the proposed merger and other events and unanticipated spending and costs that could reduce the combined company's cash resources;
- the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the Merger Agreement;
- the effect of the announcement, pendency or completion of the proposed merger on our or Carisma's business relationships, operating results and business generally;
- costs related to the proposed merger;
- the outcome of any legal proceedings that may be instituted against us or any of our directors or officers related to the Merger Agreement or the transactions contemplated thereby;
- the ability of us or Carisma to protect our and their intellectual property rights, as applicable;
- competitive responses to the proposed merger and changes in expected or existing competition;
- the success and timing of regulatory submissions and pre-clinical and clinical trials;
- · regulatory requirements or developments;
- · changes to clinical trial designs and regulatory pathways;
- changes in capital resource requirements;
- risks related to the inability of the combined company to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs;
- legislative, regulatory, political and economic developments, among other risks and uncertainties;
- the risk that we may not be successful in identifying a partner for the further development of Vicineum;
- the risk that we may become involved in disagreements or disputes with our licensees, licensors and other counterparties relating to the
  development and/or commercialization of Vicineum, in connection with our decision to voluntarily pause further development of Vicineum in the
  US;
- the risk that we may not be able to implement the 2022 Restructuring Plan as currently anticipated or within the timing currently anticipated;
- we may incur unanticipated charges as a result of the 2022 Restructuring Plan;
- the risk that the respective courts may not grant final approval of the 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; 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 Bio," "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 United States. The decision was based on a thorough reassessment of Vicineum following recent discussions with the United States Food and Drug Administration ("FDA"), which had implications on the size, timeline and costs of an additional Phase 3 clinical trial, which the FDA previously confirmed would be required for a potential resubmission of a biologics license application ("BLA") for Vicineum for the treatment of NMIBC. We continue to believe that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with a larger infrastructure, and as such, intend to seek a partner that can execute further development to realize the full potential of Vicineum. As a result of this decision, we have turned our primary focus to the careful assessment of potential strategic alternatives with the goal of maximizing shareholder value.

### Anticipated Merger with CARISMA Therapeutics Inc.

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

The Merger is expected to close approximately two to three months from the date of this form 10-Q filing, November 7, 2022. In connection with the Merger, we will seek the approval of our stockholders to, among other things, (a) issue the shares of our common stock issuable in connection with the Merger under the rules of Nasdaq, and (b) amend our certificate of incorporation to effect a reverse stock split of the outstanding shares of our common stock at a ratio as mutually agreed to by us and Carisma and approved by our board of directors prior to the closing of the Merger (clauses (a) and (b), collectively, the "Sesen Bio Voting Proposals").

Consummation of the Merger is subject to certain closing conditions, including, among other things, (a) approval by our stockholders of the Sesen Bio Voting Proposals as described in the Merger Agreement, (b) approval by Carisma's stockholders of, among other things, the adoption of the Merger Agreement, (c) Nasdaq's approval of the listing of the shares of our common stock to be issued in connection with the Merger, (d) the effectiveness of a registration statement on Form S-4 to register the shares of our common stock to be issued in connection with the Merger, and (e) our having net cash as of closing of the Merger greater than or equal to \$100.0 million.

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

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

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

Shares of Carisma's common stock issued pursuant to the Carisma Pre-Closing Financing will be converted into shares of our common stock in the Merger in accordance with the Exchange Ratio.

Additionally, at or prior to the effective time of the Merger, we will enter into a Contingent Value Rights Agreement (the "CVR Agreement") with a rights agents (the "Rights Agent") pursuant to which we intend to declare a dividend payable to our stockholders of record as of a date agreed to by us and Carisma prior to the effective time of the Merger with respect to the receipt of one contingent value right (each, a "CVR"), for each outstanding share of our common stock held by such stockholders on such date. Each CVR will represent the contractual right to receive contingent cash payments upon the receipt by us of certain proceeds payable by Roche, if any, pursuant to the Roche Asset Purchase Agreement, upon the achievement by Roche of a specified milestone set forth in the Roche Asset Purchase Agreement, subject to certain customary deductions, including for expenses and taxes. The contingent payments under the CVR Agreement, if they become due, will be payable to the Rights Agent for subsequent distribution to the holders of the CVRs. In the event that no such proceeds are received, holders of the CVRs will not receive any payment pursuant to the CVR Agreement. There can be no assurance that any cash payment will be made or that any holders of CVRs will receive any amounts with respect thereto.

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

#### Other Recent Events

#### 2022 Restructuring Plan

On July 15, 2022, we approved a restructuring plan to reduce operating expenses and better align our workforce with the needs of our business following the decision to voluntarily pause further development of Vicineum in the United States. Execution of the 2022 Restructuring Plan is expected to be substantially completed in connection with the closing of the Merger with Carisma, which is expected to occur approximately two to three months from the date of this form 10-Q filing, November 7, 2022. The 2022 Restructuring Plan includes an incremental reduction in our workforce as well as additional cost-saving initiatives intended to preserve capital during the pendency of the Merger with Carisma and while we seek a potential partner for the further development of Vicineum. We also incurred one-time cash costs associated with the termination of certain contracts and all other activities under the 2022 Restructuring Plan.

#### Sale of Legacy Technology to Roche

On July 15, 2022, we executed the Roche Asset Purchase Agreement pursuant to which Roche purchased all patent rights and know-how related to the monoclonal antibody EBI-031 and all other IL-6 antagonist monoclonal antibody technology owned by us for up to \$70 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 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.

#### 2022 Retention Program

On August 28, 2022, our board of directors and the compensation committee of the board of directors approved a retention program for certain employees pursuant to which we will provide a cash incentive designed to retain such employees. Pursuant to this retention program, certain of our employees, including certain executive officers, will receive a cash bonus award, which vests in full upon the earlier of the completion of a strategic transaction and termination without cause, subject to continued employment through that time.

#### 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 the 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. 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 relating to our MAA for Vysyneum, as is consistent with the EMA's standard practice when an MAA is withdrawn. The EMA Withdrawal Assessment Report reflects the initial assessment and corresponding questions from the EMA and identifies major objections in the areas of quality, good clinical practice, efficacy and safety.

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 United States. The decision was based on a thorough reassessment of Vicineum following recent discussions with the FDA, which had implications on the size, timeline and costs of an additional Phase 3 clinical trial which the FDA previously confirmed would be required for a potential resubmission of a BLA for Vicineum for the treatment of NMIBC. As a result of this decision, we no longer plan to pursue regulatory approval of Vysyneum for NMIBC in the EU. We continue to believe that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with a larger infrastructure, and as such, we intend to seek a partner that can execute further development to realize the full potential of Vicineum. As a result of this decision, we have turned our primary focus to the careful assessment of potential strategic alternatives with the goal of maximizing shareholder value.

#### 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%)

\*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

<sup>\*</sup>Response-evaluable population includes any mITT patient who completed the induction phase.

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 terminated the Fujifilm MSA and Baxter CMSA and requested that Fujifilm and Baxter cease all work under the respective agreements and refrain from incurring any additional costs or expenses.

#### **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 in the United States, we have not taken steps to terminate the Zurich License Agreement, the Micromet License Agreement or the XOMA License Agreement as we intend to seek a partner for the further development of Vicineum.

#### **OUS Business Development Partnering**

In connection with our decision to voluntarily pause further development of Vicineum in the United States, we have terminated 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.

#### Greater China

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

During 2020, we received a total of \$10 million in net proceeds associated with the Qilu License Agreement. We are also entitled to receive up to an additional \$23 million upon the achievement of certain technology transfer, development and regulatory milestones, as well as a 12% royalty based upon annual net sales of Vicineum in Greater China. The royalties are payable upon the first commercial sale of Vicineum in a region and continuing until the latest of (i) twelve years after the first commercial sale of Vicineum in such region, (ii) the expiration of the last valid patent claim covering or claiming the composition of matter, method of treatment, or method of manufacture of Vicineum in such region, and (iii) the expiration of regulatory or data exclusivity for Vicineum in such region. The royalty rate is subject to reduction under certain circumstances, including when there is no valid claim of a licensed patent that covers Vicineum in a particular region or no data or regulatory exclusivity of Vicineum in a particular region.

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

In June 2021, the Qilu License Agreement was recognized by Shandong Province, Bureau of Science and Technology as "Technology Transfer". An agreement that is designated as a Technology Transfer shall be entitled to a tax incentive of value-added tax ("VAT") recovery. As such, we recorded \$0.9 million of revenue during the three months ended June 30, 2021, for additional purchase price resulting from Qilu's obligation to pay us an amount equal to its recovery of VAT.

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.

We and Qilu are in the process of negotiating a termination of the Qilu License Agreement. Upon the termination of the Qilu License Agreement, we will regain the rights to develop, manufacture and commercialize Vicineum in Greater China.

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

#### License and Related Revenue

License revenue consists of revenue recognized pursuant to our OUS business development partnership agreements, including the Qilu License Agreement, and the Roche Asset Purchase Agreement, which is assessed under ASC Topic 606, Revenue. We have terminated all of our OUS business development partnership agreements other than the Qilu License Agreement, of which we and Qilu are in the process of negotiating a termination.

# 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 during the pendency of the proposed Merger with Carisma.

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

	Three Months Ended September 30,				Nine Months Ended September 30,			
		2022	2021		2022		2021	
Programs:								
Vicineum for the treatment of NMIBC	\$	813	\$	2,989	\$	29,705	\$	10,888
Total direct program expenses		813		2,989		29,705		10,888
Personnel and other expenses:								
Employee and contractor-related expenses		1,840		1,732		6,920		6,392
Platform-related lab expenses		5		19		100		133
Facility expenses		150		124		428		392
Other expenses		123		103		483		468
Total personnel and other expenses	-	2,118		1,978		7,931		7,385
<b>Total Research and Development</b>	\$	2,931	\$	4,967	\$	37,636	\$	18,273

#### 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. We expect our general and administrative expenses to increase due to increases in professional and advisory fees during the pendency of the proposed Merger with Carisma.

# 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 September 30, 2022 and 2021

		Three Months Ended September 30,			Increase/(Decrease)		
		2022		2021	-	Dollars	Percentage
		(in thousands, except percentages)					
Revenue:							
License and related revenue	\$	40,000	\$		\$	40,000	
Total revenue		40,000		_		40,000	_
Operating expenses:							
Research and development	\$	2,931	\$	4,967	\$	(2,036)	(41) %
General and administrative		8,141		8,699		(558)	(6) %
Restructuring charge		10,947		5,522		5,425	98 %
Intangibles impairment charge				31,700		(31,700)	(100) %
Change in fair value of contingent consideration		(1,800)		(114,000)		112,200	(98) %
Total operating expenses	<u></u>	20,219		(63,112)		83,331	(132) %
Income from Operations		19,781		63,112		(43,331)	(69) %
Other income:							
Other income, net		676		1		675	67,500 %
Income Before Taxes	\$	20,457	\$	63,113	\$	(42,656)	(68)%
Benefit from income taxes				8,561		(8,561)	(100)%
Net Income After Taxes	\$	20,457	\$	71,674	\$	(51,217)	(71)%

#### License Revenue

Revenue for the three months ended September 30, 2022 was \$40.0 million, which was due to the execution of the Roche Asset Purchase Agreement for EBI-031 and all other IL-6 antagonist monoclonal antibody technology. We did not record any revenue for the three months ended September 30, 2021.

# Research and Development

Research and development expenses were \$2.9 million for the three months ended September 30, 2022, compared to \$5.0 million for the three months ended September 30, 2021. The decrease of \$2.0 million was primarily due to a decrease in costs associated with manufacturing (\$1.9 million) and a decrease in other R&D related costs (\$0.1 million), driven by the strategic decision to voluntarily pause further development of Vicineum in the US in the third quarter of 2022.

#### General and Administrative

General and administrative expenses were \$8.1 million for the three months ended September 30, 2022, compared to \$8.7 million for the three months ended September 30, 2021. The decrease of \$0.6 million was primarily due to a decrease in marketing and commercialization expenses, which were incurred in the third quarter of 2021 in preparation for potential commercial launch of Vicineum but were discontinued as a result of the Complete Response Letter from the FDA received in August 2021 (\$2.3 million) and a decrease in professional fees for accounting services (\$0.4 million). This was partially offset by an increase in legal expense (\$1.3 million), driven by legal fees associated with our assessment of strategic alternatives incurred in the third quarter of 2022 (\$2.2 million), partially offset by a decrease in legal fees associated with the internal review (\$0.4 million) and other legal expenses (\$0.5 million). Additionally, financial advisor fees increased due to financial advisor fees associated with our assessment of strategic alternatives incurred in the third quarter of 2022 (\$0.8 million).

#### Restructuring Charge

Restructuring charges were \$10.9 million for the three months ended September 30, 2022 compared to \$5.5 million for the three months ended September 30, 2021. The expense for the third quarter of 2022 consisted of severance and other employee-related costs (\$6.9 million) and termination of certain contracts and other associated costs (\$4.0 million) associated with our 2022 Restructuring Plan following the decision to voluntarily pause further development of Vicineum in the United States. The expense for the third quarter of 2021 consisted of severance and other employee-related costs (\$2.8 million) and termination of certain contracts (\$2.7 million) associated with the restructuring plan we approved on August 30, 2021 to reduce operating expenses and better align our workforce with the needs of our business following the receipt of the CRL in August 2021.

#### Intangibles impairment

Intangibles impairment charge for three months ended September 30, 2022 was zero compared to \$31.7 million in the three months ended September 30, 2021. In August 2021, we received a CRL from the FDA regarding our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. As a result an impairment analysis was conducted, which concluded that the carrying value of our intangible asset of Vicineum US rights was fully impaired as of September 30, 2021.

#### Change in Fair Value of Contingent Consideration

The non-cash change in fair value of contingent consideration was a gain of \$1.8 million for the three months ended September 30, 2022, compared to a gain of \$114.0 million for the three months ended September 30, 2021. The decrease in the fair value of contingent consideration of \$1.8 million for the three months ended September 30, 2022 was due to our conclusion that we no longer expect to owe any future earnout payments related to the Greater China region. Accordingly, we reduced our remaining \$1.8 million of contingent consideration liabilities to zero as of September 30, 2022.

The change in fair value of contingent consideration was a gain of \$114.0 million for the three months ended September 30, 2021. This was primarily driven by the receipt of a CRL from the FDA, in which the FDA determined that it cannot approve the BLA for Vicineum in its present form. Due to the inherent uncertainty in the path forward for Vicineum at the time, we reassessed the underlying assumptions used to develop the revenue projections upon which the fair value of contingent consideration was based. The most significant and impactful assumptions in our revenue projection models are timing of product launch and probabilities of clinical and regulatory success ("POS"); we expected delays in the start of commercialization and estimated lower POS as a direct result of the CRL. We anticipated needing to conduct an additional clinical trial, which would lead to delays in the start of commercialization globally. We had assessed a range of commercialization timeline assumptions and applied a probability to each outcome based on management's best estimate. In addition, we assumed a lower POS in achieving certain clinical and regulatory milestones in the range of approximately 45% to 55% globally. The milestone payments constitute debt-like obligations, and the high-yield debt index rate applied to the milestones in order to determine the estimated fair value was 7.5% as of September 30, 2021. The discount rate applied to the 2% earnout payment due on forecasted Vicineum revenues was derived from our estimated weighted-average cost of capital ("WACC"), and this WACC-derived discount rate was 8.6% as of September 30, 2021.

#### Benefit (Provision) from Income Taxes

We did not record a benefit or loss for the three months ended September 30, 2022. In the third quarter of 2021, we determined that the fair value of the Vicineum US rights was zero, which resulted in an impairment charge of \$31.7 million. In connection with this impairment charge, in the third quarter of 2021, we reduced the associated deferred tax liability which resulted in an \$8.6 million income tax benefit.

# Net income

For the three months ended September 30, 2022, net income was \$20.5 million, compared to \$71.7 million for the three months ended September 30, 2021. In the third quarter of 2022, we recorded revenue of \$40.0 million related to the execution of the Roche Asset Purchase Agreement and non-cash income of \$1.8 million related to changes in the fair value of contingent consideration, partially offset by operating expenses of \$22.0 million. In the third quarter of 2021 we recorded non-cash income of \$90.9 million, which includes changes in the fair value of contingent consideration, income tax benefit and intangible impairment charge. Additionally, we recorded R&D, G&A and restructuring charges of \$19.2 million.

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

#### Comparison of the nine months ended September 30, 2022 and 2021

	 Nine Months Ended September 30,			Increase/(Decrease)		
	2022		2021		Dollars	Percentage
	 (in thousands, except percentages)					
Revenue:						
License and related revenue	\$ 40,000	\$	6,544	\$	33,456	511 %
Total revenue	40,000		6,544		33,456	511 %
Operating expenses:						
Research and development	\$ 37,636	\$	18,273	\$	19,363	106 %
General and administrative	32,705		20,797		11,908	57 %
Restructuring charge	10,947		5,522		5,425	98 %
Intangibles impairment charge	27,764		31,700		(3,936)	(12)%
Change in fair value of contingent consideration	(52,000)		(52,240)		240	— %
Total operating expenses	57,052		24,052		33,000	137 %
Loss from Operations	(17,052)		(17,508)		456	(3)%
Other income (expense), net	 867		(45)		912	(2,027) %
Loss Before Taxes	\$ (16,185)	\$	(17,553)	\$	1,368	(8)%
Benefit from income taxes	 3,875	_	8,273		(4,398)	(53) %
Net Loss After Taxes	\$ (12,310)	\$	(9,280)	\$	(3,030)	33 %

#### License Revenue

Revenue for the nine months ended September 30, 2022 was \$40.0 million, which was due to the execution of the Roche Asset Purchase Agreement. Revenue for the nine months ended September 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 and license revenue for additional purchase price due to the recovery of VAT by Oilu.

#### Research and Development

Research and development expenses were \$37.6 million for the nine months ended September 30, 2022, compared to \$18.3 million for the nine months ended September 30, 2021. The increase of \$19.4 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) in the second quarter of 2022. Additionally, employee-related compensation increased, primarily due to the retention programs implemented in the fourth quarter of 2021 and third quarter of 2022 (\$2.6 million). The increase was partially offset by decreased costs associated with manufacturing (\$6.1 million), clinical and manufacturing related consulting fees (\$2.0 million), and other individually immaterial R&D costs (\$0.3 million), driven by the strategic decision to voluntarily pause further development of Vicineum in the US in the third quarter of 2022.

#### General and Administrative

General and administrative expenses were \$32.7 million for the nine months ended September 30, 2022, compared to \$20.8 million for the nine months ended September 30, 2021. The increase of \$11.9 million was primarily due to an increase in legal expense (\$14.6 million) driven by the preliminary settlements of the securities and derivative litigation net of expected insurance recovery (\$8.2 million) and legal fees associated with our assessment of strategic alternatives (\$2.6 million). Additionally, legal fees related to the internal review (\$2.8 million), securities litigation counseling (\$0.9 million) and other legal expenses (\$0.1 million) increased during the nine months ended September 30, 2022. In addition, employee-related compensation increased, primarily driven by the retention programs implemented in the fourth quarter of 2021 and third quarter of 2022 (\$1.3 million). This was partially offset by decreases in marketing and commercial expenses (\$4.0 million), which were

incurred during the first half of 2021 in preparation for potential commercial launch of Vicineum but were discontinued as a result of the CRL received in August 2021.

#### Restructuring Charge

Restructuring charges were \$10.9 million for the nine months ended September 30, 2022 compared to \$5.5 million for the nine months ended September 30, 2021. The expense for the nine months ended September 30, 2022 consisted of severance and other employee-related costs (\$6.9 million) and termination of certain contracts and other associated costs (\$4.0 million) following the decision to pause further development of Vicineum in the US. The expense for the nine months ended September 30, 2021 consisted of severance and other employee-related costs (\$2.8 million) and termination of certain contracts (\$2.7 million) following the receipt of the CRL in August 2021.

# Change in Fair Value of Contingent Consideration

The non-cash change in fair value of contingent consideration was a gain of \$52.0 million for the nine months ended September 30, 2022, compared to a gain of \$52.2 million for the nine months ended September 30, 2021. The decrease in the fair value of contingent consideration of \$52.0 million for the nine months ended September 30, 2022 was driven by our strategic decision to voluntarily pause further development of Vicineum in the US and our conclusion that we no longer expect to owe any future earnout payments related to the Greater China region. The decision was based on a thorough reassessment of Vicineum following recent discussions with the FDA, which had implications for the size, timeline and costs for an additional Phase 3 clinical trial for the treatment of NMIBC. Additionally, during the second quarter of 2022, we observed an evolution of the current market treatment paradigm in NMIBC, with substantial uptake of intravesical chemotherapy (monotherapy and combination therapy) during the ongoing BCG shortage. We continue to believe that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with a larger infrastructure, and as such, intend to seek a partner that can execute further development to realize the full potential of Vicineum. We expect that any partner who acquires Vicineum from us will be obligated to make any payments to the former shareholders of Viventia under the Share Purchase Agreement

The change in fair value of contingent consideration was a gain of \$52.2 million for the nine months ended September 30, 2021. This was primarily driven by the receipt of a CRL in August 2021, in which the FDA determined that it could not approve the BLA for Vicineum in its present form. Due to the inherent uncertainty in the path forward for Vicineum at the time, we reassessed the underlying assumptions used to develop the revenue projections upon which the fair value of its contingent consideration is based. The most significant and impactful assumptions in our revenue projection models are timing of product launch and POS; we expected delays in the start of commercialization and estimate lower POS as a direct result of the CRL. We anticipated needing to conduct an additional clinical trial, which would lead to delays in the start of commercialization globally. We had assessed a range of commercialization timeline assumptions and applied a probability to each outcome based on management's best estimate. In addition, we assumed a lower POS in achieving certain clinical and regulatory milestones in the range of approximately 45% to 55% globally. The milestone payments constitute debtlike obligations, and the high-yield debt index rate applied to the milestones in order to determine the estimated fair value was 7.5% as of September 30, 2021. The discount rate applied to the 2% earnout payment due on forecasted Vicineum revenues was derived from our estimated WACC, and this WACC-derived discount rate was 8.6% as of September 30, 2021.

#### Provision for Income Taxes

For the nine months ended September 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 reduced the associated deferred tax liability to zero, which resulted in a \$4.0 million income tax 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," in the Notes to Condensed Consolidated Financial Statements in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 for further information regarding the impairment charge.

For the nine months ended September 30, 2021, we recorded a benefit from income taxes of \$8.3 million. In the third quarter of 2021, we determined that the fair value of the Vicineum United States rights were zero, which resulted in an impairment charge of \$31.7 million. In connection with this impairment charge, in the third quarter of 2021, we reduced the associated deferred tax liability which resulted in an \$8.6 million income tax benefit.

#### Net Loss

For the nine months ended September 30, 2022 net loss was \$12.3 million, compared to net loss of \$9.3 million, for the nine months ended September 30, 2021. The increase of \$3.0 million was due to an increase in operating expense (\$33.0 million), primarily driven by the reduction of our prepaid balances related to consumables and manufacturing reservations in the second quarter of 2022 (\$25.2 million) and the preliminary settlements of the securities and derivative litigation net of expected insurance recovery (\$8.2 million). Additionally, the benefit from income taxes decreased (\$4.4 million) in 2022 compared to

2021. This was partially offset by increased revenue (\$33.5 million) primarily driven by the execution of the Roche Asset Purchase agreement.

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

#### Overview

As of September 30, 2022, we had cash, cash equivalents and marketable securities of \$184.9 million, net working capital of \$157.7 million and an accumulated deficit of \$328.6 million. We incurred cash flows from operating activities of \$22.2 million for the nine months ended September 30, 2022, compared to negative cash flows of \$56.3 million for the nine months ended September 30, 2021. We believe that, based on our current operating plans and financial forecasts, our cash, cash equivalents and marketable securities of \$184.9 million as of September 30, 2022, are sufficient to fund our current operating plan for at least twelve months from the date of this Form 10-Q filing, November 7, 2022.

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

The Merger is expected to close approximately two to three months from the date of this form 10-Q filing, November 7, 2022. Consummation of the Merger is subject to certain closing conditions, including, among other things, (a) approval by our stockholders of the proposals described in the Merger Agreement, (b) approval by Carisma's stockholders of, among other things, the adoption of the Merger Agreement, (c) Nasdaq's approval of the listing of the shares of our common stock to be issued in connection with the Merger, (d) the effectiveness of a registration statement on Form S-4 to register the shares of our common stock to be issued in connection with the Merger, and (e) our having net cash as of closing of the Merger greater than or equal to \$100.0 million.

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

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

Since our inception, we have received no revenue from sales of our products, and we anticipate that operating losses will continue for the foreseeable future. We have financed our operations to date primarily through private placements of our common stock, preferred stock, common stock warrants and convertible bridge notes, venture debt borrowings, our IPO, follow-on public offerings, sales effected in ATM offerings, our OUS business development partnerships and license agreements, sale of assets, and, to a lesser extent, from a collaboration.

We have entered into an Open Market Sale Agreement with Jefferies LLC ("Jefferies") dated November 29, 2019, as amended by Amendment No. 1 dated October 30, 2020, Amendment No. 2 dated February 17, 2021 and Amendment No. 3, dated June 1, 2021 (as amended, the "Sale Agreement"), under which we may issue and sell shares of our common stock, par value \$0.001 per share from time to time through Jefferies (the "ATM Offering"). In June and July 2021, we filed prospectus supplements with the SEC in connection with the offer and sale of up to an aggregate of \$200 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 September 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 nine months ended September 30, 2022. We raised \$175.0 million of net proceeds from the sale of 56.9 million shares of common stock at a weighted-average price of \$3.17 per share during the nine month

including \$38.2 million of net proceeds from the sale of 9.8 million shares of common stock at a weighted-average price of \$4.01 per share during the three months ended September 30, 2021. Share issue costs, including sales agent commissions, related to the ATM Offering totaled \$1.2 million and \$5.4 million for the three and nine months ended September 30, 2021, respectively.

# **Funding Requirements**

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

We are subject to a number of risks similar to other clinical companies that have determined to focus primarily on pursuing a strategic transaction, including, but not limited to, those which are described under Part 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 activities with our CMOs;
- · terminate our property leases; and
- explore, evaluate and pursue any strategic alternatives if the Merger is not completed.

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

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

Until such time, if ever, as we can generate substantial revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, or government or other third-party funding. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include liens or other restrictive covenants limiting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our assessment of strategic alternatives. If we do not successfully consummate the proposed Merger with Carisma, our board of directors may decide to explore other strategic alternatives, including, without limitation, another strategic transaction and/or a liquidation and dissolution of our company

#### Contractual and Other Obligations

For information related to our cash requirements from known contractual and other obligations, see the description of Contingent Consideration in Note 5 "Fair Value Measurement and Financial Instruments," the information in Note 10 "Commitments and Contingencies", our leases in Note 11 "Leases", and the description of our license agreements 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 nine months ended September 30, 2022 and 2021 (in thousands):

	Nine Months Ended September 30,				
	2022 20			2021	
Net Cash Provided by (Used in) Operating Activities	\$	22,214	\$	(56,278)	
Net Cash Used in Investing Activities		(113,733)		(4)	
Net Cash Provided by Financing Activities		_		176,129	
Net (Decrease) Increase in Cash, Cash Equivalents and Restricted Cash	\$	(91,519)	\$	119,847	

#### Net Cash Used in Operating Activities

Net cash provided by operating activities was \$22.2 million for the nine months ended September 30, 2022 and consisted primarily of a net loss of \$12.3 million, adjusted for non-cash items including, a decrease in the fair value of contingent consideration (\$52.0 million), intangible impairment charge (\$27.8 million), share-based compensation (\$5.9 million), and a net increase in operating assets and liabilities (\$52.9 million).

Net cash used in operating activities was \$56.3 million for the nine months ended September 30, 2021 and consisted primarily of a net loss of \$9.3 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 (\$3.4 million), a decrease in the fair value of contingent consideration (\$52.2 million), increase in impairment charge (\$31.7 million), and a net decrease in operating assets and liabilities of (\$29.9 million).

# Net Cash Used in Investing activities

Net cash used in investing activities was \$113.7 million for the nine months ended September 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 nine months ended September 30, 2021.

#### Net Cash Provided by Financing activities

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

Net cash provided by financing activities was \$176.1 million for the nine months ended September 30, 2021 and consisted primarily of \$175.0 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 of Vicineum in the United States. The decision was based on a thorough reassessment of Vicineum following recent discussions with the FDA, which had implications on the size, timeline and costs of an additional Phase 3 clinical trial for the treatment of NMIBC Management updated the discounted cash flow model using the market participant approach and considered preliminary terms of potential partnering deal to conclude the fair value of our intangible asset of Vicineum EU rights. 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 and was reduced to zero in the second quarter of 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, size, length and cost of a clinical trial, and time to potential market launch. We identified these changes as potential impairment indicators and performed a quantitative impairment analysis in advance of our typical annual assessment date of October 1. 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. Milestone payments constitute debt-like obligations, and therefore a high-yield debt index rate was applied to the milestones in order to determine the estimated fair value. This index rate was 8.0% as of December 31, 2021.

On July 15, 2022, we made the strategic decision to voluntarily pause further development of Vicineum in the United States. The decision was based on a thorough reassessment of Vicineum following recent discussions with the FDA, which had implications on the size, timeline and costs of an additional Phase 3 clinical trial for the treatment of NMIBC. We continue to believe that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with a larger infrastructure, and as such, we intend to seek a partner for the further development of Vicineum. Accordingly, during the second quarter of 2022, we concluded that we are no longer expected to pay related milestone and earnout payments to the former shareholders of Viventia, with the exception of the potential 2% earnout payment related to the Greater China region since those territory rights had been out-licensed. Qilu held the exclusive license to develop Vicineum in the Greater China

region, and accordingly, the \$1.8 million estimated earnout payment in the Greater China region remained as long-term contingent consideration as of June 30, 2022.

We and Qilu are in the process of negotiating a termination of the Qilu License Agreement. Upon the termination of the Qilu License Agreement, we will regain the rights to develop, manufacture and commercialize Vicineum in Greater China. However, we do not plan to develop or commercialize Vicineum in that region or any other, as we are pursuing the Merger with Carisma. We are also seeking to sell or out-license Vicineum and all the related obligations related to Vicineum. We expect that any partner who acquires or licenses Vicineum from us will be obligated to make any payments, including those related to sales in the Greater China region (if any), that become payable to the former shareholders of Viventia under the Share Purchase Agreement. If a sale or license of Vicineum has not occurred at the time the Merger is completed, Carisma has indicated it may continue to seek a sale or license of Vicineum and has no plans to develop Vicineum. Accordingly, as of September 30, 2022, we concluded that we no longer expect to owe any future earnout payments related to the Greater China region and reduced our remaining \$1.8 million of contingent consideration liabilities to zero as of September 30, 2022.

#### Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and net operating loss and research and development credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. A valuation allowance is recorded to the extent it is more likely than not that some portion or all of the deferred tax assets will not be realized.

Unrecognized income tax benefits represent income tax positions taken on income tax returns that have not been recognized in the financial statements. We recognize the benefit of an income tax position only if it is more likely than not (greater than 50%) that the tax position will be sustained upon tax examination, based solely on the technical merits of the tax position. Otherwise, no benefit is recognized. The tax benefits recognized are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. We recognize accrued interest and penalties related to uncertain tax positions as income tax expense in our condensed consolidated statements of operations. As of September 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 September 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 September 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 (collectively, the "Lead Plaintiffs") collectively as the lead plaintiffs under the Private Securities Litigation Reform Act. On November 1, 2021, two stockholders filed motions to reconsider asking the court to appoint a different lead plaintiff. On November 24, 2021, defendants filed a motion to transfer venue to the US District Court for the District of Massachusetts. That motion was fully briefed as of December 13, 2021, but the court has not ruled on that motion. On December 6, 2021, the Lead Plaintiffs filed an amended class action complaint (the "Amended Complaint"). The Amended Complaint 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, and that motion was fully briefed on May 6, 2022. On June 3, 2022, before the court ruled on the motion to dismiss, the parties requested that the court hold any decision on the motion to dismiss in abeyance to provide the parties with an opportunity to engage in mediation. On June 30, 2022 and July 6, 2022, we and the plaintiffs engaged in mediation sessions in an attempt to resolve the Securities Litigation and continued to discuss a potential settlement over the following weeks. On July 19, 2022, the parties reached an agreement in principle to settle the Securities Litigation. Pursuant to that agreement, we and the individual defendants will pay or cause to be paid to members of the class who submit timely and valid proofs of claims. In exchange, the Lead Plaintiffs will dismiss the action and all class members who do not timely and validly opt-out of the settlement will provide broad customary releases to us and the individual defendants. On August 3, 2022, the parties entered into a Stipulation and Agreement of Settlement to settle the Securities Litigation, which was filed with the court on August 17, 2022. The Stipulation and Agreement of Settlement related to the Securities Litigation provides for a settlement payment of \$21.0 million to the class and the dismissal of all claims against us and the other defendants. The settlement payment is being funded by us and our insurance carriers. On September 1, 2022, the US District Court for the Southern District of New York issued an order denying the motions to appoint a different lead plaintiff. On September 28, 2022, the court issued an order granting preliminary approval of the proposed settlement of the Securities Litigation. The court has set a final settlement approval hearing for January 23, 2023 at 10:00 a.m. local time.

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 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 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, we and the plaintiffs to the Federal Derivative Litigation and the State Derivative Litigation engaged in mediation in an attempt to resolve the litigation, with settlement discussions continuing over the following days. On July 19, 2002, the parties reached an agreement in principle to settle the Federal Derivative Litigation, the State Derivative Litigation and other potential related derivative claims (collectively, the "Derivative Litigation"). Pursuant to that agreement, the individual defendants will cause us to adopt certain enhancements to our corporate governance policies and procedures. In exchange, plaintiffs will dismiss the Derivative Litigation and, on behalf of us, provide broad customary releases to the individual defendants. On August 22, 2002, the parties entered into a Stipulation of Settlement to settle the Derivative Litigation, which was filed with the court on August 30, 2022. The Stipulation of

Settlement related to the Derivative Litigation confirms that we previously adopted certain corporate governance enhancements in response to, among other things, the filing of the Derivative Litigation, and that, subject to final court approval, we will adopt additional corporate governance enhancements. The Stipulation of Settlement also provides for a \$630,000 payment for plaintiffs' attorneys fees due to the benefits the corporate governance enhancements are intended to provide to us. The payment of plaintiffs' attorneys fees is being funded by us. On September 2, 2022, the court issued an order granting preliminary approval of the Stipulation of Settlement related to the Derivative Litigation. The court has set a final settlement approval hearing for November 8, 2022 at 2:00 p.m. local time.

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

On October 21, 2022, we received two separate letters and on November 4, 2022, we received one letter from purported stockholders demanding that we amend the Registration Statement filed with the SEC on October 14, 2022 (the "Registration Statement") to provide additional disclosures that such stockholders allege were improperly omitted from the Registration Statement, including information regarding the financial projections for Carisma, the financial analyses performed by our financial advisor in support of its fairness opinion, and the background and process leading to the execution of the Merger Agreement. We believe that these demands are without merit and intend to vigorously defend against them. At this time, no assessment can be made as to the likely outcome or whether the outcome will be material to us.

#### Item 1A. Risk Factors.

During the nine months ended September 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.

#### Risks Related to the Merger with CARISMA Therapeutics Inc.

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

The Merger Agreement has set the calculation of the Exchange Ratio for the Carisma capital stock, and the Exchange Ratio is based on the fully-diluted capitalization of Carisma and us, in each case immediately prior to the closing of the Merger (after giving effect to the Carisma Pre-Closing Financing). The Merger Agreement does not include a price-based termination right. Therefore, if before the completion of the Merger the market price of our common stock declines from the market price on the date of the Merger Agreement, then Carisma's stockholders could receive merger consideration with substantially lower value than the value of such merger consideration on the date of the Merger Agreement. Similarly, if before the completion of the Merger the market price of our common stock increases from the market price of our common stock on the date of the Merger Agreement, then Carisma's stockholders could receive merger consideration with substantially greater value than the value of such merger consideration on the date of the Merger Agreement. Because the Exchange Ratio does not adjust as a direct result of changes in the market price of our common stock, changes in the market price of our common stock will change the value of the total merger consideration payable to Carisma's stockholders pursuant to the Merger Agreement.

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

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

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

benefit to the extent the combined company is able to realize only part of the strategic and financial benefits currently anticipated from the Merger and the Carisma Pre-Closing Financing.

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

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

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

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

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

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

Certain of our executive officers and directors participate in arrangements that provide them with interests in the Merger that are different from the interests of our stockholders, including, among others, severance benefits, the acceleration of equity vesting, continued indemnification and the potential ability to sell an increased number of shares of common stock of the combined company in accordance with Rule 144 under the Securities Act. Further, Thomas R. Cannell, D.V.M., our President and Chief Executive Officer and a current member of our board of directors, is expected to continue as a member of the combined company's board of directors following the Merger. These interests, among others, may influence our executive officers and directors to support or approve the Merger.

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

If the proposed Merger is completed, our current stockholders will own a smaller percentage of the combined company than their ownership in our company prior to the Merger. Immediately after the Merger, our pre-Merger stockholders are expected to own approximately 41.7% of the outstanding shares of capital stock of the combined company and Carisma's pre-Merger stockholders, excluding shares of Carisma common stock purchased in connection with the Carisma Pre-Closing Financing and the conversion of Carisma's \$35.0 million outstanding convertible note, are expected to own approximately 58.3% of the outstanding shares of capital stock of the combined company, subject to certain assumptions, including our net cash as of the closing of the Merger being \$125.0 million.

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

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

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

The terms of the Merger Agreement prohibit us from soliciting alternative takeover proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances when our board of directors determines in good faith that an unsolicited alternative takeover proposal is or is reasonably likely to result in a superior takeover proposal and that failure to cooperate with the proponent of the proposal is reasonably likely to be inconsistent with our board's fiduciary duties. Any such transactions could be favorable to our stockholders. In addition, if we terminate the Merger Agreement under certain circumstances, including terminating because of a decision of ours to enter into a definitive agreement with respect to a superior offer, we would be required to pay a termination fee of \$7.6 million to Carisma and/or reimburse Carisma's expenses up to a maximum of \$1.75 million. This termination fee described above may discourage third parties from submitting alternative takeover proposals to our stockholders, and may cause our board of directors to be less inclined to recommend an alternative takeover proposal.

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

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

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

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

# Lawsuits may be filed against us and the members of our board of directors arising out of the proposed Merger, which may delay or prevent the proposed Merger.

Putative stockholder complaints, including stockholder class action complaints, and other complaints may be filed against us and our board of directors in connection with the transactions contemplated by the Merger Agreement. For example, on October 21, 2022, we received two separate letters and on November 4, 2022, we received one letter from purported stockholders demanding that we amend the Registration Statement filed with the SEC on October 14, 2022 to provide additional disclosures that such stockholders allege were improperly omitted from the Registration Statement, including information regarding the financial projections for Carisma, the financial analyses performed by our financial advisor in support of its fairness opinion, and the background and process leading to the execution of the Merger Agreement. We believe that these demands are without merit and intends to vigorously defend against them. The outcome of such demands or any future demands that we may receive or any litigation is uncertain, and we may not be successful in defending against any such future claims. Lawsuits that may be filed against us and our board of directors, could delay or prevent the Merger, divert the attention of our management team and employees from our day-to-day business and otherwise adversely affect our business and financial condition.

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

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

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

Merger Agreement or that any such alternatives are possible or would be successful, if pursued. To the extent that we seek and are able to raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect their rights as a common stockholder. Debt financing or preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through strategic transactions or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. Even if we are able to pursue such alternatives, the failure to complete the Merger may result in negative publicity and/or a negative impression of us in the investment community, could significantly harm the market price of our common stock and may affect our relationship with employees and other partners in the business community.

If the Merger is not completed, our board of directors may decide that it is in the best interests of our stockholders to dissolve our company and liquidate our assets. In that event, the amount of cash available for distribution to our stockholders would 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 incurs fees and expenses related to the Merger. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution of our company, we would be required under the Delaware General Corporation 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 liquidation and dissolution of our company. If a liquidation and dissolution were pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, our stockholders could lose all or a significant portion of their investment in the event of a liquidation and dissolution of our company.

#### Our stockholders may not receive any payment on the CVRs and the CVRs may otherwise expire valueless.

The right of our stockholders to receive any future payment on or derive any value from the CVRs will be contingent solely upon the occurrence of a certain triggering event. In particular, CVR holders will be entitled to a pro rata portion of the \$30.0 million milestone payment to be made by Roche to us upon Roche's initiation of a Phase 3 clinical trial with legacy IL-6 antagonist antibody technology previously owned by us for a certain indication if initiated prior to December 31, 2026, pursuant to the Roche Asset Purchase Agreement, less certain permitted deductions. We may not receive any future payment pursuant to the Roche Asset Purchase Agreement after the closing of the Merger. If this milestone is not achieved for any reason within the time period specified in the CVR Agreement or the consideration received is not greater than the amounts permitted to be retained or deducted by us, no payments will be made under the CVRs, and the CVRs will expire valueless.

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

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

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

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

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

We have never paid cash dividends on any of our capital stock. Pursuant to the terms of the Merger Agreement, we may, in addition to the CVRs, declare and pay a special cash dividend to our stockholders of record prior to the Merger consisting of cash in an amount not to exceed \$25.0 million, subject to us having net cash as of the closing of the Merger greater than or equal to \$100.0 million. The amount of such special cash dividend is currently uncertain, pending the determination of our outstanding obligations and net cash position as of the closing of the Merger. Other than such potential special cash dividend in connection with the closing of the Merger, we do not currently anticipate declaring or paying cash dividends on our capital stock in the foreseeable future.

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

As of September 20, 2022, we had 17 full-time employees. Our ability to successfully complete the Merger depends in large part on our ability to retain certain remaining personnel. Despite our efforts to retain these employees, one or more may terminate their employment with us on short notice. The loss of the services of certain employees could potentially harm our ability to consummate the Merger, to run our day-to-day business operations, as well as to fulfill our reporting obligations as a public company.

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

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

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

On January 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 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. However, there can be no assurance that we will be able to regain compliance with Nasdaq's minimum bid price requirement. If we 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 would adversely affect our ability to consummate the Merger and may adversely affect our ability to raise additional financing through the public or private sale of equity securities, significantly affect the ability of investors to trade our common stock, or negatively affect the value and liquidity of our common stock. Delisting also could have other negative results, including the potential loss of employee confidence, the loss of institutional investors or interest in business development opportunities.

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

• a limited availability of market quotations for our common stock;

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

#### Risks Related to our Business and Operations

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 voluntarily 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 in connection with the closing of the proposed Merger with Carisma, which is expected to occur approximately two to three months from the date of this form 10-Q filing, November 7, 2022. The 2022 Restructuring Plan includes an incremental reduction in our workforce as well as additional cost-saving initiatives intended to preserve capital during the pendency of the proposed Merger with Carisma and while we seek a potential partner for the further development of Vicineum.

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.

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

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

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

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

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

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

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

We did not issue any unregistered equity securities during the nine months ended September 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
2.1+	Agreement and Plan of Merger and Reorganization, dated as of September 20, 2022, by and among Sesen Bio, Inc., Seahawk Merger Sub, Inc., and CARISMA Therapeutics Inc. Incorporated by reference to Exhibit 2.1 to our Current Report on Form 8-K filed on September 21, 2022 (File No. 001-36296).
3.1	Restated Certificate of Incorporation of Eleven Biotherapeutics, Inc. Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed on February 18, 2014 (File No. 001-36296).
3.2	Certificate of Amendment of Certificate of Incorporation. Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed on May 17, 2018 (File No. 001-36296).
3.3	Certificate of Amendment of Certificate of Incorporation, Incorporated by reference to Exhibit 3.3 to our Quarterly Report on Form 10-Q filed on May 10, 2021 (File No. 001-36296).
3.4	Amended and Restated By-Laws. Incorporated by reference to Exhibit 3.2 to our Current Report on Form 8-K filed on May 17, 2018 (File No. 001-36296).
4.1	Specimen Stock Certificate evidencing the shares of common stock. Incorporated by reference to Exhibit 4.1 to our Registration Statement on Form S-1/A filed on January 23, 2014 (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).

- 10.1† Asset Purchase Agreement, dated as of July 15, 2022 by and among Sesen Bio, Inc., F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on July 18, 2022 (File No. 001-36296).
- 10.2 Form of Contingent Value Rights Agreement. Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on September 21, 2022 (File No. 001-36296).
- 10.3 <u>Form of Carisma Support Agreement. Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed on September 21, 2022 (File No. 001-36296).</u>
- 10.4 <u>Form of Sesen Bio Support Agreement. Incorporated by reference to Exhibit 10.3 to our Current Report on Form 8-K filed on September 21, 2022 (File No. 001-36296).</u>
- 10.5 Form of Lock-Up Agreement. Incorporated by reference to Exhibit 10.4 to our Current Report on Form 8-K filed on September 21, 2022 (File No. 001-36296).
- 31.1\* Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2\* Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1\*\* Certification of the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2\*\* Certification of the Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101\* Interactive Data File (Form 10-Q for the Quarterly Period ended September 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.
- † In accordance with Item 601(b)(10)(iv) of Regulation S-K, certain provisions of the Asset Purchase Agreement have been redacted. We will provide an unredacted copy of the exhibit on a supplemental basis to the SEC or its staff upon request.
- + Exhibits and/or schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company hereby undertakes to furnish supplementally copies of any of the omitted exhibits and schedules upon request by the SEC; provided, however, that we may request confidential treatment pursuant to Rule 24b-2 under the Exchange Act, for any exhibits or schedules so furnished.

# **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: November 7, 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: November 7, 2022 By: /s/ Monica Forbes

Name: Monica Forbes

Title: Chief Financial Officer

(Principal Financial Officer)

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

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

- 1. I have reviewed this Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2022 of Sesen Bio, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 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)

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

#### I, Monica Forbes, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2022 of Sesen Bio, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2022 By: /s/ Monica Forbes

Name: Monica Forbes

Title: Chief Financial Officer

(Principal Financial Officer)

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

In connection with the Quarterly Report on Form 10-Q of Sesen Bio, Inc. (the "Company") for the fiscal quarter ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 7, 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)

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

In connection with the Quarterly Report on Form 10-Q of Sesen Bio, Inc. (the "Company") for the fiscal quarter ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 7, 2022 By: /s/ Monica Forbes

Name: Monica Forbes

Title: Chief Financial Officer

(Principal Financial Officer)