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

FORM 10-Q

(Mark One)

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

For the quarterly period ended **September 30, 2021**

OR

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

For the transition period from ____ to ____

Commission File Number: 001-36296

Sesen Bio, Inc.

(Exact name of registrant as specified in its charter)

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

(617**)** 444-8550

(Registrant's telephone number, including area code)

Not applicable.

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

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

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

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

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

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

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

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

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

There were 199,463,645 shares of the registrant's common stock outstanding as of November 1, 2021.

SESEN BIO, INC.

Quarterly Report on Form 10-Q for the Quarterly Period ended September 30, 2021

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 175,236	$ 52,389
Accounts receivable	1,107	—
Prepaid expenses and other current assets	24,137	7,478
Restricted cash	—	3,000
Total current assets	200,480	62,867
Non-current assets:		
Restricted cash	20	20
Property and equipment, net	53	123
Intangible assets	14,700	46,400
Goodwill	13,064	13,064
Long term prepaid expenses	7,192	—
Other assets	162	349
Total non-current assets	35,191	59,956
Total Assets	$ 235,671	$ 122,823
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 3,909	$ 3,102
Accrued expenses	8,186	3,973
Deferred revenue	—	1,500
Contingent consideration	—	8,985
Other current liabilities	499	489
Total current liabilities	12,594	18,049
Non-current liabilities:		
Contingent consideration, net of current portion	56,600	99,855
Deferred tax liability	3,969	12,528
Deferred revenue, net of current portion	1,500	1,500
Other non-current liabilities	—	118
Total non-current liabilities	62,069	114,001
Total liabilities	74,663	132,050
Stockholders' Equity (Deficit):		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized at September 30, 2021 and December 31, 2020; no shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock, $0.001 par value per share; 400,000,000 and 200,000,000 shares authorized at September 30, 2021 and December 31, 2020, respectively; 199,463,645 and 140,449,647 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	199	140
Additional paid-in capital	486,010	306,554
Accumulated deficit	(325,201)	(315,921)
Total Stockholders' Equity (Deficit)	161,008	(9,227)
Total Liabilities and Stockholders' Equity	$ 235,671	$ 122,823

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

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

	Three Months ended September 30,		Nine Months ended September 30,	
	2021	2020	2021	2020
License and related revenue	$ —	$ 11,236	$ 6,544	$ 11,236
Operating expenses:				
Research and development	4,967	10,196	18,273	23,625
General and administrative	8,699	4,115	20,797	10,882
Restructuring charge	5,522	—	5,522	—
Intangibles impairment charge	31,700	—	31,700	—
Change in fair value of contingent consideration	(114,000)	18,400	(52,240)	(16,820)
Total operating expenses	(63,112)	32,711	24,052	17,687
Income (Loss) from Operations	63,112	(21,475)	(17,508)	(6,451)
Other income (expense), net	1	(1)	(45)	195
Income (Loss) Before Taxes	63,113	(21,476)	(17,553)	(6,256)
Benefit (provision) from income taxes	8,561	(1,132)	8,273	(1,132)
Net Income (Loss) and Comprehensive Income (Loss) After Taxes	$ 71,674	$ (22,608)	$ (9,280)	$ (7,388)
Net income (loss) attributable to common stockholders - basic	$ 71,622	$ (22,608)	$ (9,280)	$ (7,535)
Net income (loss) attributable to common stockholders - diluted	$ 71,623	$ (22,608)	$ (9,280)	$ (7,535)
Net income (loss) per common share - basic	$ 0.36	$ (0.19)	$ (0.05)	$ (0.07)
Weighted-average common shares outstanding - basic	196,778	117,886	176,547	113,437
Net income (loss) per common share - diluted	$ 0.36	$ (0.19)	$ (0.05)	$ (0.07)
Weighted-average common shares outstanding - diluted	201,017	117,886	176,547	113,437

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

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at December 31, 2019	106,801,409	$ 107	$ 266,717	$ (293,524)	$ (26,700)
Net income	—	—	—	41,564	41,564
Share-based compensation	—	—	407	—	407
Sales of common stock under 2014 ESPP	2,785	—	1	—	1
Issuance of common stock under ATM Offering, net of issuance costs of $0.1 million	3,187,359	3	3,176	—	3,179
Balance at March 31, 2020	**109,991,553**	**$ 110**	**$ 270,301**	**$ (251,960)**	**$ 18,451**
Net loss	—	—	—	(26,344)	(26,344)
Share-based compensation	—	—	491	—	491
Issuance of common stock and common stock warrants, net of issuance costs of $0.1 million	6,636,100	6	4,768	—	4,774
Balance as of June 30, 2020	**116,627,653**	**$ 116**	**$ 275,560**	**$ (278,304)**	**$ (2,628)**
Net loss	—	—	—	(22,608)	(22,608)
Share-based compensation	—	—	453	—	453
Sales of common stock under 2014 ESPP	25,401	—	9	—	9
Issuance of common stock under ATM Offering, net of issuance costs of $0.3 million	6,991,953	7	8,214	—	8,221
Balance at September 30, 2020	**123,645,007**	**$ 123**	**$ 284,236**	**$ (300,912)**	**$ (16,553)**

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

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

	Nine Months ended September 30,	
	2021	2020
Cash Flows from Operating Activities:		
Net loss	$ (9,280)	$ (7,388)
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation	74	92
Share-based compensation	3,386	1,351
Change in fair value of contingent consideration	(52,240)	(16,820)
Intangibles impairment charge	31,700	—
Changes in operating assets and liabilities:		
Accounts receivable (net)	(1,107)	—
Prepaid expenses and other assets	(23,665)	(899)
Accounts payable	807	(378)
Accrued expenses and other liabilities	(4,453)	1,714
Deferred revenue	(1,500)	—
Net cash used in operating activities	(56,278)	(22,328)
Cash Flows from Investing Activities:		
Purchases of equipment	(4)	(8)
Net cash used in investing activities	(4)	(8)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock under ATM Offering, net of issuance costs	174,961	16,174
Proceeds from exercises of stock options	42	10
Proceeds from the exercise of common stock warrants	1,126	—
Net cash provided by financing activities	176,129	16,184
Net increase (decrease) in cash, cash equivalents and restricted cash	119,847	(6,152)
Cash, cash equivalents and restricted cash - beginning of period	55,409	48,141
Cash, cash equivalents and restricted cash - end of period	$ 175,256	$ 41,989
Supplemental cash flow disclosure:		
Right-of-use assets obtained in exchange for lease obligations	$ —	$ 290
Cash paid for amounts included in the measurement of lease liabilities	$ 131	$ 113
Supplemental disclosure of non-cash financing activities:		
Deemed Dividend on adjustment of exercise price on certain warrants	$ —	$ 147

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

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

1. DESCRIPTION OF BUSINESS

Sesen Bio, Inc. ("Sesen" or the "Company"), a Delaware corporation formed in February 2008, is a late-stage clinical company advancing targeted fusion protein therapeutics ("TFPTs") for the treatment of patients with cancer. The Company's most advanced product candidate, VicineumTM, 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 bacillus Calmette-Guérin ("BCG")-unresponsive non-muscle invasive bladder cancer ("NMIBC"). The Company has an ongoing single-arm, multi-center, open-label Phase 3 clinical trial of Vicineum as a monotherapy in patients with BCG-unresponsive NMIBC (the "VISTA Trial"). The VISTA Trial completed enrollment in April 2018 with a total of 133 patients. On December 18, 2020, the Company submitted its completed Biologics License Application (the "BLA") for Vicineum for the treatment of BCG-unresponsive NMIBC to the United States Food and Drug Administration ("FDA"). On February 12, 2021, the FDA notified the Company that it has accepted for filing the BLA. The FDA also granted Priority Review for the BLA and set a target Prescription Drug User Fee Act ("PDUFA") date for a decision on the BLA of August 18, 2021. On July 13, 2021, the Company participated in a productive Late-Cycle Meeting with the FDA regarding the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. In the meeting, the FDA confirmed that there was no Advisory Committee meeting planned at that time, and that no post-marketing requirements, including a confirmatory trial, had been identified at that time. Also in the meeting, the Company and the FDA discussed remaining questions related to manufacturing facilities inspection, product quality information requests and additional information related to chemistry, manufacturing and controls ("CMC"), and a timeline to submit additional supporting information was agreed upon. On August 13, 2021, the Company received a complete response letter ("CRL") from the FDA indicating that the FDA had determined that it could not approve the BLA for Vicineum in its present form and provided recommendations specific to additional clinical/statistical data and analyses in addition to CMC issues pertaining to a recent pre-approval inspection and product quality. On October 29, 2021, the Company participated in a Type A meeting with the FDA to discuss questions related to CMC raised in the CRL (the "CMC Type A Meeting"). During the CMC Type A Meeting, the Company and the FDA reviewed issues related to CMC to be further discussed during the review of the BLA for Vicineum upon potential resubmission. The Company believes it has a clear understanding of what additional information regarding CMC is required for resubmission of the BLA. Additionally, although not an issue raised in the CRL, the FDA confirmed that Vicineum manufactured using the proposed commercial process is comparable to Vicineum used in prior clinical trials. The FDA also confirmed that the Company can utilize Vicineum manufactured during process validation for any potential future clinical trials needed to address issues raised in the CRL, and that these potential trials can proceed while addressing CMC issues. The Company is preparing for a separate Type A Meeting to discuss the recommendations specific to additional clinical/statistical data and analyses that the FDA raised in the CRL (the "Clinical Type A Meeting"), which the Company expects to occur later this year. The Company operates in one segment under the direction of its Chief Executive Officer (chief operating decision maker). The Company was formerly known as Eleven Biotherapeutics, Inc. until its name changed in May 2018.

Viventia Acquisition

In September 2016, the Company entered into a Share Purchase Agreement with Viventia Bio, Inc., a corporation incorporated under the laws of the Province of Ontario, Canada ("Viventia"), the shareholders of Viventia named therein (the "Selling Shareholders") and, solely in its capacity as seller representative, Clairmark Investments Ltd., a corporation incorporated under the laws of the Province of Ontario, Canada ("Clairmark") (the "Share Purchase Agreement"), pursuant to which the Company agreed to and simultaneously completed the acquisition of all of the outstanding capital stock of Viventia from the Selling Shareholders (the "Viventia Acquisition"). In connection with the closing of the Viventia Acquisition, the Company issued 4.0 million shares of its common stock to the Selling Shareholders, which at that time represented approximately 19.9% of the voting power of the Company as of immediately prior to the issuance of such shares. Clairmark is an affiliate of Leslie L. Dan, who served as a director of the Company until his retirement in July 2019.

In addition, under the Share Purchase Agreement, the Company is obligated to pay to the Selling Shareholders certain post-closing contingent cash payments upon the achievement of specified milestones and based upon net sales, in each case subject to the terms and conditions set forth in the Share Purchase Agreement, including: (i) a one-time milestone payment of $12.5 million payable upon the first sale of Vicineum (the "Purchased Product") in the United States; (ii) a one-time milestone payment of $7 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 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 (collectively, the "Contingent Consideration"). 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, 2021, none of these individuals are employees or members of the Company's board of directors.

2. BASIS OF PRESENTATION

The accompanying financial statements have been prepared in accordance with United States generally accepted accounting principles (“GAAP”). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the 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, 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, 2021 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 March 15, 2021, 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); research and development expenses; revenue recognition and going concern considerations.

Principles of Consolidation

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

Foreign Currency Translation

The functional currency of the Company and each of its subsidiaries is the U.S. 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, 2020.

4. RECENT ACCOUNTING PRONOUNCEMENTS

Adopted in 2021

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"). ASU 2019-12 simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments in ASU 2019-12 also improve consistent application of and simplify GAAP

for other areas of Topic 740 by clarifying and amending existing guidance. ASU 2019-12 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. Early adoption is permitted. The method with which the amendments in this ASU are to be applied varies depending on the nature of the tax item impacted by amendment. The Company adopted this guidance effective January 1, 2021, and it did not have a material impact on its financial position, results of operations or cash flows.

5. FAIR VALUE MEASUREMENT AND FINANCIAL INSTRUMENTS

The carrying values of cash and cash equivalents, restricted cash, prepaid expenses and other current assets, and accounts payable on the Company's condensed consolidated balance sheets approximated their fair values as of September 30, 2021 and December 31, 2020 due to their short-term nature.

Certain of the Company's financial instruments are measured at fair value using a three-level hierarchy that prioritizes the inputs used to measure fair value. This fair value hierarchy prioritizes the use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

Level 1: Inputs are quoted prices for identical instruments in active markets.

Level 2: Inputs are quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; or model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3: Inputs are unobservable and reflect the Company's own assumptions, based on the best information available, including the Company's own data.

The following tables set forth the carrying amounts and fair values of the Company's financial instruments measured at fair value on a recurring basis as of September 30, 2021 and December 31, 2020 (in thousands):

	September 30, 2021				
			Fair Value Measurement Based on		
	Carrying Amount	Fair Value	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:					
Money market funds (cash equivalents)	$ 16,380	$ 16,380	$ 16,380	$ —	$ —
Liabilities:					
Contingent consideration - short term	$ —	$ —	$ —	$ —	$ —
Contingent consideration - long term	$ 56,600	$ 56,600	$ —	$ —	$ 56,600

	December 31, 2020				
			Fair Value Measurement Based on		
	Carrying Amount	Fair Value	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:					
Money market funds (cash equivalents)	$ 16,374	$ 16,374	$ 16,374	$ —	$ —
Liabilities:					
Contingent consideration - short term	$ 8,985	$ 8,985	$ —	$ —	$ 8,985
Contingent consideration - long term	$ 99,855	$ 99,855	$ —	$ —	$ 99,855

The Company evaluates transfers between fair value levels at the end of each reporting period. There were no transfers of assets or liabilities between fair value levels during the nine months ended September 30, 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.

The estimated fair value of the Company’s contingent consideration was determined using probabilities of successful achievement of clinical and regulatory milestones and commercial sales, the period in which these milestones and sales are expected to be achieved ranging from 2024 to 2033, the level of commercial sales of Vicineum forecasted for the United States, Europe, Japan, China and other potential markets and discount rates ranging from 7.5% to 8.6% as of September 30, 2021 and 8.4% to 8.8% as of December 31, 2020. There have been no changes to the valuation methods utilized during the nine months ended September 30, 2021.

The following table sets forth a summary of the change in the fair value of the Company's total contingent consideration liability, measured on a recurring basis at each reporting period, for the nine months ended September 30, 2021 (in thousands):

Balance at December 31, 2020	$108,840
Change in fair value of contingent consideration - short term	(8,985)
Change in fair value of contingent consideration - long term	(43,255)
Balance at September 30, 2021	$ 56,600

The fair value of the Company’s contingent consideration is determined based on the present value of projected future cash flows associated with sales based milestones and earnouts on net sales and is heavily dependent on discount rates to estimate the fair value at each reporting period. Earnouts are determined using an earnout rate of 2% on all commercial net sales of Vicineum through December 2033. The discount rate applied to the 2% earnout is derived from the Company’s estimated weighted-average cost of capital (“WACC”), which has fluctuated from 8.8% as of December 31, 2020 to 8.6% as of September 30, 2021. Milestone payments constitute debt-like obligations, and therefore a high-yield debt index rate is applied to the milestones in order to determine the estimated fair value. This index rate changed from 8.4% as of December 31, 2020 to 7.5% as of September 30, 2021. The decrease in the fair value of contingent consideration of $52.2 million for the nine months ended September 30, 2021 was driven by the receipt of the CRL from the FDA, in which the FDA determined that it could not approve the BLA for Vicineum in its present form. Due to the inherent uncertainty in the path forward for Vicineum at this time, the Company reassessed the underlying assumptions used to develop the revenue projections upon which the fair value of its contingent consideration is based. The most significant and impactful assumptions in our revenue projection models are timing of product launch and probabilities of clinical and regulatory success (POS); the Company expects delays in the start of commercialization and estimates lower POS as a direct result of the CRL. The Company anticipates needing to conduct an additional clinical trial, which will lead to delays in the start of commercialization globally. The Company has assessed a range of commercialization timeline assumptions and applied a probability to each outcome based on management’s best estimate. In addition, the Company now assumes a lower POS in achieving certain clinical and regulatory milestones in the range of approximately 45% to 55% globally. The Company participated in a Type A Meeting with the FDA on October 29, 2021 to discuss questions related to CMC raised in the CRL, and expects to engage in a Type A meeting with the FDA later this year to discuss questions related to clinical matters raised in the CRL. Both meetings are intended to help the Company determine the appropriate path forward for Vicineum. Any changes in these assumptions and estimates as a result of these meetings, or other information obtained, may have a significant impact on the remeasurement of the contingent consideration liability in the future.

6.INTANGIBLE ASSETS AND GOODWILL

Intangible Assets

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, 2021 and December 31, 2020 (in thousands):

	September 30, 2021	December 31, 2020
IPR&D intangible assets:		
Vicineum United States rights	$ —	$ 31,700
Vicineum European Union rights	14,700	14,700
Total Intangibles	**$ 14,700**	**$ 46,400**

The fair value of the acquired intangible asset for the U.S. and E.U. rights of Vicineum is determined using a risk-adjusted discounted cash flow approach, which includes probability adjustments for projected revenues and operating expenses based on the success rates assigned to each stage of development for each geographical region; as well as discount rates applied to the projected cash flows. In August 2021, the Company received a CRL from the FDA regarding its BLA for Vicineum for the treatment of NMIBC, the Company's lead product candidate. In the CRL, the FDA determined that it could not approve the BLA for Vicineum in its present form and provided recommendations specific to additional clinical/statistical data and analyses in addition to CMC issues pertaining to a recent pre-approval inspection and product quality. The Company participated in a Type A Meeting with the FDA on October 29, 2021 to discuss questions related to CMC raised in the CRL, and expects to engage in a Type A meeting with the FDA in the fourth quarter of 2021 to discuss the clinical issues raised in the CRL. Both meetings are intended to help the Company determine the appropriate path forward for Vicineum. Given the inherent uncertainty at this time in the development plans for Vicineum as a result of the CRL, an impairment analysis was conducted, which concluded that the carrying value of our intangible assets of Vicineum United States rights was fully impaired as of September 30, 2021. However, while similar delays in timelines and reduced probabilities of success also affected the carrying value of our intangible assets of Vicineum E.U. rights, this asset was not impaired as of September 30, 2021. The $31.7 million of impairment charges for the period ended September 30, 2021 are due to delays in the expected start of commercialization and lower probabilities of success, combined with higher operating expenses expected to be incurred prior to commercialization, resulting in lower expected future cash flows estimated in the US market as of September 30, 2021. However, while similar delays in timelines and reduced probabilities of success also affected the estimated fair value of our intangible assets of Vicineum E.U. rights, this asset was not impaired as of September 30, 2021. At this time, management has assessed that the carrying value of the Vicineum EU rights is not at significant risk of impairment in the future within the current range of commercialization timelines and POS assumptions. This is primarily due to the fact that the EU asset is burdened with significantly less expense than the US asset, as our strategic operating plan is to sublicense Vicineum to business development partners in all regions outside the US, including the EU, with the Company earning a potential combination of upfront, milestone, and royalty payments, and the business development partner bearing the majority of regulatory and commercialization costs.

Goodwill

Goodwill on the Company's condensed consolidated balance sheets is the result of the Viventia Acquisition in September 2016. Goodwill had a carrying value of $13.1 million as of September 30, 2021 and December 31, 2020. Given the inherent uncertainty at this time in the development plans for Vicineum as a result of the CRL, a quantitative impairment analysis was conducted during the quarter, in advance of the Company's typical annual assessment date of October 1. While an impairment was recognized in one of its intangible assets, Vicineum U.S. Rights, the Company concluded that the carrying value of its goodwill of $13.1 million was not impaired as of September 30, 2021, with the fair value of equity of the reporting unit exceeding the estimated carrying value of the reporting unit by approximately 45%. The Company believes it has sufficient future cash flows from additional geographic regions outside the US to support the value of its goodwill. The Company projects future cash flows based on various timeline assumptions and applies a probability to each outcome based on management's best estimate. In addition, probabilities of success in achieving certain clinical and regulatory success in our current development profile (ranging from 45% to 55% globally) also have a material effect on the estimated fair value of its reporting unit as of the impairment assessment date. The Company will continue to evaluate its timelines for commercialization and probability of success of development of Vicineum for the treatment of BCG-unresponsive NMIBC. The Company participated in a Type A Meeting with the FDA on October 29, 2021 to discuss questions related to CMC raised in the CRL, and expects to engage in a Type A meeting with the FDA in the fourth quarter of 2021 to discuss questions related to clinical matters raised in the CRL. Both meetings are intended to help the Company determine the appropriate path forward for Vicineum, and will assess the outcome of those meetings, and other information obtained, to determine if further impairment testing is required. Further reductions to probabilities of success, additional development and commercial launch delays, or increases in underlying discount rates have the potential to result in future goodwill impairment.

7. LEASES

The Company accounts for operating leases under ASC Topic 842, *Leases*. The Company's lease portfolio includes an operating lease for its 31,100 square foot facility in Winnipeg, Manitoba which consists of manufacturing, laboratory, warehouse and office space. In September 2020, the Company entered into an extension of this lease for an additional two years, through September 2022, with a right to extend the lease for one subsequent three year term. The minimum monthly rent under this lease is CAD $18,100 (approximately $14,300 at exchange rates in effect on September 30, 2021). In addition to rent expense, the Company expects to incur CAD $18,200 per month related to operating expenses (approximately $14,300 at exchange rates in effect on September 30, 2021). Operating lease cost under this lease, including the related operating costs, were $79,000 and $245,000 for the three and nine months ended September 30, 2021 and $75,000 and $223,000 for the three and nine months ended September 30, 2020, respectively.

The asset component of the Company’s operating leases is recorded as operating lease right-of-use assets and reported within other assets on the Company's condensed consolidated balance sheets. The short-term lease liability is recorded in other current liabilities and the long-term lease liability is recorded in other liabilities on the Company’s condensed consolidated balance sheets. Operating lease cost is recognized on a straight-line basis over the term of the lease.

In addition, the Company has short-term property leases for modular office space for 1) its corporate headquarters in Cambridge, MA and 2) office space in Philadelphia, PA. The short-term leases renew every three months to six months and currently extend through June 2022 and November 2021, respectively. The minimum monthly rent for these office spaces is $2,100 and $18,000, respectively, which is subject to change if and as the Company adds space to or deducts space from the leases. The Company recorded $63,000 and $201,000 in rent expense for the three and nine months ended September 30, 2021 and $64,000 and $195,000 for the three and nine months ended September 30, 2020, respectively. The Company's accounting policy election was disclosed 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, 2020.

8. ACCRUED EXPENSES

The following table sets forth the composition of accrued expenses as of September 30, 2021 and December 31, 2020 (in thousands):

	September 30, 2021	December 31, 2020
Research and development	$ 2,148	$ 1,372
Payroll-related expenses	1,628	1,892
Professional fees	2,089	684
Restructuring charge related	2,237	—
Other	84	25
Total Accrued Expenses	**$ 8,186**	**$ 3,973**

9. STOCKHOLDERS' EQUITY (DEFICIT)

Equity Financings

ATM Offering

In November 2019, the Company entered into an Open Market Sale Agreement [SM] (the "Sale Agreement") with Jefferies LLC ("Jefferies"), under which the Company may issue and sell shares of its common stock, par value $0.001 per share, from time to time for an aggregate sales price of up to $35 million through Jefferies (the "ATM Offering"). In October 2020 and February 2021, the Company entered into Amendments No. 1 and No. 2 to the Sale Agreement, respectively. Amendments No. 1 and No. 2 modified the Sale Agreement to reflect that the Company may issue and sell shares of its common stock from time to time for an aggregate sales price of up to an additional $50 million and $34.5 million, respectively. In June 2021, the Company entered into Amendment No. 3 to the Sale Agreement, which modified the Sale Agreement to remove the maximum dollar amount of shares of common stock that may be sold pursuant to the Sale Agreement. In June and July 2021, the Company filed prospectus supplements with the SEC in connection with the offer and sale of up to an aggregate of $200 million of common stock pursuant to the Sale Agreement. Sales are made by any method that is deemed to be an ATM offering as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended, including but not limited to sales made directly on or through the Nasdaq Global Market or any other existing trading market for our common stock. The Company may sell shares of its common stock efficiently from time to time, but has no obligation to sell any of its common stock and may at any time suspend offers under the Sale Agreement or terminate the Sale Agreement. Subject to the terms and conditions of the Sale Agreement, Jefferies will use its commercially reasonable efforts to sell common stock from time to time, as the sales agent, based upon the Company’s instructions, which include a prohibition on sales below a minimum price set by the Company from time to time. The Company

has provided Jefferies with customary indemnification rights, and Jefferies is entitled to a commission at a fixed rate equal to 3.0% of the gross proceeds for each sale of common stock under the Sale Agreement. The Company raised $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, compared to $8.2 million of net proceeds from the sale of 7.0 million shares of common stock at a weighted-average price of $1.21 per share during the three months ended September 30, 2020. 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, compared to $16.2 million of net proceeds from the sale of 16.8 million shares of common stock at a weighted-average price of $0.99 per share during the nine months ended September 30, 2020. 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, as amended (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, 2021 and December 31, 2020.

Common Stock

Following approval by the Company’s stockholders on May 3, 2021, an amendment became effective to the Certificate of Incorporation that increased the number of authorized shares of common stock from 200 million to 400 million, of which 199 million and 140 million shares were issued and outstanding as of September 30, 2021 and December 31, 2020, respectively. In addition, the Company had reserved for issuance the following number of shares of common stock for the purposes described below as of September 30, 2021 and December 31, 2020 (in thousands):

	September 30, 2021	December 31, 2020
Shares of common stock issued	199,464	140,450
Shares of common stock reserved for issuance for:		
Warrants	199	2,247
Stock options	15,511	10,147
Shares available for grant under 2014 Stock Incentive Plan	11,983	4,863
Shares available for sale under 2014 Employee Stock Purchase Plan	2,300	—
Total shares of common stock issued and reserved for issuance	**229,457**	**157,707**

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

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

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

Warrants

All of the Company's outstanding warrants are non-tradeable and permanently classified as equity because they meet the derivative scope exception under ASC Topic 815-40, *Derivatives and Hedging - Contracts in Entity's Own Equity* ("ASC 815-40"). The following table sets forth the Company's warrant activity for the nine months ended September 30, 2021 (in thousands):

			Year-to-Date Warrant Activity				
Issued	**Exercise Price**	**Expiration**	**December 31, 2020**	**Issued**	**(Exercised)**	**(Expired)**	**September 30, 2021**
Mar-2018	$0.55*	Mar-2023	1,705	—	(1,573)	—	132
Nov-2017	$0.55*	Nov-2022	487	—	(475)	—	12
May-2015	$11.83	Nov-2024	28	—	—	—	28
Nov-2014	$11.04	Nov-2024	27	—	—	—	27
			2,247	**—**	**(2,048)**	**—**	**199**

** Exercise price shown (i) reflects modification (ii) subject to further adjustment based on down round provision added by amendment described in "Item 15. Exhibits and Financial Statement Schedules - Note. 10 Stockholders' (Deficit) Equity" in the audited annual consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.*

10. EARNINGS (LOSS) PER SHARE

A net loss cannot be diluted. Therefore, when the Company is in a net loss position, basic and diluted loss per common share are the same. If the Company achieves profitability, the denominator of a diluted earnings per common share calculation includes both the weighted-average number of shares outstanding and the number of common stock equivalents, if the inclusion of such common stock equivalents would be dilutive. Dilutive common stock equivalents potentially include warrants, stock options and non-vested restricted stock awards and units using the treasury stock method, along with the effect, if any, from outstanding convertible securities. The majority of the Company's outstanding warrants to purchase common stock have participation rights to any dividends that may be declared in the future and are therefore considered to be participating securities. Participating securities have the effect of diluting both basic and diluted earnings per share during periods of income. During periods of loss, no loss is allocated to the participating securities since the holders have no contractual obligation to share in the losses of the Company.

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

For periods with net income, diluted net earnings per share is calculated by either (i) adjusting the weighted-average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period as determined using the treasury stock method or (ii) the two-class method considering common stock equivalents, whichever is more dilutive. The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders.
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, 2021. The two-class method was not applied for the nine months ended September 30, 2021 and for the three and nine months ended September 30, 2020 as the Company's participating securities do not have any obligation to absorb net losses.

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

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

	Three Months ended September 30,		Nine Months ended September 30,	
	2021	2020	2021	2020
	(in thousands, except per share amounts)			
Basic Earnings (Loss) Per Share:				
Numerator:				
Net income (loss)	$ 71,674	$ (22,608)	$ (9,280)	$ (7,388)
Less: Deemed Dividend	—	—	—	(147)
Less: Income attributable to participating securities - basic	(52)	—	—	—
Net income (loss) attributable to common stockholders - basic	$ 71,622	$ (22,608)	$ (9,280)	$ (7,535)
Denominator:				
Weighted average common shares outstanding - basic	196,778	117,886	176,547	113,437
Net income (loss) per share applicable to common stockholders - basic	$ 0.36	$ (0.19)	$ (0.05)	$ (0.07)
Dilutive Earnings (Loss) Per Share:				
Numerator:				
Net income (loss)	$ 71,674	$ (22,608)	$ (9,280)	$ (7,388)
Less: Deemed Dividend	—	—	—	(147)
Less: Income attributable to participating securities - diluted	(51)	—	—	—
Net income (loss) attributable to common stockholders - diluted	$ 71,623	$ (22,608)	$ (9,280)	$ (7,535)
Denominator:				
Weighted average shares outstanding	196,778	117,886	176,547	113,437
Dilutive impact from:				
Stock options and employee stock purchase plan	4,239	—	—	—
Weighted average common shares outstanding - diluted	201,017	117,886	176,547	113,437
Net income (loss) per share applicable to common stockholders - diluted	$ 0.36	$ (0.19)	$ (0.05)	$ (0.07)

The following potentially dilutive securities outstanding as of September 30, 2021 and 2020 have been excluded from the denominator of the diluted income (loss) per share of common stock outstanding calculation as their effect is anti-dilutive.
(in thousands):

	Three Months ended September 30,		Nine Months ended September 30,	
	2021	2020	2021	2020
Warrants	55	2,485	199	2,485
Stock options	11,273	10,227	15,511	10,227
	11,328	**12,712**	**15,710**	**12,712**

11. 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 income (operations) and comprehensive income (loss) for the three and nine months ended September 30, 2021 and 2020 (in thousands):

	Three Months ended September 30,		Nine Months ended September 30,	
	2021	2020	2021	2020
Research and development	$ 152	$ 95	$ 536	$ 266
General and administrative	1,016	358	2,849	1,085
	$ 1,168	$ 453	$ 3,385	$ 1,351

2014 Stock Incentive Plan

The Company's 2014 Stock Incentive Plan, as amended ("2014 Plan"), was adopted by its board of directors in December 2013 and subsequently approved by its stockholders in January 2014. The 2014 Plan became effective immediately prior to the closing of the Company's IPO in February 2014 and provides for the grant of incentive and non-qualified stock options, restricted stock awards and restricted stock units, stock appreciation rights and other stock-based awards, with amounts and terms of grants determined by the Company's board of directors at the time of grant, to the Company's employees, officers, directors, consultants and advisors.

At the Annual Meeting of the Company's stockholders in June 2019, the Company's stockholders approved an amendment to the 2014 Plan that (i) increased by 7.9 million the number of shares of common stock reserved for issuance under the 2014 Plan and (ii) eliminated the “evergreen” or automatic replenishment provision of the 2014 Plan, pursuant to which the number of shares of common stock authorized for issuance under the 2014 Plan was automatically increased on an annual basis. At the Annual Meeting of the Company’s stockholders in May 2021, the Company’s stockholders approved an amendment to the 2014 Plan that increased by 12 million the number of shares of common stock reserved for issuance under the 2014 Plan. There were approximately 12.0 million shares of common stock available for issuance under the 2014 Plan as of September 30, 2021.

Stock options outstanding under the 2014 Plan generally vest over a four-year period at the rate of 25% of the grant vesting on the first anniversary of the date of grant and 6.25% of the grant vesting at the end of each successive three month period thereafter. Stock options granted under the 2014 Plan are exercisable for a period of ten years from the date of grant. There were approximately 12.7 million stock options outstanding under the 2014 Plan as of September 30, 2021.

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

Also pursuant to the Retention Program and effective as of October 1, 2021, the Company’s executive officers, except for the Chief Executive Officer, were granted a one-time performance-based restricted stock unit (“PSU”) award equal to the value of approximately fifty percent of current base salary. Each PSU represents a contingent right to receive one share of the Company’s common stock upon the satisfaction of pre-determined performance criteria. Subject to continued employment, such awards vest on September 30, 2023 upon the determination by the Compensation Committee of the level of achievement of certain key milestones consisting of a clinical trial milestone, an employee retention milestone and cash management milestones.

2009 Stock Incentive Plan

The Company maintains a 2009 Stock Incentive Plan, as amended and restated ("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, 2021.

Out-of-Plan Inducement Grants

From time to time, the Company has granted equity awards to its newly hired employees, including executives, in accordance with the Nasdaq Stock Market LLC ("Nasdaq") employment inducement grant exemption (Nasdaq Listing Rule 5635(c)(4)). Such grants are made outside of the 2014 Plan and act as an inducement material to the employee's acceptance of employment with the Company. There were approximately 2.6 million stock options outstanding which were granted as employment inducement awards outside of the 2014 Plan as of September 30, 2021.

Stock Options

The following table sets forth a summary of the Company's total stock option activity, including awards granted under the 2014 Plan and 2009 Plan and inducement grants made outside of stockholder approved plans, for the nine months ended September 30, 2021:

	Number of Shares under Option (in thousands)	Weighted-average Exercise Price per Option	Weighted-average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2020	10,147	$1.26	8.5	$ 3,160
Granted	8,026	$3.40		
Exercised	(34)	$1.23		
Canceled or forfeited	(2,628)	$3.75		
Outstanding at September 30, 2021	15,511	$1.95	8.3	$ 63
Exercisable at September 30, 2021	6,706	$1.61	7.6	$ 49

The Company recognized share-based compensation expense related to stock options of $1.2 million and $3.4 million for the three and nine months ended September 30, 2021, respectively and $0.5 million and $1.4 million for the three and nine months ended September 30, 2020, respectively. As of September 30, 2021, there was $11.5 million of total unrecognized compensation cost related to non-vested stock options which the Company expects to recognize over a weighted-average period of 2.83 years. The weighted-average grant-date fair value of stock options granted was $2.20 per option for the nine months ended September 30, 2021 and $0.56 per option for the nine months ended September 30, 2020. The total intrinsic value of stock options exercised during the nine months ended September 30, 2021 was de minimis.

For the nine months ended September 30, 2021 and 2020, the grant-date fair value of stock options was determined using the following weighted-average inputs and assumptions in the Black-Scholes option pricing model:

	September 30, 2021	September 30, 2020
Fair market value	$3.40	$0.87
Grant exercise price	$3.40	$0.87
Expected term (in years)	6.03	6.1
Risk-free interest rate	0.9	1.3
Expected volatility	74.6	71.5
Dividend yield	—%	—%

12. EMPLOYEE BENEFIT PLANS

2014 Employee Stock Purchase Plan

The Company's 2014 Employee Stock Purchase Plan ("2014 ESPP") was adopted by its board of directors in December 2013 and subsequently approved by its stockholders in January 2014. The 2014 ESPP became effective immediately prior to the closing of the Company's IPO in February 2014 and established an initial reserve of 0.2 million shares of the Company's common stock for issuance to participating employees. At the Annual Meeting of the Company's stockholders in May 2021, the Company's stockholders approved an amendment to the 2014 ESPP that increased by 2.3 million the number of shares of common stock reserved for issuance under the 2014 ESPP. The purpose of the 2014 ESPP is to enhance employee interest in the success and progress of the Company by encouraging employee ownership of common stock of the Company. The 2014

ESPP provides employees with the opportunity to purchase shares of common stock at a 15% discount to the market price through payroll deductions or lump sum cash investments. The Company estimates the number of shares to be issued at the end of an offering period and recognizes expense over the requisite service period. Shares of the common stock issued and sold pursuant to the 2014 ESPP are shown on the consolidated statements of changes in stockholders' equity (deficit). As of September 30, 2021, there were 2.3 million shares of common stock available for sale under the 2014 ESPP.

Defined Contribution Plans

United States - 401(k) Plan

The Company maintains a 401(k) defined contribution retirement plan which covers all of its U.S. employees. Employees are eligible to participate immediately upon 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 $4,000 per year. The expenses incurred for the periods presented were de minimis.

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.

13. 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,	
	2021	**2020**
Country:		
United States	$ (38,864)	$ (18,838)
Canada	21,311	12,582
Total Loss before Income Taxes	**$ (17,553)**	**$ (6,256)**

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

	Nine Months Ended September 30,	
	2021	**2020**
Current Tax Benefit (Provision):		
Federal	$ 8,559	$ —
State	—	—
Foreign	$ (286)	(1,132)
Total Current Benefit (Provision)	**$ 8,273**	**$ (1,132)**

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

	September 30, 2021	**December 31, 2020**
Deferred tax liabilities:		
IPR&D	$ (3,969)	$ (12,528)
Property and equipment	—	—
Total Deferred Tax Liabilities	**$ (3,969)**	**$ (12,528)**

For 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 United States 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. Please refer to Note 6, "Intangible Assets and

Goodwill," for further information regarding the impairment charge. For the nine months ended September 30, 2020, the Company recorded a provision for income taxes of $1.1 million. This provision consisted of income taxes paid to foreign jurisdictions pursuant to the License Agreement with Qilu.

14. 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. These patents cover some key aspects of Vicineum. Upon the Company's receipt of the CRL regarding the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC, the Company became obligated to pay $0.5 million in a milestone payment to Zurich. The Company is also obligated to pay up to a 4% royalty on the net product sales for products covered by or manufactured using a method covered by a valid claim in the Zurich patent rights. Royalties owed to Zurich will be reduced if the total royalty rate owed by the Company to Zurich and any other third party is 10% or greater, provided that the royalty rate to Zurich may not be less than 2% of net sales. The obligation to pay royalties in a particular country expires upon the expiration or termination of the last of the Zurich patent rights that covers the manufacture, use or sale of a product. There is no obligation to pay royalties in a country if there is no valid claim that covers the product or a method of manufacturing the product. The Company recorded an expense of $0.3 million and $0.5 million related to achievement of a development milestone, (the submission of the Company’s BLA with the FDA in December 2020), in the three months ended December 31, 2020 and a regulatory milestone, (the Company’s receipt of the CRL from the FDA in August 2021), in the three months ended September 30, 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. These patents cover some key aspects of Vicineum. Under the terms of the License Agreement with Micromet, as of September 30, 2021, the Company may be obligated to pay up to €2.4 million in milestone payments for the first product candidate that achieves applicable regulatory and sales-based development milestones (approximately $2.8 million at exchange rates in effect on September 30, 2021). The Company is also required to pay up to a 3.5% royalty on the net sales for products covered by the agreement, which includes Vicineum. The royalty rate owed to Micromet in a particular country will be reduced to 1.5% if there are no valid claims covering the product in that country. The obligation to pay royalties in a particular country expires upon the later of the expiration date of the last valid claim covering the product and the tenth anniversary of the first commercial sale of the product in such country. Finally, the Company is required to pay to Micromet an annual license maintenance fee of €50,000 (approximately $57,965 at exchange rates in effect as of September 30, 2021), which can be credited towards any royalty payment the Company owes to Micromet. The Company recorded an expense of €0.7 million ($0.9 million) related to achievement of a development milestone in the three months ended December 31, 2020, due to the submission of the Company's BLA for Vicineum with the FDA in December 2020. The Company recorded an expense of €0.5 million (approximately $0.6 million) related to the submission of the Marketing Authorization Application ("MAA") to the European Medicines Agency (“EMA”) for Vysyneum™ in the first quarter of 2021. Vysyneum is the proprietary brand name that was conditionally approved by the EMA for oportuzumab monatox in the European Union.

License Agreement with XOMA

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

Out-License Agreements

Roche License Agreement

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

Financial Terms

The Company received from Roche an upfront license fee of $7.5 million in August 2016 upon the effectiveness of the License Agreement with Roche following approval by the Company's stockholders, and Roche agreed to pay up to an additional $262.5 million upon the achievement of specified regulatory, development and commercialization milestones with respect to up to two unrelated indications. Specifically, an aggregate amount of up to $197.5 million is payable to the Company for the achievement of specified milestones with respect to the first indication, consisting of (i) $72.5 million in development milestones, the next of which is $20.0 million for initiation of the first Phase II study, (ii) $50 million in regulatory milestones and (iii) $75 million in commercialization milestones. In September 2016, Roche paid the Company the first development milestone of $22.5 million as a result of the Investigational New Drug application for EBI-031 becoming effective on or before September 15, 2016. Additional amounts of up to $65 million are payable upon the achievement of specified development and regulatory milestones in a second indication.

In addition, the Company is entitled to receive royalty payments in accordance with a tiered royalty rate scale, with rates ranging from 7.5% to 15% of net sales of potential future products containing EBI-031 and up to 50% of these rates for net sales of potential future products containing other IL-6 compounds, with each of the royalties subject to reduction under certain circumstances and to the buy-out options of Roche.

Buy-Out Options

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

Termination

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

OUS Business Development Partnership Agreements

Qilu License Agreement

On July 30, 2020, the Company and its a wholly-owned subsidiary, Viventia Bio, Inc., entered into an exclusive license agreement with Qilu Pharmaceutical Co., Ltd. ("Qilu") 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 "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 Licensed Product in the Greater China. The Company retains (i) development, and commercialization rights in the rest of the world excluding Greater China, the Middle East and North Africa region ("MENA") and Turkey and (ii) manufacturing rights with respect to Vicineum in the rest of the world excluding China.

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

Qilu also agreed to pay the Company a 12% royalty based upon annual net sales of Licensed Products in Greater China. The royalties are payable on a Licensed Product-by-Licensed Product and region-by-region basis commencing on the first commercial sale of a Licensed Product in a region and continuing until the latest of (i) twelve years after the first commercial sale of such 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 Licensed Product in such region, and (iii) the expiration of regulatory or data exclusivity for such 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 Licensed Product in a particular region or no data or regulatory exclusivity of a Licensed Product in a particular region.

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

The License Agreement with Qilu will expire on a Licensed Product-by-Licensed Product and region-by-region basis on the date of the expiration of all applicable Royalty Terms. Either party may terminate the License Agreement with Qilu 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 License Agreement with Qilu is terminated under certain circumstances. The License Agreement with Qilu includes customary representations and warranties, covenants and indemnification obligations for a transaction of this nature.

The License Agreement with Qilu is subject to the provisions of Accounting Standards Codification 606, Revenue from Contracts with Customers ("ASC 606"), which was adopted effective January 1, 2018. In 2020, the initial transaction price was estimated to be $11.2 million and was based on the up-front fixed consideration of $12 million less amounts withheld for VAT. The Company concluded that its agreements under the License Agreement with Qilu 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 dollar 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 recorded the outstanding $2.8 million to accounts receivables as of March 31, 2021 and received the payment as of June 30, 2021.

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

MENA License Agreement

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

The MENA License Agreement is subject to the provisions of ASC 606. The initial transaction price was estimated by management as $1.5 million as of December 31, 2020 and was based on 50% of the upfront payment, or the amount not subject to a refund if certain regulatory approvals in MENA are not obtained. The Company also concluded that its agreements under

the MENA License Agreement represented two distinct performance obligations, the first of which is a bundled performance obligation related to the delivery of the license, associated know-how and certain documentation. The second performance obligation relates to the delivery of manufactured product. The first performance obligation (delivery of the license, associated know-how and certain documentation) was achieved during the quarter ended March 31, 2021; as such, revenue of $1.5 million has been recognized. Additional variable consideration, determined to be allocated entirely to the bundled license performance obligation, to be paid to the Company based upon future sales levels will be recognized as revenue when the underlying sales of the licensed product occurs. In addition, variable consideration related to any future delivery of product will be recognized in future periods as the product is delivered. As of September 30, 2021, none of these additional amounts were reasonably certain to be achieved due to the nature and timing of the underlying activities.

EIP License Agreement

On August 5, 2021, we entered into an exclusive license agreement with Eczacibasi Pharmaceuticals Marketing ("EIP") pursuant to which we granted EIP an exclusive license to register and commercialize Vicineum for the treatment of BCG-unresponsive NMIBC in Turkey and Northern Cyprus. Under the terms of the licensing agreement, we are entitled to receive an upfront payment of $1.5 million, are eligible to receive additional regulatory and commercial milestone payments of $2.0 million and are also entitled to receive a 30% royalty on net sales in Turkey and Northern Cyprus. The EIP License Agreement is subject to the provisions of ASC 606 and as of September 30, 2021, none of these amounts have been received by the Company. No initial transaction price was estimated by management as of September 30, 2021 as the upfront payment is subject to a refund if certain regulatory approvals in the US are not obtained. The Company also concluded that its promises under this license agreement represented two distinct performance obligations, the first of which is a bundled performance obligation related to the delivery of the license and associated know-how. The second performance obligation relates to the delivery of manufactured product. Additional variable consideration, determined to be allocated entirely to the bundled license performance obligation, to be paid to the Company based upon future regulatory milestones will be recognized as achievement of those milestones. In addition, variable consideration related to any future delivery of product will be recognized in future periods as the product is delivered. As of September 30, 2021, none of these additional amounts were reasonably certain to be achieved due to the nature and timing of the underlying activities.

15. RESTRUCTURING AND RELATED ACTIVITIES

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

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

	September 30, 2021
	(in thousands)
Severance and benefits costs	$ 2,792
Contract termination costs	2,730
Other restructuring costs	—
Total restructuring costs	$ 5,522
Cash payments	(856)
Balance at September 30, 2021	$ 4,666

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, 2021. The Company expects that substantially all of the accrued restructuring costs as of September 30, 2021 will be paid in cash by the end of September 2022.

16. 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 U.S. District Court for the Southern District of New York. The three complaints allege violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder based on statements made by the Company concerning its BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. The three complaints seek compensatory damages and costs and expenses, including attorneys' fees. On October 29, 2021, the court consolidated the three cases under the caption In re Sesen Bio, Inc. Securities Litigation, Master File No. 1:21-cv-07025-AKH, and appointed Ryan Bibb, Rodney Samaan, Lionel Dreshaj and Benjamin Dresaj collectively as the "lead plaintiff" under the Private Securities Litigation Reform Act. On November 1, 2021, two stockholders filed motions to reconsider asking the court to appoint a different lead plaintiff. The court has not ruled on those motions at this time.

On 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 U.S. District Court for the District of Massachusetts, with the Company named as a nominal defendant. The two 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 two 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 cases under the caption In re Sesen Bio, Inc. Derivative Litigation, Lead Case No. 1:21-cv-11538.

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

17. SUBSEQUENT EVENTS

Pursuant to the Retention Program described in Note 11 above, and effective as of October 1, 2021, the Company's non-executive employees received a combination of a cash bonus award and a one-time restricted stock unit ("RSU") award which vests in full on September 30, 2022, subject to continued employment through September 30, 2022. Each RSU represents a contingent right to receive one share of the Company's common stock. Also pursuant to the Retention Program and effective as of October 1, 2021, the Company's executive officers, except for the Chief Executive Officer, were granted a one-time performance-based restricted stock unit ("PSU") award equal to the value of approximately 50% of current base salary. Each PSU represents a contingent right to receive one share of the Company's common stock upon the satisfaction of pre-determined performance criteria. Subject to continued employment, such awards vest on September 30, 2023 upon the determination by the Compensation Committee of the level of achievement of certain key milestones consisting of a clinical trial milestone, an employee retention milestone and cash management milestones.

On October 29, 2021, the Company participated in a Type A meeting with the FDA to discuss questions related to CMC raised in the CRL. During the CMC Type A Meeting, the Company and the FDA reviewed issues related to CMC to be further discussed during the review of the BLA for Vicineum upon potential resubmission. The Company believes it has a clear understanding of what additional information regarding CMC is required for resubmission of the BLA. Additionally, although not an issue raised in the CRL, the FDA confirmed that Vicineum manufactured using the proposed commercial process is comparable to Vicineum used in prior clinical trials. The FDA also confirmed that the Company can utilize Vicineum manufactured during process validation for any potential future clinical trials needed to address issues raised in the CRL, and that these potential trials can proceed while addressing CMC issues. The Company is preparing for a separate Clinical Type A Meeting, which the Company expects to occur later this year.

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, 2020, included in our Annual Report on Form 10-K filed with the United States Securities and Exchange Commission ("SEC") on March 15, 2021. In addition to historical financial information, some of the information contained in the following discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended ("Exchange Act"). All statements other than statements of historical facts, including statements regarding our future results of operations and financial position, the impact of the COVID-19 pandemic, business strategy, current and prospective products, product approvals, research and development costs, current and prospective collaborations, timing and likelihood of success, plans and objectives of management for future operations and future results of current and anticipated products, are forward-looking statements.

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

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

- our plans and ability to resolve the issues identified in the complete response letter ("CRL") we received from the US Food and Drug Administration ("FDA") regarding our Biologics License Application ("BLA") for Vicineum™ for the treatment of bacillus Calmette-Guérin ("BCG")-unresponsive non-muscle invasive bladder cancer ("NMIBC");
- our plans and ability to resolve the concerns identified in the European Medicines Agency's ("EMA") Withdrawal Assessment Report related to our marketing authorization application ("MAA") for Vysyneum™ (the "EMA Withdrawal Report");
- the Company's belief that it has a clear understanding of what additional information regarding CMC is required for potential resubmission of the BLA for Vicineum;
- the Company's ability to utilize Vicineum manufactured during process validation for any potential clinical trials needed to address issues raised in the CRL, and that any such potential clinical trials can proceed while addressing CMC issues;
- the Type A meeting to discuss the recommendations specific to additional clinical/statistical data and analyses that the FDA raised in the CRL to discuss next steps for Vicineum for the treatment of BCG-unresponsive NMIBC (the "Clinical Type A Meeting") and the anticipated timing of any such meeting;
- our expectation that we will need to conduct an additional clinical trial for Vicineum for the treatment of BCG-unresponsive NMIBC to address questions related to clinical matters raised in the CRL;
- our intentions to use the information from the CMC Type A Meeting and the Clinical Type A Meeting to determine the appropriate path forward with regulators;
- our plans and ability to resubmit the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC to the FDA following the issuance of the CRL by the FDA, and if approved by the FDA, our ability to commercialize Vicineum for the treatment of BCG unresponsive NMIBC in the United States;
- our plans and ability to resume pursuing regulatory approval of Vysyneum for the treatment of BCG-unresponsive NMIBC in the European Union when there is more clarity from the FDA on next steps for Vicineum in the US;
- our intentions to work closely with the FDA to understand next steps for Vicineum for the treatment of BCG-unresponsive NMIBC in the US;
- our intentions to work closely with the EMA to understand next steps for Vysyneum for the treatment of BCG-unresponsive NMIBC in the European Union;
- our ongoing voluntary internal review by outside counsel and other experts on the conduct of, and data generated from, the clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC, and the overall safety and effectiveness of Vicineum;
- the potential impact of the COVID-19 pandemic on our business;
- our expected future loss and accumulated deficit levels;
- the difficulties and expenses associated with obtaining and maintaining regulatory approval of Vicineum for the treatment of BCG-unresponsive NMIBC in the United States, the European Union and other foreign jurisdictions, and the labeling under any approval we may obtain;
- our expectation that the first wave of potential country approvals for Vicineum for the treatment of BCG-unresponsive NMIBC in the MENA region may occur as early as 2025;
- our projected financial position and estimated cash burn rate;
- our belief that we have sufficient future cash flows from additional geographic regions outside the US to support the value of our goodwill and EU IPR&D;

- our plans to continue to evaluate timelines for commercialization and probability of success of development of Vicineum for the treatment of BCG-unresponsive NMIBC;
- our estimations regarding any remeasurement of contingent consideration liability in the future;
- our estimations regarding any potential impairment to our goodwill and indefinite lived intangible assets in the future;
- our estimates regarding expenses, future revenues, capital requirements and needs for, and ability to obtain, additional financing;
- our need to raise substantial additional capital to fund our operations;
- the success, cost and timing of our pre-clinical studies and clinical trials in the United States and other foreign jurisdictions;
- our dependence on third parties, including contract research organizations ("CROs") in the conduct of our pre-clinical studies and clinical trials;
- the timing and costs associated with our manufacturing process and technology transfer to FUJIFILM Diosynth Biotechnologies U.S.A., Inc. ("Fujifilm") for the production of Vicineum drug substance, and our reliance on Fujifilm to perform under our agreement with Fujifilm;
- the timing and costs associated with our manufacturing process and technology transfer to Baxter Oncology GmbH ("Baxter") for the production of Vicineum drug product, and our reliance on Baxter to perform under our agreement with Baxter;
- the timing and costs associated with our manufacturing process and technology transfer to Qilu Pharmaceutical Co., Ltd. ("Qilu") for the production of Vicineum drug substance and drug product, and our reliance on Qilu to perform under our agreement with Qilu;
- market acceptance of our product candidates, including Vicineum for the treatment of BCG-unresponsive NMIBC, the size and growth of the potential markets for our product candidates, and our ability to serve those markets;
- obtaining and maintaining intellectual property protection for our product candidates and our proprietary technology;
- our strategic operating plan to sublicense Vicineum for the treatment of BCG-unresponsive NMIBC to business development partners in all regions outside the US, including the EU, to earn a potential combination of upfront, milestone, and royalty payments, and the business development partner to bear the majority of regulatory and commercialization costs;
- our expectations regarding the amount and timing of milestone and royalty payments pursuant to our out-license agreements and business development partnership agreements, including our license agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (collectively, "Roche") and our exclusive license agreement with Qilu for the development, manufacture and commercialization of Vicineum in Greater China;
- our plans to seek additional business development partnerships; and
- the success of competing therapies and products that are or become available.

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

- we may not be able to resolve the issues raised in the CRL we received from the FDA regarding our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC;
- we may not be able to resolve the concerns identified in the EMA Withdrawal Assessment Report;
- after the CMC Type A Meeting and the Clinical Type A Meeting with the FDA to discuss our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC, we may not have a viable path forward for continued clinical development of Vicineum, which would prevent us from resubmitting our BLA for Vicineum;
- we may not achieve profitable operations or access needed capital;
- clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC, or any of our other product candidates, may not demonstrate safety and efficacy to the satisfaction of the FDA, EMA or other foreign regulatory authorities or otherwise produce favorable results;
- we may not obtain marketing approval of Vicineum for the treatment of BCG-unresponsive NMIBC in the United States, the European Union, or other foreign jurisdictions;
- Vicineum may not gain market acceptance for the treatment of BCG-unresponsive NMIBC in the United States, the European Union or other foreign jurisdictions;
- market opportunity for Vicineum may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed;
- we may experience issues or delays with implementation of commercial-scale manufacturing of Vicineum;

- we may be unable to establish sales, marketing and distribution capabilities or scale up and validate external manufacturing capabilities of Vicineum (including completing the manufacturing process and technology transfer to any third-party manufacturers) for the treatment of BCG-unresponsive NMIBC in the United States, if approved;
- our competitors may discover, develop or commercialize products before, or more successfully than, we do;
- we may be unable to obtain, maintain, defend and enforce patent claims and other intellectual property rights;
- we may be unable to defend against pending or threatened litigation, which may be costly and time-consuming;
- our ongoing voluntary internal review by outside counsel and other experts on the conduct of, and data generated from, the clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC, and the overall safety and effectiveness of Vicineum could result in significant expenses and other harm to our business;
- we may fail to comply with all regulatory requirements or experience unanticipated problems with our products;
- we may recognize impairment of our goodwill and indefinite lived intangible assets;
- such other factors described in “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K and in Item 1A. Risk Factors in this Quarterly Report on Form 10-Q.

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 risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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

Overview

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

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

On December 18, 2020, we submitted our completed BLA for Vicineum for the treatment of BCG-unresponsive NMIBC to the FDA. On February 12, 2021, the FDA notified us that it had accepted our BLA filing. The FDA also granted Priority Review for the BLA and set a target PDUFA date for a decision on the BLA of August 18, 2021. On August 13, 2021, we received a CRL from the FDA indicating that the FDA had determined that it could not approve the BLA for Vicineum in its present form, and provided recommendations specific to additional clinical/statistical data and analyses in addition to CMC issues pertaining to a recent pre-approval inspection and product quality. On August 20, 2021, we withdrew our MAA to the EMA for Vysyneum for the treatment of BCG-unresponsive NMIBC in order to pause our plans to pursue regulatory approval of Vysyneum in the European Union until there is more clarity from the FDA on next steps for Vicineum in the United States. On October 20, 2021, the EMA issued its Withdrawal Assessment Report relating to our MAA for Vysyneum, as is consistent with the EMA's standard practice when an MAA is withdrawn. The Assessment Report reflects the initial assessment and corresponding questions from the EMA and identifies major objections in the areas of Quality, Good Clinical Practice, Efficacy and Safety. Due to the high concordance between FDA and European Commission approvals, we believe that the probability of success of future approval in the European Union for Vysyneum increases if FDA approval for Vicineum has already been obtained. On

October 29, 2021, we participated in a Type A meeting with the FDA to discuss questions related to CMC raised in the CRL. During the CMC Type A Meeting, we and the FDA reviewed issues related to CMC to be further discussed during the review of the BLA for Vicineum upon potential resubmission. We believe we have a clear understanding of what additional information regarding CMC is required for resubmission of the BLA. Additionally, although not an issue raised in the CRL, the FDA confirmed that Vicineum manufactured using the proposed commercial process is comparable to Vicineum used in prior clinical trials. The FDA also confirmed that we can utilize Vicineum manufactured during process validation for any potential future clinical trials needed to address issues raised in the CRL, and that these potential trials can proceed while addressing CMC issues. We are preparing for a separate Type A Meeting to discuss the recommendations specific to additional clinical/statistical data and analyses that the FDA raised in the CRL, which we expect to occur later this year. We intend to use information from the CMC Type A Meeting and the Clinical Type A Meeting to determine the appropriate path forward with regulators.

In August 2019, we reported updated preliminary efficacy data from our ongoing single-arm, multi-center, open-label Phase 3 clinical trial of Vicineum as a monotherapy in patients with BCG-unresponsive NMIBC (the "VISTA Trial"). As of the May 29, 2019 data cutoff date, the preliminary complete response rates ("CRRs") in evaluable carcinoma *in situ* ("CIS") patients following three, six, nine and 12 months of treatment in the clinical trial were consistent with those observed in the previously completed Phase 1 and Phase 2 Vicineum clinical trials for the treatment of NMIBC. The VISTA Trial completed enrollment in April 2018 with a total of 133 patients across three cohorts based on histology and time to disease recurrence after adequate BCG treatment (under 2018 FDA guidance on treatment of NMIBC, adequate BCG is defined as at least two courses of BCG with at least five doses in an initial induction course of treatment, plus at least two doses in a second course of treatment):

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

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

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

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

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

** Response-evaluable population includes any modified intention-to-treat ("mITT") patient who completed the induction phase.*

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

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

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

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

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

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

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

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

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

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

† Recurrence-free rate is defined as the percentage of patients that are recurrence-free at the given assessment time point.
** Response-evaluable population includes any mITT patient who completed the induction phase.*

Duration of Response: The median DoR for patients in Cohort 1 and Cohort 2 combined (n=93) is 287 days (lower 95% confidence interval ("CI") = 154 days, upper 95% confidence interval is not estimable ("NE") due to the limited number of events occurring beyond the median), using the Kaplan-Meier method. The Kaplan-Meier method is a non-parametric statistical analysis used to estimate survival times and times to event when incomplete observations in data exist. 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 based on the May 29, 2019 data cutoff date. These additional preliminary data include the following:

- ***Time to Cystectomy:*** Across all 133 patients treated with Vicineum in the VISTA Trial, greater than 75% of all patients are estimated to remain cystectomy-free at 3 years, using the Kaplan-Meier method. Additional *ad hoc* analysis shows that approximately 88% of responders are estimated to remain cystectomy-free at 3 years. Time to cystectomy is defined as the time from the date of first dose of study treatment to surgical bladder removal. The first 2018 FDA guidance on treatment of BCG-unresponsive NMIBC patients states that the goal of therapy in such patients is to avoid cystectomy. Therefore, time to cystectomy is a key secondary endpoint in the VISTA Trial.
- ***Time to Disease Recurrence:*** High-grade papillary (Ta or T1) NMIBC is associated with higher 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 May 29, 2019 data cut from the Phase III VISTA trial. The clinical data shown are based on the data submitted in the BLA on December 18, 2020. Final numbers are pending. On August 13, 2021, the FDA issued a CRL for the BLA, which included requests for additional clinical and statistical data. We intend to discuss these topics with the FDA at a Type A meeting we expect to occur later this year.

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

Other Vicineum Activity

On December 18, 2020, we submitted the completed BLA, including Module 3 (CMC), to the FDA.

On February 12, 2021, the FDA notified us that it had accepted our BLA filing. The FDA also granted Priority Review for the BLA and a target PDUFA date for a decision on the BLA of August 18, 2021.

On March 5, 2021, we submitted our MAA to the EMA for Vicineum (oportuzumab monatox) for the treatment of BCG-unresponsive NMIBC under the EMA's centralized procedure. We received notice on March 25, 2021 from the EMA that our MAA for Vicineum was found to be valid and that the review procedure had officially started.

On March 31, 2021, we were informed that the Committee for Medicinal Products for Human Use of the EMA had conditionally accepted the proprietary brand name Vysyneum for our product candidate, oportuzumab monatox, in the European Union. The name Vysyneum has identical pronunciation to the U.S. proprietary brand name Vicineum and was developed in accordance with the criteria outlined in the EMA's Guideline on the acceptability of names for human medicinal products.

On July 13, 2021, we participated in a productive Late-Cycle Meeting with the FDA regarding the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. In the meeting, the FDA confirmed that there was no Advisory Committee meeting planned at that time, and that no post-marketing requirements, including a confirmatory trial, had been identified at that time. Also in the meeting, we and the FDA discussed remaining questions related to manufacturing facilities inspection, product quality information requests and additional information related to CMC, and a timeline to submit additional supporting information was agreed upon.

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

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

On September 17, 2021, we disclosed that we have voluntarily engaged outside counsel and other experts to conduct a review focusing on the conduct of, and data generated from, the clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC, and the overall safety and effectiveness of Vicineum. We expect to incur substantial costs in conducting this internal review, but because the internal review is ongoing, we cannot predict the duration, scope, or result of the review.

On October 20, 2021, the EMA issued its Withdrawal Assessment Report relating to our MAA for Vysyneum, as is consistent with the EMA's standard practice when an MAA is withdrawn. The Assessment Report reflects the initial assessment and corresponding questions from the EMA and identifies major objections in the areas of Quality, Good Clinical Practice, Efficacy and Safety. Due to the high concordance between FDA and European Commission approvals, we believe that the probability of success of future approval in the European Union for Vysyneum increases if FDA approval for Vicineum has already been obtained. We intend to use information from the CMC Type A Meeting and the Clinical Type A Meeting to determine the appropriate path forward with regulators.

On October 27, 2021, the FDA published a Warning Letter (the "FDA Warning Letter") issued to a former study investigator in our VISTA trial for Vicineum arising from a 2021 FDA inspection related to the review of our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. We discontinued use of the clinical site and the study investigator over four years ago when we learned of professional misconduct by the study investigator that was unrelated to the VISTA trial. The FDA Warning Letter indicates that the study investigator did not comply with applicable statutory requirements and applicable regulations regarding conduct of clinical investigations. The study investigator operated a clinical site that was previously part of the VISTA trial, which was closed by us on May 26, 2017. The study investigator's medical license was temporarily suspended on May 29, 2017 due to inaccurate recordkeeping, which was unassociated with Sesen Bio and the patients in the VISTA trial. We notified the FDA of the misconduct at that time. When the clinical site was closed, five patients had completed treatment and were in post-treatment follow-up. There was no evidence found that patients were harmed by the study investigator's actions. We included the corresponding patient data from the clinical site in its BLA submission to the FDA, which were thoroughly analyzed and discussed during the BLA review.

On October 29, 2021, we participated in a Type A meeting with the FDA to discuss questions related to CMC raised in the CRL. During the CMC Type A Meeting, we and the FDA reviewed issues related to CMC to be further discussed during the review of the BLA for Vicineum upon potential resubmission. We believe we have a clear understanding of what additional information regarding CMC is required for resubmission of the BLA. We are preparing for a separate Type A Meeting to discuss the recommendations specific to additional clinical/statistical data and analyses that the FDA raised in the CRL, which we expect to occur later this year.

Manufacturing

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

In April 2019, the first full, commercial-scale current Good Manufacturing Practice ("cGMP") run was completed at Fujifilm. Full quality release testing was completed and all Phase 3 release specifications were met, supporting Fujifilm's ability to

produce the bulk drug substance form of Vicineum for commercial purposes if we receive regulatory approval to market Vicineum for the treatment of BCG-unresponsive NMIBC.

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

In February 2020, manufacturing of the pre-process performance qualification ("pre-PPQ") cGMP batch was completed at Fujifilm. Full quality release testing of the drug substance was completed and all quality acceptance criteria were met.

On August 4, 2020, we completed manufacturing of the drug substance PPQ batches at Fujifilm and in September 2020, we successfully completed the final of three drug product PPQ batches at Baxter. All of the completed drug substance PPQ batches and drug product PPQ batches met all quality acceptance criteria.

In December 2020, we received and analyzed all of the analytical comparability test results from the drug substance and drug product PPQ batches. For analytical comparability, we conducted testing across four categories: release testing, biophysical characterization, forced degradation studies, and stability studies. This approach is in alignment with requirements of the FDA, the EMA and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. The test results for product intended for commercial use were found to be highly comparable to our clinical supply of Vicineum. The comparability data from the PPQ campaigns for both drug substance and drug product were the final material components of our completed BLA, which was submitted to the FDA on December 18, 2020.

In December 2020, we entered into a commercial manufacturing and supply framework agreement with Qilu (the "Qilu Framework Agreement") for Qilu to be a contract manufacturer for the global commercial supply of Vicineum.

In January 2021, we signed a Scope of Work (" SOW #10") with Fujifilm under the Fujifilm MSA for the manufacturing of commercial batches of Vicineum in 2021.

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

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

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

Greater China

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

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

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

In June 2021, the Qilu License Agreement was recognized by Shandong Province, Bureau of Science and Technology as "Technology Transfer". An agreement that is designated as a Technology Transfer shall be entitled to a tax incentive of value-added tax ("VAT") recovery. As such, we recorded $0.9 million of revenue during the three months ended June 30, 2021 for

additional purchase price resulting from Qilu's obligation to pay Sesen an amount equal to its recovery of VAT. We will not be subject to VAT on future potential milestone payments.

MENA

On November 30, 2020, we entered into an exclusive license agreement with Hikma Pharmaceuticals LLC ("Hikma") (the “Hikma License Agreement”) pursuant to which we granted Hikma an exclusive, sublicensable, royalty-bearing license, under certain intellectual property owned or exclusively licensed by us, to commercialize Vicineum in the MENA region. We retain development and commercialization rights in the rest of the world excluding Greater China and MENA. In consideration for the rights granted by us, Hikma agreed to pay to us an upfront payment, sales related milestones payments, and royalties and on net sales in the MENA region for the term of the Hikma License Agreement. We continue to work closely with our partner, Hikma Pharmaceuticals, to submit marketing authorization applications for Vicineum in 2021 in seven key markets in the region: the Kingdom of Saudi Arabia, Jordan, Morocco, Egypt, Lebanon, Kuwait and Algeria. These seven markets represent a significant opportunity in the MENA region, as Saudi Arabia, Jordan and Morocco have some of the most advanced healthcare systems in the region while Egypt is the second largest economy in Africa. We anticipate the first wave of potential country approvals for Vicineum in the MENA region as early as 2025.

Turkey

On August 5, 2021, we entered into an exclusive license agreement with Eczacibasi Pharmaceuticals Marketing (“EIP”) pursuant to which we granted EIP an exclusive license to register and commercialize Vicineum for the treatment of BCG-unresponsive NMIBC in Turkey and Northern Cyprus. Under the terms of the licensing agreement, we are entitled to receive an upfront payment of $1.5 million, which we agreed to defer the payment of this amount until the conclusion of our Type A meetings with the FDA. We are also eligible to receive additional regulatory and commercial milestone payments of $2.0 million and are entitled to receive a 30% royalty on net sales in Turkey and Northern Cyprus. We have deferred the upfront payment due from EIP until conclusion of the Type A meetings with the FDA which are expected to be completed by the end of 2021.

National Cancer Institute

In June 2017, we entered into a Cooperative Research and Development Agreement (“CRADA”) with the National Cancer Institute (“NCI”) for the development of Vicineum in combination with AstraZeneca’s immune checkpoint inhibitor durvalumab for the treatment of BCG-unresponsive NMIBC. Vicineum is believed to work via a dual mechanism of action to directly kill cancer cells and activate a local inflammatory process that stimulates T-cells, which then proliferate and destroy the cancer cells. Because of this second mechanism, there may be potential for a synergistic effect when given in combination with checkpoint inhibitors. This hypothesis is being tested by the NCI in a Phase 1 clinical trial in patients with BCG-unresponsive NMIBC to evaluate the safety, efficacy and biological correlates of Vicineum in combination with durvalumab (“NCI Trial”). This Phase 1 clinical trial is open and actively recruiting patients.

Components of Our Results of Operations

License and Related Revenue

License revenue consists of revenue recognized pursuant to our OUS business development partnership agreements which is assessed under ASC 606. In the future, we may generate revenue from a combination of up-front payments, milestone payments and royalties in connection with our OUS business development partnership agreements.

Research and Development

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

- the nature and scope of activities required to resolve the CRL issued by the FDA in response to our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC and the concerns identified in the EMA Withdrawal Assessment Report, which we expect will include the completion of an additional clinical trial;
- employee-related expenses, including salaries, benefits, travel and share-based compensation expense;
- expenses incurred under agreements with contract research organizations ("CROs") and investigative sites that conduct our clinical trials;
- expenses associated with developing manufacturing capabilities;
- expenses associated with transferring manufacturing capabilities to contract manufacturing organizations ("CMOs") for commercial-scale production;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies;
- expenses associated with regulatory activities; and
- expenses associated with license milestone fees

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

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

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

A change in the outcome of any of these variables with respect to the development of Vicineum for the treatment of BCG-unresponsive NMIBC could mean a significant change in the costs and timing associated with the development of Vicineum for the treatment of BCG-unresponsive NMIBC. For example, we expect needing to conduct an additional clinical trial to address clinical issues raised in the CRL from the FDA. If the FDA, EMA or another regulatory authority were to require us to conduct clinical trials or other testing to complete the clinical development of Vicineum for the treatment of BCG-unresponsive NMIBC, we could be required to expend significant additional financial resources and time on the completion of clinical development of Vicineum for the treatment of BCG-unresponsive NMIBC. We expect our research and development costs to relate to Vicineum for the foreseeable future as we seek to resolve the CRL issued by the FDA with regard to our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC and the EMA Withdrawal Assessment Report, and obtain regulatory approval for Vicineum in the US and the European Union, and if successful in obtaining such regulatory approvals, advance Vicineum through the commercialization scale-up, clinical and other activities.

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

deferred further development of Vicineum for the treatment of squamous cell carcinoma of the head and neck and VB6-845d in order to focus our efforts and our resources on our ongoing development and, if approved, commercialization of Vicineum for the treatment of BCG-unresponsive NMIBC.

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,	
	2021	2020	2021	2020
Programs:				
Vicineum for the treatment of BCG-unresponsive NMIBC	$ 2,989	$ 8,506	$ 10,888	$ 19,005
Total direct program expenses	2,989	8,506	10,888	19,005
Personnel and other expenses:				
Employee and contractor-related expenses	1,732	1,314	6,392	3,688
Platform-related lab expenses	19	184	133	264
Facility expenses	124	109	392	322
Other expenses	103	83	468	346
Total personnel and other expenses	1,978	1,690	7,385	4,620
Total Research and Development	**$ 4,967**	**$ 10,196**	**$ 18,273**	**$ 23,625**

General and Administrative

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

Restructuring Charge

On August 30, 2021, we approved a restructuring plan to reduce operating expenses and better align our workforce with the needs of our business following receipt of the CRL from the FDA regarding the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC (the “Restructuring Plan”). The Restructuring Plan includes a reduction in our workforce by 18 positions (or approximately 35% of our workforce) as well as additional cost-saving initiatives intended to preserve capital while we continue development of Vicineum. Restructuring costs related to the Restructuring Plan were recorded in operating expenses in our Condensed Consolidated Statements of Income (Operations) and Comprehensive Income (Loss) in the three months ended September 30, 2021. We expect that substantially all of the accrued restructuring costs as of September 30, 2021 will be paid in cash by the end of September 2022.

Intangibles Impairment Charge

Our intangible assets consist of indefinite-lived, acquired in-process research and development ("IPR&D") worldwide product rights to Vicineum as a result of the acquisition of Viventia in 2016. IPR&D assets acquired in a business combination are considered indefinite-lived until the completion or abandonment of the associated research and development efforts. We recognize an impairment loss when and to the extent that the estimated fair value of an intangible asset is less than its carrying value. In addition, on a quarterly basis, we perform a qualitative review of our business operations to determine whether events or changes in circumstances have occurred which could indicate that the carrying value of our intangible assets was not recoverable. If an impairment indicator is identified, an interim impairment assessment is performed. The fair value of the acquired intangible asset for the U.S. and E.U. rights of Vicineum is determined using a risk-adjusted discounted cash flow approach, which includes probability adjustments for projected revenues and operating expenses based on the success rates assigned to each stage of development for each geographical region; as well as discount rates applied to the projected cash flows. . In August 2021, we received a CRL from the FDA regarding its BLA for Vicineum for the treatment of NMIBC, our lead product candidate. In the CRL, the FDA determined that it could not approve the BLA for Vicineum in its present form and provided recommendations specific to additional clinical/statistical data and analyses in addition to CMC issues pertaining to a recent pre-approval inspection and product quality. We participated in a Type A Meeting with the FDA on October 29, 2021 to discuss questions related to CMC raised in the CRL, and expect to engage in a Type A meeting with the FDA in the fourth quarter of 2021 to discuss the clinical issues raised in the CRL. Both meetings are intended to help us determine the appropriate path forward for Vicineum. Given the inherent uncertainty at this time in the development plans for Vicineum as a result of the CRL, an impairment analysis was conducted, which concluded that the carrying value of our intangible assets of Vicineum United States rights was fully impaired as of September 30, 2021. The $31.7 million of impairment charges for the period ended September 30, 2021 are due to delays in the expected start of commercialization and lower probabilities of success, combined with higher operating expenses expected to be incurred prior to commercialization, resulting in lower

expected future cash flows estimated in the US market as of September 30, 2021. However, while similar delays in timelines and reduced probabilities of success also affected the estimated fair value of our intangible assets of Vicineum E.U. rights, this asset was not impaired as of September 30, 2021. At this time, management has assessed that the carrying value of the Vicineum EU rights is not at significant risk of impairment in the future within the current range of commercialization timelines and POS assumptions. This is primarily due to the fact that the EU asset is burdened with significantly less expense than the US asset, as our strategic operating plan is to sublicense Vicineum to business development partners in all regions outside the US, including the EU, with the Company earning a potential combination of upfront, milestone, and royalty payments, and the business development partner bearing the majority of regulatory and commercialization costs.

Change in Fair Value of Contingent Consideration

In connection with the acquisition of Viventia Bio, Inc. ("Viventia") in September 2016, we recorded contingent consideration pertaining to the amounts potentially payable to the former shareholders of Viventia pursuant to the terms of the Share Purchase Agreement among us, Viventia and the other signatories thereto (the "Share Purchase Agreement") and are based on launch timing in certain markets, probabilities of clinical and regulatory success, which are used to estimate future revenue levels. The fair value of contingent consideration is assessed at each balance sheet date and changes, if any, to the fair value are recognized in earnings (or loss) for the period.

Other Income (Expense), Net

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

Benefit (Provision) from 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 foreign 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, 2021 and 2020

	Three Months ended September 30,		Increase/(Decrease)	
	2021	2020	Dollars	Percentage
	(in thousands, except percentages)			
License and related revenue	$ —	$ 11,236	$ (11,236)	(100)%
Operating expenses:				
Research and development	$ 4,967	$ 10,196	$ (5,229)	(51)%
General and administrative	8,699	4,115	4,584	111 %
Restructuring charge	5,522	—	5,522	— %
Intangibles impairment charge	31,700	—	31,700	— %
Change in fair value of contingent consideration	(114,000)	18,400	(132,400)	(720)%
Total operating expenses	(63,112)	32,711	(95,823)	(293)%
Income (Loss) from Operations	63,112	(21,475)	84,587	(394)%
Other income (expense), net:				
Other income (expense), net	1	(1)	2	(200)%
Income (Loss) Before Taxes	**$ 63,113**	**$ (21,476)**	$ 84,589	(394)%
Benefit (provision) from income taxes	$ 8,561	$ (1,132)	$ 9,693	(856)%
Net Income (Loss) and Comprehensive Income (Loss) After Taxes	**$ 71,674**	**$ (22,608)**	$ 94,282	(417)%

License and Related Revenue

We had no revenue for the three months ended September 30, 2021. Revenue for the three months ended September 30, 2020 was $11.2 million, which was due to the recognition of revenue pursuant to the license agreement with our OUS business development partner for Greater China.

Research and Development

Research and development expenses were $5.0 million for the three months ended September 30, 2021 compared to $10.2 million for the three months ended September 30, 2020. The decrease of $5.2 million was due primarily to lower costs associated with technology transfer and manufacturing ($6.3 million), partially offset by increased license fees related to a milestone payment to the University of Zurich triggered by the receipt of the CRL ($0.5 million), regulatory fees triggered by withdrawal of our MAA to the EMA for Vysyneum ($0.3 million) and regulatory consultant fees ($0.2 million). We anticipate that R&D expenses may increase beginning in 2022 due to additional clinical trial activity costs.

General and Administrative

General and administrative expenses were $8.7 million for the three months ended September 30, 2021 compared to $4.1 million for the three months ended September 30, 2020. The increase of $4.6 million was due primarily to increases in sales and marketing expense for Vicineum pre-commercial launch planning ($2.4 million), employee-related compensation driven by increased headcount as part of the commercial build ($1.3 million) and professional fees for accounting services ($0.2 million). The majority of these expenses were incurred prior to receipt of the CRL in August 2021. Additionally, legal fees increased due to legal proceedings and the on-going independent review related to Vicineum ($0.9 million). Such increase was partially offset by certain other decreases in G&A expenses, none of which were individually material ($0.2 million)

Restructuring Charge

Restructuring expenses were $5.5 million for the three months ended September 30, 2021 compared to no restructuring expenses for the three months ended September 30, 2020. The increase of $5.5 million was due to one-time costs associated with the Restructuring Plan of approximately $2.7 million associated with the termination of certain contracts and severance and other employee-related costs of approximately $2.8 million.

Intangibles Impairment Charge

Intangibles impairment charge for three months ended September 30, 2021 was $31.7 million compared to no impairment in the three month ended September 30, 2020. In August 2021, we received a CRL from the FDA regarding our BLA for Vicineum for the treatment of NMIBC, our lead product candidate. In the CRL, the FDA determined that it could not approve the BLA for

Vicineum in its present form and has provided recommendations specific to additional clinical/statistical data and analyses in addition to CMC issues pertaining to a recent pre-approval inspection and product quality. We participated in a Type A meeting with the FDA on October 29, 2021 to discuss questions related to CMC raised in the CRL, and expect to engage in a Type A meeting to discuss clinical issues raised in the CRL later this year. Both meetings are intended to help us determine the appropriate path forward for Vicineum. Given the inherent uncertainty at this time in the development plans for Vicineum as a result of the CRL, an impairment analysis was conducted, which concluded that the carrying value of our intangible assets of Vicineum United States rights was fully impaired as of September 30, 2021. The $31.7 million of impairment charges for the period ended September 30, 2021 are due to delays in the expected start of commercialization and lower probabilities of success, combined with higher operating expenses expected to be incurred prior to commercialization, resulting in lower expected future cash flows estimated in the US market at this time.

Fair Value of Contingent Consideration

The non-cash change in fair value of contingent consideration was income of $114.0 million for the three months ended September 30, 2021 compared to an $18.4 million loss for the three months ended September 30, 2020. The decrease in the fair value of contingent consideration of $114.0 million for the three months ended September 30, 2021 was 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 this 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 probabilities of clinical and regulatory success (POS); we expect delays in the start of commercialization and estimate lower POS as a direct result of the CRL. We anticipate needing to conduct an additional clinical trial, which will lead to delays in the start of commercialization globally. We have assessed a range of commercialization timeline assumptions and applied a probability to each outcome based on management’s best estimate. In addition, we now assumes a lower POS in achieving certain clinical and regulatory milestones in the range of approximately 45% to 55% globally. We participated in a Type A Meeting with the FDA on October 29, 2021 to discuss questions related to CMC raised in the CRL, and expect to engage in a Type A meeting with the FDA in the fourth quarter of 2021 to discuss the clinical issues raised in the CRL. Both meetings are intended to help us determine the appropriate path forward for Vicineum. Any changes in these assumptions and estimates as a result of these meetings, or other information obtained, may have a significant impact on the remeasurement of the contingent consideration liability in the future. 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 decreased from 14.5% as of June 30, 2020, to 11.8% as of September 30, 2020 and from 6.6% as of June 30, 2021 to 7.5% as of September 30, 2021. The discount rate applied to the 2% earnout payment due on forecasted Vicineum revenues is derived from our estimated weighted-average cost of capital ("WACC"), and this WACC-derived discount rate decreased from 13.2% as of June 30, 2020 to 9.4% as of September 30, 2020 and increased from 6.8% as of June 30, 2021 to 8.Hi Nora6% as of September 30, 2021.

The change in the fair value of contingent consideration was an $18.4 million loss for the three months ended September 30, 2020. This was primarily attributable to lower discount rates, based on prevailing market conditions as of September 30, 2020, and to a lesser extent by refinement of timelines in certain OUS markets.

Other (Expense) Income, Net

Other expense, net was de minimis during the three months ended September 30, 2020 and September 30, 2021.

Benefit (Provision) from Income Taxes

For the three months ended September 30, 2021, we recorded a benefit from income taxes of $8.6 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 wrote-down the associated deferred tax liability by $8.6 million as a benefit. Please refer to Note 6, "Intangible Assets and Goodwill," for further information regarding the impairment charge. For the three months ended September 30, 2020, we recorded a provision for income taxes of $1.1 million. This provision consisted of income taxes paid to foreign jurisdictions pursuant to the License Agreement with Qilu.

Comparison of the Nine Months ended September 30, 2021 and 2020

	Nine Months ended September 30,		Increase/(Decrease)	
	2021	2020	Dollars	Percentage
	(in thousands, except percentages)			
License and related revenue	$ 6,544	$ 11,236	$ (4,692)	(42)%
Operating expenses:				
Research and development	$ 18,273	$ 23,625	$ (5,352)	(23)%
General and administrative	20,797	10,882	9,915	91 %
Restructuring charge	5,522	—	5,522	— %
Intangibles impairment charge	31,700	—	31,700	— %
Change in fair value of contingent consideration	(52,240)	(16,820)	(35,420)	211 %
Total operating expenses	24,052	17,687	6,365	36 %
Loss from Operations	(17,508)	(6,451)	(11,057)	171 %
Other (expense) income, net:				
Other income (expense), net	(45)	195	(240)	(123)%
Loss Before Taxes	**$ (17,553)**	**$ (6,256)**	$ (11,297)	181 %
Benefit (provision) from income taxes	$ 8,273	$ (1,132)	$ 9,405	(831)%
Net Loss and Comprehensive Loss After Taxes	**$ (9,280)**	**$ (7,388)**	$ (1,892)	26 %

License and Related Revenue

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 our OUS partner for Greater China, and license revenue for additional purchase price due to the recovery of VAT by our OUS business development partner for Greater China. Revenue for the nine months ended September 30, 2020 was $11.2 million, which was due to the recognition of revenue pursuant to the license agreement with our OUS business development partner for Greater China.

Research and Development

Research and development expense was $18.3 million for the nine months ended September 30, 2021 compared to $23.6 million for the nine months ended September 30, 2020. The decrease of $5.3 million was primarily due to lower costs associated with technology transfer and manufacturing costs ($9.7 million). This was partially offset by increases in regulatory consulting fees ($1.8 million), employee-related compensation driven by the anticipated commercial launch ($0.9 million), license fees related to a milestone payment to Amgen triggered by filing of the MAA ($0.6 million), and a milestone payment to the University of Zurich triggered by the receipt of the CRL ($0.5 million), and withdrawal of our MAA to the EMA for Vysyneum ($0.3 million). We anticipate that R&D expenses may increase beginning in 2022 due to additional clinical trial activity costs.

General and Administrative

General and administrative expenses were $20.8 million for the nine months ended September 30, 2021 compared to $10.9 million for the nine months ended September 30, 2020. The increase of $9.9 million was primarily due to increases in

marketing and commercial expenses of $4.0 million in preparation for the commercial launch, prior to the issuance of the CRL in August 2021. Additionally, increases in employee compensation and benefits ($3.4 million), legal expense ($1.6 million), professional fee ($0.3 million), insurance expense ($0.3 million) and other expenses ($0.3 million) contributed to the increase.

Restructuring Charge

Restructuring expenses were $5.5 million for the nine months ended September 30, 2021 compared to no restructuring expenses for the nine months ended September 30, 2020. The increase of $5.5 million was due to one-time costs associated with the Restructuring Plan of approximately $2.7 million associated with the termination of certain contracts and severance and other employee-related costs of approximately $2.8 million.

Intangibles Impairment Charge

Intangibles impairment charge was $31.7 million for the nine months ended September 30, 2021 compared to no impairment for the nine months ended September 30, 2020. In August 2021, we received a CRL from the FDA regarding our BLA for Vicineum for the treatment of NMIBC, our lead product candidate, in which the FDA determined that it could not approve the BLA for Vicineum in its present form. The $31.7 million of impairment charges for the period ended September 30, 2021 are due to expected delays in the start of commercialization and lower probabilities of success, combined with higher operating expenses expected to be incurred prior to commercialization, resulting in lower expected future cash flows estimated in the US market at this time.

Fair Value of Contingent Consideration

The non-cash change in fair value of contingent consideration was income of $52.2 million for the nine months ended September 30, 2021, compared to income of $16.8 million for the nine months ended September 30, 2020. The decrease in the fair value of contingent consideration of $52.2 million for the nine months ended September 30, 2021 was driven by the receipt of a CRL from the FDA, 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 this 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 probabilities of clinical and regulatory success (POS); we expect delays in the start of commercialization and estimates lower POS as a direct result of the CRL. We anticipate needing to conduct an additional clinical trial, which will lead to delays in the start of commercialization globally. We have assessed a range of commercialization timeline assumptions and applied a probability to each outcome based on management's best estimate. In addition, we now assumes a lower POS in achieving certain clinical and regulatory milestones in the range of approximately 45% to 55% globally. We participated in a Type A Meeting with the FDA on October 29, 2021 to discuss questions related to CMC raised in the CRL, and expect to engage in a Type A meeting with the FDA in the fourth quarter of 2021 to discuss the clinical issues raised in the CRL. Both meetings are intended to help us determine the appropriate path forward for Vicineum. Any changes in these assumptions and estimates as a result of these meetings, or other information obtained, may have a significant impact on the remeasurement of the contingent consideration liability in the future. 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 remained 11.8% as of December 31, 2019 and September 30, 2020 and decreased from 8.4% as of December 31, 2020 to 7.5% as of September 30, 2021. The discount rate applied to the 2% earnout payment due on forecasted Vicineum revenues is derived from our estimated WACC, and this WACC-derived discount rate fluctuated from 5.6% as of December 31, 2019 to 9.4% as of September 30, 2020 and from 8.8% as of December 31, 2020 to 8.6% as of September 30, 2021.

The change in fair value of contingent consideration was income of $16.8 million for the nine months ended September 30, 2020. This was primarily attributable to significantly higher discount rates as a result of financial market conditions as of
September 30, 2020, offset by changes to the competitive landscape.

Other (Expense) Income, Net

Other expense, net was de minimis for the nine months ended September 30, 2021, compared to $0.2 million for the nine months ended September 30, 2020. The decrease of $0.2 million was due primarily to lower interest income.

Benefit (Provision) from Income Taxes

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 wrote-down the associated deferred tax liability by $8.6 million as a benefit. Please refer to Note 6, "Intangible Assets and Goodwill," for further information regarding the impairment charge. For the nine months ended September 30, 2020, we recorded a provision for income taxes of $1.1 million. This provision consisted of income taxes paid to foreign jurisdictions pursuant to the License Agreement with Qilu.

Liquidity and Capital Resources

Overview

As of September 30, 2021, we had cash and cash equivalents of $175.2 million, net working capital of $187.9 million and an accumulated deficit of $325.2 million. We incurred negative cash flows from operating activities of $30.8 million for the year ended December 31, 2020 and $56.3 million for the nine months ended September 30, 2021. We believe that our cash and cash equivalents of $175.2 million as of September 30, 2021, are sufficient to fund our operating plan through 2023. Since our inception, we have received no revenue from sales of our products, and we anticipate that operating losses will continue for the foreseeable future as we seek to address the issues raised in the CRL we received for our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC and the concerns identified in the EMA Withdrawal Assessment Report, complete the follow-up stage of our ongoing Phase 3 VISTA Trial of Vicineum for the treatment of BCG-unresponsive NMIBC, complete any additional clinical trials for Vicineum, and seek marketing approval from the FDA and the European Commission and, if approved, commercialize Vicineum. We have financed our operations to date primarily through private placements of our common stock, preferred stock, common stock warrants and convertible bridge notes, venture debt borrowings, our IPO, follow-on public offerings, sales effected in ATM offerings, our OUS business development partnerships and license agreements and, to a lesser extent, from a collaboration. In November 2019, we entered into an Open Market Sale Agreement ^{SM} (the "Sale Agreement") with Jefferies LLC ("Jefferies"), under which we may issue and sell shares of our common stock, par value $0.001 per share from time to time for an aggregate sales price of up to $35 million through Jefferies (the "ATM Offering"). In October 2020 and February 2021, we entered into Amendments No. 1 and No. 2 to the Sale Agreement, respectively. Amendments No. 1 and No.2 modified the Sale Agreement to reflect that we may issue and sell shares of our common stock from time to time for an aggregate sales price of up to an additional $50.0 million and $34.5 million, respectively. In June 2021, we entered into Amendment No. 3 to the Sale Agreement, which modified the Sale Agreement to remove the maximum dollar amount of shares of common stock that may be sold pursuant to the Sale Agreement. In June and July 2021, we filed prospectus supplements with the SEC in connection with the offer and sale of up to an aggregate of $200 million of our common stock pursuant to the Sale Agreement. Sale of common stock under the Sale Agreement are made by any method that is deemed to be an ATM offering as defined in Rule 415(a)(4) of the Securities Act of 1933, including but not limited to sales made directly on or through the Nasdaq Global Market or any other existing trading market for our common stock. We may sell shares of our common stock efficiently from time to time, but have no obligation to sell any of our common stock and may at any time suspend offers under the Sale Agreement or terminate the Sale Agreement. Subject to the terms and conditions of the Sale Agreement, Jefferies will use its commercially reasonable efforts to sell common stock from time to time, as the sales agent, based upon our instructions, which include a prohibition on sales below a minimum price set by us from time to time. We have provided Jefferies with customary indemnification rights, and Jefferies is entitled to a commission at a fixed rate equal to 3.0% of the gross proceeds for each sale of common stock under the Sale Agreement. We raised $175.0 million of net proceeds from the sale of 56.9 million shares of common stock at a weighted-average price of $3.17 per share during the nine months ended September 30, 2021, 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. We raised $16.2 million of net proceeds from the sale of 16.8 million shares of common stock at a weighted-average price of $0.99 per share during the nine months ended September 30, 2020, including $8.2 million of net proceeds from the sale of 7 million shares of common stock at a weighted-average price of $1.21 per share during the three months ended September 30, 2020. 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 compared to $0.3 million and $0.5 million for the three and nine months ended September 30, 2020, respectively.

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

Funding Requirements

Our future success is dependent on our ability to develop, and if approved, commercialize our product candidates, including Vicineum for the treatment of BCG-unresponsive NMIBC, and ultimately upon our ability to attain profitable operations. In order to commercialize our product candidates, including Vicineum for the treatment of BCG-unresponsive NMIBC, we need to complete clinical development and comply with comprehensive regulatory requirements. We are subject to a number of risks similar to other late-stage clinical companies, including, but not limited to, successful discovery and development of our product candidates, raising additional capital, development and commercialization by our competitors of new technological innovations, protection of proprietary technology and market acceptance of our products. The successful discovery, development and, if approved, commercialization of product candidates, including Vicineum for the treatment of BCG-unresponsive NMIBC, requires substantial working capital, and we expect to seek additional funds through equity or debt financings or through additional OUS business development partnerships, collaborations, licensing transactions or other sources. We may be unable to obtain equity or debt financings or enter into additional OUS business development partnerships, collaborations or licensing transactions at favorable terms, or at all, and, if necessary, we may be required to implement cost reduction strategies.

We will incur substantial expenses if and as we:

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

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

- the scope, initiation, progress, timing, costs and results of pre-clinical development and laboratory testing and clinical trials for Vicineum for the treatment of BCG-unresponsive NMIBC and our other product candidates;
- the ongoing COVID-19 pandemic and its impact on our business;
- our ability to establish additional OUS business development partnerships, collaborations or licensing arrangements on favorable terms, if at all, particularly manufacturing, marketing and distribution arrangements for our product candidates;
- the costs and timing of the implementation of commercial-scale manufacturing activities, including those associated with the manufacturing process and technology transfer to third-party manufacturers to facilitate such commercial-scale manufacturing of Vicineum;
- the costs and timing of establishing and implementing sales, marketing and distribution capabilities for Vicineum for the treatment of BCG-unresponsive NMIBC, if approved;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- our obligation to make milestone, royalty and other payments to third-party licensors under our licensing agreements;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- the outcome, timing and cost of regulatory review by the FDA, EMA and comparable foreign regulatory authorities for Vicineum for the treatment of BCG-unresponsive NMIBC, including the potential for the FDA, EMA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect to perform;
- our ability to achieve certain future regulatory, development and commercialization milestones under our out-license and OUS business development partnership agreements
- the effect of competing technological and market developments; and
- the revenue, if any, received from commercial sales of Vicineum for the treatment of BCG-unresponsive NMIBC, if approved.

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

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

Cash Flows

The following table sets forth a summary of our cash flows for the nine months ended September 30, 2021 and 2020 (in thousands):

	Nine Months ended September 30,	
	2021	2020
Net Cash Used in Operating Activities	$ (56,278)	$ (22,328)
Net Cash Used in Investing Activities	(4)	(8)
Net Cash Provided by Financing Activities	176,129	16,184
Net Increase (Decrease) in Cash, Cash Equivalents and Restricted Cash	**$ 119,847**	**$ (6,152)**

Net Cash Used in Operating Activities

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 our license agreements, adjusted for non-cash items, including share-based compensation of $3.4 million, a decrease in the fair value of contingent consideration of $52.2 million, increase in impairment charge of $31.7 million and a net decrease in operating assets and liabilities of $29.9 million.

Net cash used in operating activities was $22.3 million for the nine months ended September 30, 2020 and consisted primarily of net loss of $7.4 million, which includes $11.2 million of revenue recognized pursuant to the License Agreement with Qilu, adjusted for non-cash items, including share-based compensation of $1.4 million, a decrease in the fair value of contingent consideration of $16.8 million and a net increase in operating assets and liabilities of $0.4 million.

Net Cash Used in Investing Activities

Net cash used in investing activities was de minimis during the nine months ended September 30, 2020 and September 30, 2021.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $176.1 million and $16.2 million for the nine months ended September 30, 2021 and September 30, 2020, respectively, and consisted, primarily, of net proceeds from the sale of common stock under the ATM Offering and, with respect to the nine months ended September 30, 2020, sales of common stock under our 2014 ESPP.

Critical Accounting Policies and Use of Estimates

The preparation of our consolidated financial statements in accordance with United States generally accepted accounting principles and the rules and regulations of the SEC require the use of estimates and assumptions, based on complex judgments considered reasonable, and affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. Our critical accounting policies are those policies which require the most significant judgments and estimates in the preparation of our consolidated financial statements. Management has determined that our most critical accounting policies are those relating to the fair value of intangible assets, goodwill and contingent consideration; income taxes (including the valuation allowance for deferred tax assets); research and development costs; revenue recognition and going concern considerations.

Indefinite-Lived Intangible Assets

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

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

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

In August 2021, we received a CRL from the FDA regarding its BLA for Vicineum for the treatment of NMIBC, our lead product candidate. In the CRL, the FDA determined that it could not approve the BLA for Vicineum in its present form and provided recommendations specific to additional clinical/statistical data and analyses in addition to CMC issues pertaining to a recent pre-approval inspection and product quality. We participated in a Type A Meeting with the FDA on October 29, 2021 to discuss questions related to CMC raised in the CRL, and expect to engage in a Type A meeting with the FDA in the fourth quarter of 2021 to discuss the clinical issues raised in the CRL. Both meetings are intended to help us determine the appropriate path forward for Vicineum. Given the inherent uncertainty at this time in the development plans for Vicineum as a result of the CRL, an impairment analysis was conducted, which concluded that the carrying value of our intangible assets of Vicineum United States rights was fully impaired as of September 30, 2021. The $31.7 million of impairment charges for the period ended September 30, 2021 are due to delays in the expected start of commercialization and lower probabilities of success, combined with higher operating expenses expected to be incurred prior to commercialization, resulting in lower expected future cash flows estimated in the US market as of September 30, 2021. However, while similar delays in timelines and reduced probabilities of success also affected the estimated fair value of our intangible assets of Vicineum E.U. rights, this asset was not impaired as of September 30, 2021. At this time, management has assessed that the carrying value of the Vicineum EU rights is not at significant risk of impairment in the future within the current range of commercialization timelines and POS assumptions. This is primarily due to the fact that the EU asset is burdened with significantly less expense than the US asset, as our strategic operating plan is to sublicense Vicineum to business development partners in all regions outside the US, including the EU, with our earning a potential combination of upfront, milestone, and royalty payments, and the business development partner bearing the majority of regulatory and commercialization costs.

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. Given the inherent uncertainty at this time in the development plans for Vicineum as a result of the CRL, an impairment analysis was conducted. While an impairment was recognized in one of our intangible assets, Vicineum U.S. Rights, we concluded that the carrying value of our goodwill of $13.1 million was not impaired as of September 30, 2021. We believe we have sufficient future cash flows from additional geographic regions outside the US to support the value of its goodwill. We project future cash flows based on various timeline assumptions and applies a probability to each outcome based on management’s best estimate. In addition, probabilities of success in achieving certain clinical and regulatory success can also have a material effect on the estimated fair value of the equity of its reporting unit as of the impairment assessment date. We will continue to evaluate our timelines for commercialization and probability of success of development of Vicineum for the treatment of NMIBC. We have requested two separate Type A meetings with the FDA. The CMC Type A Meeting was held on October 29, 2021. The clinical Type A Meeting is expected to occur later this year. As a result of the CMC Type A Meeting, we do not believe any changes to the key assumptions are required and therefore management determined there is no impact to the evaluation of goodwill impairment. We also expect to assess the outcome of the Clinical Type A Meeting to determine if further impairment testing is required. Further reductions to estimated probabilities of success, additional development delays or increases in underlying discount rates have the potential to result in future goodwill impairment.

Contingent Consideration

Contingent consideration on our condensed consolidated balance sheet is the result of our acquisition of Viventia in September 2016 and represents the discounted present value of future launch milestones and net sales royalties due to the former shareholders of Viventia pursuant to the Share Purchase Agreement. For additional information, see "Item 1. Financial Statements - Notes to Condensed Consolidated Financial Statements - Note 1. Description of Business" of this Quarterly Report on Form 10-Q. 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.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and net operating loss and research and development credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. A valuation allowance is recorded to the extent it is more likely than not that some portion or all of the deferred tax assets will not be realized. As of September 30, 2021, we reduced our deferred tax liabilities by $8.6 million as a result of intangibles impairment charge, driven by the CRL.

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 consolidated statements of operations. As of September 30, 2021 and December 31, 2020, we did not have any uncertain tax positions.

Revenue

We record revenue from our out-license agreements and OUS business development partnership agreements, including the License Agreement with Roche and our OUS partnerships. Under each of these agreements, we granted the counterparty an exclusive license to develop and commercialize the underlying licensed product. These agreements contain up-front license fees, development and regulatory milestone payments, sales-based milestone payments, and sales-based royalty payments.

We determine whether our out-license agreements and OUS business development partnership agreements are in scope of ASC 606, which we adopted as of January 1, 2018. Under ASC 606, in determining the appropriate amount of revenue to be recognized as we fulfill our obligations under these agreements, we perform the following steps:

1) Identification of the contract;
2) Determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;
3) Measurement of the transaction price, including the constraint on variable consideration;
4) Allocation of the transaction price to the performance obligations;
5) Recognition of revenue when or as the Company satisfies each performance obligation.

Development and Regulatory Milestones and Other Payments

At the inception of an arrangement that includes development milestone payments, we evaluate whether the development milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated development milestone value is included in the transaction price. Development milestone payments that are not within our control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. For payments pursuant to sales milestones and royalty payments, we will note recognize revenue until the subsequent sale of a licensed product occurs. For arrangements with one than one performance obligations, the milestones are generally allocated entirely to the license performance obligation, as (1) the terms of milestone and royalty payments relate specifically to the license and (2) allocating milestones and royalties to the license performance obligation is consistent with the overall allocation objective, because management’s estimate of milestones and royalties approximates the standalone selling price of the license.

Research and Development Costs

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

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

Recently Issued Accounting Standards

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

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

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 principle financial officer, to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as the end of the period covered by this Quarterly Report on Form 10-Q. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2021.

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, 2021, 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 the Company and certain of its officers in the U.S. District Court for the Southern District of New York. The three complaints allege violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder, based on statements made by the Company concerning its BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. The three complaints seek compensatory damages and costs and expenses, including attorneys' fees. On October 29, 2021, the court consolidated the three cases under the caption In re Sesen Bio, Inc. Securities Litigation, Master File No. 1:21-cv-07025-AKH, and appointed Ryan Bibb, Rodney Samaan, Lionel Dreshaj and Benjamin Dresaj collectively as the "lead plaintiff" under the Private Securities Litigation Reform Act. On November 1, 2021, two stockholders filed motions to reconsider asking the court to appoint a different lead plaintiff. The court has not ruled on those motions at this time.

On 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 U.S. District Court for the District of Massachusetts, with the Company named as nominal defendant. The two 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 two 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 cases under the caption In re Sesen Bio, Inc. Derivative Litigation, Lead Case No. 1:21-cv-11538.

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

Item 1A. Risk Factors.

During the nine months ended September 30, 2021, 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, 2020. You should carefully consider the information described therein and in this Quarterly Report on Form 10-Q, which could materially affect our business condition, results of operations and cash flows.

Risks Related to Clinical Development and Regulatory Approval of Vicineum

We are dependent on our lead product candidate, Vicineum for the treatment of BCG-unresponsive NMIBC. If we are unable to obtain marketing approval for or successfully commercialize our lead product candidate, either alone or through an out-license or a commercialization partnership, or experience significant delays in doing so, our business could be materially harmed.

We currently have no products approved for sale and have invested a significant portion of our efforts and financial resources in the development of Vicineum for the treatment of BCG-unresponsive NMIBC. On August 13, 2021, we received a complete response letter ("CRL") from the FDA indicating that the FDA determined that it could not approve the BLA for Vicineum in its present form, and provided recommendations specific to additional clinical/statistical data and analyses in addition to CMC issues pertaining to a recent pre-approval inspection and product quality. On October 29, 2021, the Company participated in a Type A meeting with the FDA to discuss questions related to CMC raised in the CRL (the "CMC Type A Meeting"). During the CMC Type A Meeting, the Company and the FDA reviewed issues related to CMC to be further discussed during the review of the BLA for Vicineum upon potential resubmission. The Company believes it has a clear understanding of what additional information regarding CMC is required for resubmission of the BLA. The Company is preparing for a separate Type A Meeting to discuss the recommendations specific to additional clinical/statistical data and analyses that the FDA raised in the CRL, which the Company expects to occur later this year.

On October 20, 2021, the EMA issued its Withdrawal Assessment Report relating to our MAA for Vysyneum, as is consistent with the EMA's standard practice when an MAA is withdrawn. The Assessment Report reflects the initial assessment and corresponding questions from the EMA and identifies major objections in the areas of Quality, Good Clinical Practice, Efficacy and Safety. We may be unable to address the issues identified in the CRL from the FDA or resubmit our BLA for Vicineum, or address the concerns identified in the EMA Withdrawal Assessment Report or resubmit our MAA for Vysyneum, including because of a lack of capital or otherwise.

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

Our prospects are substantially dependent on our ability and the ability of our out-licensing and commercialization partners to obtain marketing approval for and successfully commercialize Vicineum for the treatment of BCG-unresponsive NMIBC. In addition, either the substance of the issues identified by the FDA in the CRL, or the CRL itself, or the concerns identified in the EMA Withdrawal Assessment Report could have an adverse impact on future efforts to obtain marketing authorization for Vicineum from other foreign regulatory authorities, or on our future efforts to commercialize Vicineum and gain acceptance of Vicineum from third party payors. The success of Vicineum will depend on several factors, including the following:

- addressing the issues identified in the CRL we received from the FDA and the concerns identified in the EMA Withdrawal Assessment Report, including conducting any additional clinical trials and the outcome of any such clinical trials;
- receipt of marketing approvals from the FDA, the European Commission or comparable foreign regulatory authorities, including our ability to address the issues identified by the FDA in the CRL or the EMA Withdrawal Assessment Report;
- developing and maintaining the commercial manufacturing supply and distribution chain for Vicineum;
- performance of current and our future out-licensing or commercialization partners, if any;
- extent of any required post-marketing approval commitments to applicable regulatory authorities;
- obtaining and maintaining patent, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protection of our rights in our intellectual property portfolio;
- launch of commercial sales, if and when marketing approval is received;
- demonstration of an acceptable safety profile prior to and following any marketing approval;
- marketplace acceptance, if and when approved, by patients, the medical community and third-party payors;
- establishing and maintaining pricing sufficient to realize a meaningful return on our investment; and
- competition with other therapies

If we or our commercialization partners are unable to develop, receive marketing approval for, or successfully commercialize Vicineum for the treatment of BCG-unresponsive NMIBC or experience delays as a result of any of these factors or otherwise, our business could be materially harmed.

If additional clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC are required and such trials fail to demonstrate safety and efficacy to the satisfaction of the FDA, the EMA or other foreign regulatory authorities or do not otherwise produce favorable results, we will be unable to complete, the development and potential commercialization of Vicineum for the treatment of BCG-unresponsive NMIBC.

Before obtaining marketing approval from regulatory authorities for the sale of Vicineum for the treatment of BCG-unresponsive NMIBC, we must complete pre-clinical development and conduct extensive clinical trials to demonstrate the safety and efficacy of Vicineum in humans. In order to address the issues identified in the CRL we received from the FDA for our BLA for Vicineum and the concerns identified in the EMA Withdrawal Assessment Report, we expect that we will need to complete one or more additional clinical trials. Such trials will require us to incur substantial additional costs and will delay the potential commercialization of Vicineum for the treatment of BCG-unresponsive NMIBC. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of pre-clinical studies and early clinical trials may not be predictive of the success of later clinical trials, and preliminary results of a clinical trial do not necessarily predict final results. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. If we are unable to demonstrate safety and efficacy of Vicineum for the treatment of BCG-unresponsive NMIBC to the satisfaction of the FDA, the EMA or other foreign regulatory authorities, we will not be able to obtain the required regulatory approvals which would prevent us from commercializing Vicineum and our ability to generate revenues in the future would be materially impaired.

Clinical trial results may fail to support approval of our product candidates.

In order to address the issues identified in the CRL we received from the FDA for our BLA for Vicineum and the concerns identified in the EMA Withdrawal Assessment Report for our MAA for Vysyneum, we expect that we will need to complete one or more additional clinical trials. Even if such clinical trials are successfully completed as planned, the results may not support approval of Vicineum for the treatment of BCG-unresponsive NMIBC under the laws and regulations of the FDA, the European Commission or comparable foreign regulatory authorities. We cannot be certain that additional clinical data will demonstrate Vicineum is both safe and effective for its intended uses to satisfaction of the FDA, the EMA or comparable foreign regulatory authorities. Pre-clinical and clinical data and analyses are often able to be interpreted in different ways. Even if we view our results favorably, if a regulatory authority has a different view, we may still fail to obtain regulatory approval of Vicineum. This, in turn, would significantly adversely affect our business prospects.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad, and any approval we are granted for our product candidates in the United States would not assure approval of product candidates in foreign jurisdictions.

In order to market and sell any product candidate that we may develop outside of the United States, we or our third-party licensees or commercialization partners must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States it is required that the product be approved for reimbursement before the product can be sold in that country. We or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. For example, on March 5, 2021, we submitted our MAA to the EMA for Vicineum for the treatment of BCG-unresponsive NMIBC under the EMA's centralized procedure. On August 20, 2021, we withdrew our MAA to the EMA for Vysyneum for the treatment of BCG-unresponsive NMIBC. Given in order to pause our plans to pursue regulatory approval of Vysyneum in the European Union until there is more clarity from the FDA on the next steps for Vicineum in the United States. Additionally, on October 20, 2021, the EMA issued its Withdrawal Assessment Report relating to our MAA for Vysyneum, as is consistent with the EMA's standard practice when an MAA is withdrawn. The Assessment Report reflects the initial assessment and corresponding questions from the EMA and identifies major objections in the areas of Quality, Good Clinical Practice, Efficacy and Safety. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of our product candidates by regulatory authorities in other jurisdictions, the commercial prospects of our product candidates may be significantly diminished, and our business prospects could decline.

Risks Related to our Business and Operations

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

On August 30, 2021, we approved a restructuring plan to reduce operating expenses and better align our workforce with the needs of our business following receipt of the CRL from the FDA regarding our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. The restructuring plan includes a reduction in our workforce by 18 positions (approximately 35%) as well as additional cost-saving initiatives intended to preserve capital while we continue development of Vicineum. Restructuring expenses in the third quarter of 2021 were approximately $5.5 million, consisting primarily of severance and other employee-related costs of $2.8 million and contract termination costs of $2.7 million.

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

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

On August 19, 2021, August 31, 2021 and October 7,2021, three substantially identical securities class action lawsuits captioned Bibb v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-07025, Cizek v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-07309 and Markman v. Sesen Bio, Inc. et al., Case No. 1:21-cv-08308 were filed against us and certain of our officers in the U.S. District

Court for the Southern District of New York. The three complaints allege violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder based on statements made by us concerning our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. The three complaints seek compensatory damages and costs and expenses, including attorneys' fees. On October 29, 2021, the court consolidated the three cases under the caption In re Sesen Bio, Inc. Securities Litigation, Master File No. 1:21-cv-07025-AKH, and appointed Ryan Bibb, Rodney Samaan, Lionel Dreshaj and Benjamin Dresaj collectively as the "lead plaintiff" under the Private Securities Litigation Reform Act. On November 1, 2021, two stockholders filed motions to reconsider asking the court to appoint a different lead plaintiff. The court has not ruled on those motions at this time.

On 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 U.S. District Court for the District of Massachusetts, with Sesen Bio, Inc. named as a nominal defendant. The two derivative complaints allege breach of fiduciary duties, waste of corporate assets, and violations of federal securities laws based on statements made by us concerning our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. The D'Arcy complaint further alleges unjust enrichment, abuse of control, gross mismanagement and aiding and abetting thereof. The two 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 cases under the caption In re Sesen Bio, Inc. Derivative Litigation, Lead Case No. 1:21-cv-11538.

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

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

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

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, 2021.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Index

Exhibit No.	Description
3.1	Restated Certificate of Incorporation of Eleven Biotherapeutics, Inc. Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed on February 18, 2014 (File No. 001-36296).
3.2	Certificate of Amendment of Certificate of Incorporation. Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed on May 17, 2018 (File No. 001-36296).
3.3	Certificate of Amendment of Certificate of Incorporation. Incorporated by reference to Exhibit 3.3 to our Quarterly Report on Form 10-Q filed on May 10, 2021 (File No. 001-36296).
3.4	Amended and Restated By-laws. Incorporated by reference to Exhibit 3.2 to our Current Report on Form 8-K filed on May 17, 2018 (File No. 001-36296).
4.1	Specimen Stock Certificate evidencing the shares of common stock. Incorporated by reference to Exhibit 4.1 to our Registration Statement on Form S-1/A filed on January 23, 2014 (Reg. No. 333-193131).
4.2	Form of Warrant issued to Silicon Valley Bank and Life Science Loans, LLC dated November 25, 2014. Incorporated by reference to Exhibit 10.23 to our Registration Statement on Form S-1 filed with the SEC on December 19, 2014 (Reg. No. 333-201176).
4.3	Form of Common Warrant. Incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed with the SEC 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 with the SEC 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 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 October 29, 2019 (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, 2021 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 File (embedded within the Inline XBRL document and included in Exhibit 101).

* Filed herewith.

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

SESEN BIO, INC.
(Registrant)

Date: November 8, 2021

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)

Exhibit 31.1

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

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

1. I have reviewed this Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2021 of Sesen Bio, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: November 8, 2021

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

Exhibit 31.2

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

I, Monica Forbes, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2021 of Sesen Bio, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: November 8, 2021

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

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Sesen Bio, Inc. (the "Company") for the fiscal quarter ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 8, 2021

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

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Sesen Bio, Inc. (the "Company") for the fiscal quarter ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 8, 2021

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