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 **June 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 196,002,620 shares of the registrant's common stock outstanding as of August 2, 2021.

SESEN BIO, INC.

Quarterly Report on Form 10-Q for the Quarterly Period ended June 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)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 151,036	$ 52,389
Accounts receivable	2,303	—
Prepaid expenses and other current assets	21,760	7,478
Restricted cash	—	3,000
Total current assets	175,099	62,867
Non-current assets:		
Restricted cash	20	20
Property and equipment, net	109	123
Intangible assets	46,400	46,400
Goodwill	13,064	13,064
Long term prepaid expenses	6,150	—
Other assets	205	349
Total non-current assets	65,948	$ 59,956
Total Assets	$ 241,047	$ 122,823
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 1,228	$ 3,102
Accrued expenses	5,301	3,973
Deferred revenue	1,500	1,500
Contingent consideration	10,300	8,985
Other current liabilities	498	489
Total current liabilities	18,827	18,049
Non-current liabilities:		
Contingent consideration, net of current portion	160,300	99,855
Deferred tax liability	12,528	12,528
Deferred revenue, net of current portion	—	1,500
Other non-current liabilities	43	118
Total non-current liabilities	172,871	114,001
Total liabilities	191,698	132,050
Stockholders' Equity (Deficit):		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized at June 30, 2021 and December 31, 2020; no shares issued and outstanding at June 30, 2021 and December 31, 2020	—	—
Common stock, $0.001 par value per share; 400,000,000 and 200,000,000 shares authorized at June 30, 2021 and December 31, 2020, respectively; 188,460,951 and 140,449,647 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	188	140
Additional paid-in capital	446,036	306,554
Accumulated deficit	(396,875)	(315,921)
Total Stockholders' Equity (Deficit)	49,349	(9,227)
Total Liabilities and Stockholders' Equity	$ 241,047	$ 122,823

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

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

	Three Months ended June 30,		Six Months ended June 30,	
	2021	2020	2021	2020
License and related revenue	$ 2,234	$ —	$ 6,544	$ —
Operating expenses:				
Research and development	7,228	4,562	13,306	13,429
General and administrative	6,805	3,318	12,098	6,766
Change in fair value of contingent consideration	13,600	18,480	61,760	(35,220)
Total operating expenses	27,633	26,360	87,164	(15,025)
(Loss) Income from Operations	(25,399)	(26,360)	(80,620)	15,025
Other (expense) income , net	(43)	16	(46)	195
Net (Loss) Income and Comprehensive (Loss) Income Before Taxes	(25,442)	(26,344)	(80,666)	15,220
Provision for income taxes	—	—	(288)	—
Net (Loss) Income and Comprehensive (Loss) Income After Taxes	$ (25,442)	$ (26,344)	$ (80,954)	$ 15,220
Net (loss) income attributable to common stockholders - basic	$ (25,442)	$ (26,491)	$ (80,954)	$ 14,751
Net (loss) income attributable to common stockholders - diluted	(25,442)	(26,491)	(80,954)	12,600
Net (loss) income per common share - basic	$ (0.15)	$ (0.24)	$ (0.49)	$ 0.13
Weighted-average common shares outstanding - basic	175,393	112,569	166,264	111,189
Net (loss) income per common share - diluted	$ (0.15)	$ (0.24)	$ (0.49)	$ 0.11
Weighted-average common shares outstanding - diluted	175,393	112,569	166,264	111,203

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Equity
	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)**

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)

	Six Months ended June 30,	
	2021	2020
Cash Flows from Operating Activities:		
Net (loss) income	$ (80,954)	$ 15,220
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation	64	61
Share-based compensation	2,217	898
Change in fair value of contingent consideration	61,760	(35,220)
Changes in operating assets and liabilities:		
Accounts receivable (net)	(2,303)	—
Prepaid expenses and other assets	(20,287)	2,719
Accounts payable	(1,875)	(628)
Accrued expenses and other liabilities	1,262	(1,376)
Deferred revenue	(1,500)	—
Net cash used in operating activities	(41,616)	(18,326)
Cash Flows from Investing Activities:		
Purchases of equipment	(49)	(8)
Net cash used in investing activities	(49)	(8)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock under ATM Offering, net of issuance costs	136,804	7,953
Proceeds from exercises of stock options	39	—
Proceeds from the exercise of common stock warrants	469	—
Proceeds from sale of common stock pursuant to ESPP	—	1
Net cash provided by financing activities	137,312	7,954
Net Increase (decrease) in cash, cash equivalents and restricted cash	95,647	(10,380)
Cash, cash equivalents and restricted cash - beginning of period	55,409	48,141
Cash, cash equivalents and restricted cash - end of period	$ 151,056	$ 37,761
Supplemental cash flow disclosure:		
Cash paid for amounts included in the measurement of lease liabilities	$ 87	$ 75
Supplemental disclosure of non-cash investing activities:		
Purchase of equipment included in accrued expenses	$ 27	$ —
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, 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 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 the target Prescription Drug User Fee Act ("PDUFA") date for a decision on the BLA is August 18, 2021. In addition to the file acceptance and granting of Priority Review, the FDA also indicated that it is not currently planning to hold an advisory committee meeting to discuss the BLA for Vicineum. 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 is no Advisory Committee meeting planned at this time, and that no post-marketing requirements, including a confirmatory trial, have been identified at this 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. In the US, the Company believes it remains on track for an FDA decision on its BLA for Vicineum by the target PDUFA date of August 18, 2021. 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 June 30, 2021, none of these individuals are employees or members of the Company's board of directors.

Liquidity and Going Concern

As of June 30, 2021, the Company had cash and cash equivalents of $151.0 million, net working capital of $156.3 million and an accumulated deficit of $396.9 million. The Company incurred negative cash flows from operating activities of $30.8 million for the year ended December 31, 2020 and $41.6 million for the six months ended June 30, 2021. Since its inception, the

Company has received no revenue from sales of its products, and management anticipates that operating losses will continue as the Company completes the follow-up stage of its ongoing Phase 3 VISTA Trial for Vicineum for the treatment of BCG-unresponsive NMIBC and seeks marketing approval from the FDA and the European Medicines Agency ("EMA"), and if approved, commercializes Vicineum. The Company has financed its operations to date primarily through private placements of its common stock, preferred stock, common stock warrants and convertible bridge notes, venture debt borrowings, its initial public offering ("IPO"), follow-on public offerings, sales effected in "at-the-market" ("ATM") offerings, out-licensing agreements and outside of United States ("OUS") business development partnership agreements, and, to a lesser extent, from a collaboration. See “Note 9. Stockholders’ Equity (Deficit)” below for information regarding the Company’s recently completed equity financings.

Under Accounting Standards Codification ("ASC") Topic 205-40, *Presentation of Financial Statements - Going Concern*, management is required at each reporting period to evaluate whether there are conditions and events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists, management evaluates whether the mitigating effect of its plans sufficiently alleviates the substantial doubt about the Company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (i) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued and (ii) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. Generally, to be considered probable of being effectively implemented, the plans must have been approved by the Company's board of directors before the date that the financial statements are issued.

The Company's future success is dependent on its ability to develop and commercialize Vicineum for the treatment of BCG-unresponsive NMIBC, and ultimately upon its ability to attain profitable operations. In order to commercialize its product candidates, including Vicineum for the treatment of BCG-unresponsive NMIBC, the Company needs to complete clinical development and comply with comprehensive regulatory requirements. The Company is subject to a number of risks similar to other late-stage clinical companies, including, but not limited to, successful discovery and development of its product candidates, raising additional capital, development and commercialization by its competitors of new technological innovations, protection of proprietary technology, market acceptance of its products and dependence on third parties for the development and commercialization of Vicineum in certain markets. The successful discovery and development of product candidates, including Vicineum for the treatment of BCG-unresponsive NMIBC, requires substantial working capital, and management expects to seek additional funds through equity or debt financings or through additional business development partnerships, collaborations or licensing transactions or other sources. The Company may be unable to obtain equity or debt financings or enter into additional business development partnerships, collaborations or licensing transactions on favorable terms, or at all. To the extent that the Company raises additional capital through the sale of equity or convertible debt securities, the ownership interests of existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include liens or other restrictive covenants limiting the Company's ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If the Company raises additional funds through government or other third-party funding, strategic collaborations, business development partnerships, alliances or licensing arrangements, it may have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable. If the Company is unable to raise additional funds when needed, it may be required to implement cost reduction strategies and delay, limit, reduce or terminate its product development, regulatory approval or future commercialization efforts or grant rights to develop and market products or product candidates that management would otherwise prefer to develop and market.

Management does not believe that the Company's cash and cash equivalents of $151.0 million as of June 30, 2021 are sufficient to fund the Company's current operating plan for at least twelve months after the issuance of these condensed consolidated financial statements. Given the history of significant losses, negative cash flows from operations, limited cash resources currently on hand, and dependence by the Company on its ability - about which there can be no certainty - to obtain additional financing to fund its operations after the current cash resources are exhausted, substantial doubt exists about the Company's ability to continue as a going concern. These condensed consolidated financial statements were prepared under the assumption that the Company will continue as a going concern and do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

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 six months ended June 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 June 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 June 30, 2021 and December 31, 2020 (in thousands):

	June 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)	$ 16,379	$ 16,379	$ 16,379	$ —	$ —
Liabilities:					
Contingent consideration - short term	$ 10,300	$ 10,300	$ —	$ —	$ 10,300
Contingent consideration - long term	$ 160,300	$ 160,300	$ —	$ —	$ 160,300

	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 six months ended June 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 regulatory milestones and commercial sales, the period in which these milestones and sales are expected to be achieved ranging from 2021 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 6.6% to 6.8% as of June 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 six months ended June 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 six months ended June 30, 2021 (in thousands):

Balance at December 31, 2020	$108,840
Change in fair value of contingent consideration - short term	1,315
Change in fair value of contingent consideration - long term	60,445
Balance at June 30, 2021	$ 170,600

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 6.8% as of June 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 6.6% as of June 30, 2021. Improvements to the competitive landscape, higher probability of regulatory success, expanded patient population, as well as the refinement of estimated launch timelines for Vicineum, if approved, in certain markets and the aforementioned changes in discounts rates, resulted in an overall $61.8 million increase in the estimated fair value of contingent consideration during the six months ended June 30, 2021. The current portion of total contingent consideration reflects amounts expected to be paid out within twelve months of June 30, 2021.

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 June 30, 2021 and December 31, 2020 (in thousands):

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

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 June 30, 2021 and December 31, 2020.

7. LEASES

The Company accounts for operating leases under ASC Topic 842, *Leases.* 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 per month (approximately $14,600 at exchange rates in effect on June 30, 2021). In addition to rent expense, the Company expects to incur CAD $18,200 per month related to operating expenses (approximately $14,700 at exchange rates in effect on June 30, 2021). Operating lease cost under this lease, including the related operating costs, were $84,000 and $166,000 for the three and six months ended June 30, 2021 and $72,000 and $148,000 for the three and six months ended June 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 November and December 2021, respectively. The minimum monthly rent for these office spaces is $20,100 per month, which is subject to change if and as the Company adds space to or deducts space from the leases. The Company recorded $69,000 and $138,000 in rent expense for the three and six months ended June 30, 2021 and $65,000 and $131,000 three and six months ended June 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 June 30, 2021 and December 31, 2020 (in thousands):

	June 30, 2021	December 31, 2020
Research and development	$ 1,958	$ 1,372
Payroll-related expenses	1,798	1,892
Professional fees	876	684
Commercial expenses	620	—
Other	49	25
Total Accrued Expenses	**$ 5,301**	**$ 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 and filed a prospectus supplement with the SEC in connection with the offer and sale of up to $100 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 over the coming months, 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 $136.8 million of net proceeds from the sale of 47.1 million shares of common stock at a weighted-average price of $2.99 per share during the six months ended June 30, 2021, compared to $8.0 million of net proceeds from the sale of 9.8 million shares of common stock at a weighted-average price of $0.75 per share during the six months ended June 30, 2020. The Company raised $64.3 million of net proceeds from the sale of 16.5 million shares of common stock at a weighted-average price of $4.02 per share during the three months ended June 30, 2021, compared to $4.8 million of net proceeds from the sale of 6.6 million shares of common stock at a weighted-average price of $0.69 per share during the three months ended June 30, 2020. Share issue costs, including sales agent commissions, related to the ATM Offering totaled $2.0 million and $4.2 million during the three and six months ended June 30, 2021, respectively.

Preferred Stock

Pursuant to its Amended and Restated Certificate of Incorporation, 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 June 30, 2021 and December 31, 2020.

Common Stock

Pursuant to its Certificate of Incorporation, the Company is authorized to issue 400 million and 200 million shares of common stock, of which 188 million and 140 million shares were issued and outstanding as of June 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 June 30, 2021 and December 31, 2020 (in thousands):

	June 30, 2021	December 31, 2020
Shares of common stock issued	188,461	140,450
Shares of common stock reserved for issuance for:		
Warrants	1,394	2,247
Stock options	17,349	10,147
Shares available for grant under 2014 Stock Incentive Plan	12,290	4,863
Shares available for sale under 2014 Employee Stock Purchase Plan	2,300	—
Total shares of common stock issued and reserved for issuance	**221,794**	**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 six months ended June 30, 2021 (in thousands):

			Year-to-Date Warrant Activity				
Issued	**Exercise Price**	**Expiration**	**December 31, 2020**	**Issued**	**(Exercised)**	**(Expired)**	**June 30, 2021**
Jun-2019	$1.47	Jun-2020	—	—	—	—	—
Mar-2018	$0.55*	Mar-2023	1,705	—	(378)	—	1,327
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	**—**	**(853)**	**—**	**1,394**

** 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. (LOSS) EARNINGS PER SHARE

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

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

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

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

	Three Months ended June 30,		Six Months ended June 30,	
	2021	2020	2021	2020
	(in thousands, except per share amounts)			
Basic (Loss) Earnings Per Share:				
Numerator:				
Net (loss) income	$ (25,442)	$ (26,344)	$ (80,954)	$ 15,220
Less: Deemed Dividend	—	$ (147)	—	$ (147)
Less: Income attributable to participating securities - basic	$ —	$ —	$ —	$ (322)
Net (loss) income attributable to common stockholders - basic	$ (25,442)	$ (26,491)	$ (80,954)	$ 14,751
Denominator:				
Weighted average common shares outstanding - basic	175,393	112,569	166,264	111,189
Net (loss) income per share applicable to common stockholders - basic	$ (0.15)	$ (0.24)	$ (0.49)	$ 0.13
Dilutive Earnings (Loss) Per Share:				
Numerator:				
Net (loss) income	$ (25,442)	$ (26,344)	$ (80,954)	$ 15,220
Less: Deemed Dividend	—	$ (147)	—	$ (147)
Less: Income attributable to participating securities - diluted	$ —	$ —	$ —	$ (2,473)
Net (loss) income attributable to common stockholders - diluted	$ (25,442)	$ (26,491)	$ (80,954)	$ 12,600
Denominator:				
Weighted average shares outstanding	175,393	112,569	166,264	111,189
Dilutive impact from:				
Stock options and employee stock purchase plan	—	—	—	14
Weighted average common shares outstanding for diluted	175,393	112,569	166,264	111,203
Net (loss) income per share applicable to common stockholders - diluted	$ (0.15)	$ (0.24)	$ (0.49)	$ 0.11

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

	Three Months ended June 30,		Six Months ended June 30,	
	2021	2020	2021	2020
Warrants	1,394	2,485	1,394	55
Stock options	17,349	9,990	17,349	9,989
	18,743	**12,475**	**18,743**	**10,044**

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 operations and comprehensive (loss) income for the three and six months ended June 30, 2021 and 2020 (in thousands):

	Three Months ended June 30,		Six Months ended June 30,	
	2021	2020	2021	2020
Research and development	$ 207	$ 91	$ 386	$ 171
General and administrative	1,052	400	1,831	727
	$ 1,259	$ 491	$ 2,217	$ 898

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. Currently there are only stock options outstanding under the 2014 Plan, which 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 12.4 million stock options outstanding under the 2014 Plan as of June 30, 2021.

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 12.3 million shares of common stock available for issuance under the 2014 Plan as of June 30, 2021.

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 June 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 4.8 million stock options outstanding which were granted as employment inducement awards outside of the 2014 Plan as of June 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 six months ended June 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	7,233	$3.34		
Exercised	(31)	$1.27		
Canceled or forfeited	—	—		
Outstanding at June 30, 2021	17,349	$2.13	8.6	$ 43,999
Exercisable at June 30, 2021	5,719	$1.57	7.6	$ 18,214

The Company recognized share-based compensation expense related to stock options of $1.3 million and $2.2 million for the three and six months ended June 30, 2021, respectively and $0.5 million and $0.9 million for the three and six months ended June 30, 2020, respectively. As of June 30, 2021, there was $17.1 million of total unrecognized compensation cost related to non-vested stock options which the Company expects to recognize over a weighted-average period of 3.3 years. The weighted-average grant-date fair value of stock options granted was $2.17 per option for the six months ended June 30, 2021.and $0.55 per option for the six months ended June 30, 2020. The total intrinsic value of stock options exercised during the six months ended June 30, 2021 was de minimis.

For the six months ended June 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:

	June 30, 2021	June 30, 2020
Fair market value	$3.34	$0.87
Grant exercise price	$3.34	$0.87
Expected term (in years)	6.04	6.02
Risk-free interest rate	0.9	1.4
Expected volatility	74.7	71.3
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 June 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. 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. The Company may be obligated to pay $0.50 million in milestone payments for the first product candidate that achieves applicable clinical development milestones. Based on current status, the Company anticipates that these milestones may be triggered by Vicineum's clinical development pathway. As part of the consideration, 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 related to achievement of a development milestone in the three months ended December 31, 2020 due to the submission of the Company's BLA application with the FDA in December 2020.

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 June 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 $2.9 million at exchange rates in effect on June 30, 2021). Based on current development status, the Company anticipates that certain of these milestones may be triggered by the development pathway of Vicineum. 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 $59,420 at exchange rates in effect as of June 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 development milestones 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 Vicineum in the first quarter of 2021.

License Agreement with XOMA

The Company has a License Agreement with XOMA Ireland Limited ("XOMA") which grants it non-exclusive rights to certain XOMA patent rights and know-how related to certain expression technology, including plasmids, expression strains, plasmid maps and production systems. 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 promises 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.

Other OUS Business Development Partnership Agreements

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 also 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 promises 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 June 30, 2021, none of these additional amounts were reasonably certain to be achieved due to the nature and timing of the underlying activities.

14. SUBSEQUENT EVENTS

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 is no Advisory Committee meeting planned at this time, and that no post-marketing requirements, including a confirmatory trial, have been identified at this 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 CMC, and a timeline to submit additional supporting information was agreed upon. In the US, the Company believes it remains on track for an FDA decision on its BLA for Vicineum by the target PDUFA date of August 18, 2021.

On July 14, 2021, the Company filed a prospectus supplement with the SEC in connection with the offer and sale of up to $100 million of shares of the Company’s common stock, par value $0.001 per share, from time to time pursuant to the previously disclosed Open Market Sale Agreement with Jefferies LLC, as sales agent. The Company may sell this amount efficiently from time to time over the coming months.

On July 21, 2021, the Company announced the appointments of Dr. Peter K Honig, MPH, former Senior Vice President and Head of Global Regulatory Affairs and Group Head of Development China and Japan at Pfizer, and Dr. Michael A.S. Jewett, FRCSC, FACS, a practicing Oncologist and global Key Opinion Leader (KOL) to the Sesen Bio Board of Directors.

On August 5, 2021, the Company entered into an exclusive license agreement with Eczacibasi Pharmaceuticals Marketing ("EIP") pursuant to which the Company 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, the Company is entitled to receive an upfront payment of $1.5 million, is eligible to receive additional regulatory and commercial milestone payments and is also entitled to receive a 30% royalty on net sales in Turkey.

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 commercialize Vicineum™ for the treatment of bacillus Calmette-Guérin ("BCG") unresponsive non-muscle invasive bladder cancer ("NMIBC"), if approved;
- the expectation that the United States Food and Drug Administration ("FDA"), will make a decision regarding our Biologics License Application ("BLA") for Vicineum for the treatment of BCG-unresponsive NMIBC on or before the target Prescription Drug User Fee Act ("PDUFA") date of August 18, 2021;
- the expectation that the FDA will not hold an advisory committee meeting to discuss the BLA for Vicineum;
- the expectation that the FDA will not identify any post-marketing requirements, including a confirmatory trial, for Vicineum;
- the resolution of remaining questions from the FDA regarding our BLA for Vicineum related to manufacturing facilities inspection, product quality information requests and additional information related to chemistry, manufacturing and controls ("CMC");
- our expectation for the potential commercial launch of Vicineum for the treatment of BCG-unresponsive NMIBC in the U.S., if approved, by the fourth quarter of 2021;
- 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 and other foreign jurisdictions, and the labeling under any approval we may obtain;
- our projected financial position and estimated cash burn rate;
- our estimates regarding expenses, future revenues, capital requirements and needs for, and ability to obtain, additional financing;
- our ability to continue as a going concern;
- our need to raise substantial additional capital to fund our operations;
- the potential impairment of our goodwill and indefinite lived-intangible assets;
- the success, cost and timing of our pre-clinical studies and clinical trials in the United States and other foreign jurisdictions;
- the potential that results of pre-clinical studies and clinical trials indicate our product candidates are unsafe or ineffective;
- 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;
- our expectation that the FDA will determine that the commercial supply of Vicineum is comparable to the clinical supply of Vicineum, and that no additional clinical trials are warranted;
- 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;
- the successful development of our commercialization capabilities, including sales and marketing capabilities, for Vicineum for the treatment of BCG-unresponsive NMIBC in the United States;
- our expectation that the European Medicines Agency (“EMA”), will potentially approve our marketing authorization application for Vicineum (under the proprietary brand name Vysyneum™, which has been conditionally approved by the EMA) for the treatment of BCG-unresponsive NMIBC in 2022;
- 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:

- the FDA may not approve our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC within the anticipated timeframe, or at all;
- we may not achieve profitable operations or access needed capital;
- clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC may not demonstrate safety and efficacy to the satisfaction of the FDA 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 or other foreign jurisdictions;
- Vicineum may not gain market acceptance for the treatment of BCG-unresponsive NMIBC in the United States 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;
- 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 fail to comply with all regulatory requirements or experience unanticipated problems with our products;
- 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.

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 the target PDUFA date for a decision on the BLA is August 18, 2021. In addition to the file acceptance and granting of Priority Review, the FDA also indicated that it is not currently planning to hold an advisory committee meeting to discuss the BLA for Vicineum.

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 are 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 and are currently under review by the FDA. Final numbers are pending.

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. After we submitted the BLA to the FDA, we participated in a successful Application Orientation Meeting, that is available in certain Center for Drug Evaluation and Research review divisions, at the review team’s discretion, for priority applications where early action is expected and/or desired. The objectives of the Application Orientation Meeting were to familiarize the FDA with application datasets, discussing scientific aspects including clinical risk-benefit, and establishing early communication between applicants and 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. In addition to the file acceptance and granting of Priority Review, the FDA also indicated that it was not planning to hold an advisory committee meeting to discuss the BLA for Vicineum.

On March 5, 2021, we submitted the Marketing Authorization Application (“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 has 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. The MAA for VYSYNEUM is currently under review with the EMA with potential approval expected in 2022.

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 is no Advisory Committee meeting planned at this time, and that no post-marketing requirements, including a confirmatory trial, have been identified at this 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. In the US, we believe we remain on track for an FDA decision on our BLA for Vicineum by the target PDUFA date of August 18, 2021.

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. Based on these results, we are optimistic that the FDA will determine that the commercial supply of Vicineum is comparable to the clinical supply of Vicineum, and that no additional clinical trials are warranted. 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.

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 2022.

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 and are also entitled to receive a 30% royalty on net sales in Turkey.

Liquidity and Going Concern

As of June 30, 2021, we had cash and cash equivalents of $151.0 million, net working capital (current assets less current liabilities) of $156.3 million and an accumulated deficit of $396.9 million. We incurred negative cash flows from operating activities of $30.8 million for the year ended December 31, 2020 and $41.6 million for the six months ended June 30, 2021. Since our inception, we have received no revenue from sales of our products, and we anticipate that operating losses will continue as we complete the follow-up stage of our ongoing Phase 3 VISTA Trial of Vicineum for the treatment of BCG-unresponsive NMIBC and seek marketing approval from the FDA and EMA, 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 initial public offering ("IPO"), follow-on public offerings, sales effected in "at-the-market" ("ATM") offerings, out-license and OUS business development partnership agreements and, to a lesser extent, from a collaboration.

Under Accounting Standards Codification Topic 205-40, *Presentation of Financial Statements - Going Concern*, we are required at each reporting period to evaluate whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of our plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists, we evaluate whether the mitigating effect of our plans sufficiently alleviates the substantial doubt about our ability to continue as a going concern. The mitigating effect of our plans, however, is only considered if both (i) it is probable that our plans will be effectively implemented within one year after the date that our financial statements are issued and (ii) it is probable that our plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about our ability to continue as a going concern within one year after the date that our financial statements are issued. Generally, to be considered probable of being effectively implemented, our plans must have been approved by our board of directors before the date that our financial statements are issued.

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 and development 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. 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 collaborations, OUS business development, partnerships, alliances or licensing arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable. If we are unable to raise additional funds when needed, we may be required to implement cost reduction strategies and 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.

We continue to monitor the effect of the outbreak of a novel strain of coronavirus ("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.

We do not believe that our cash and cash equivalents of $151.0 million as of June 30, 2021 is sufficient to fund our current operating plan for at least twelve months after the issuance of our condensed consolidated financial statements. Based on our current operating plan, we anticipate having sufficient cash and cash equivalents to fund our operations through the second quarter of 2022; however, we have based this estimate on assumptions that may prove to be wrong, and our capital resources may be utilized faster than we currently expect. Given our history of significant losses, negative cash flows from operations, limited cash resources currently on hand, and dependence on our ability - about which there can be no certainty - to obtain additional financing to fund our operations after the current cash resources are exhausted, substantial doubt exists about our ability to continue as a going concern. The condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q were prepared under the assumption that we will continue as a going concern and do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Components of Our Results of Operations

License and Related Revenue

License revenue consists of revenue recognized pursuant to our OUS business development partnership agreements, including the Qilu License Agreement, for 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, including the Qilu License Agreement.

Research and Development

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

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

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

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;
- 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, if the FDA, EMA or another regulatory authority were to require us to conduct clinical trials or other testing beyond those that we currently contemplate will be required for the completion of clinical development of Vicineum for the treatment of 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 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 June 30,		Six Months ended June 30,	
	2021	2020	2021	2020
Programs:				
Vicineum for the treatment of BCG-unresponsive NMIBC	$ 4,332	$ 3,135	$ 7,898	$ 10,499
Total direct program expenses	4,332	3,135	7,898	10,499
Personnel and other expenses:				
Employee and contractor-related expenses	2,389	1,207	4,660	2,374
Platform-related lab expenses	64	35	114	80
Facility expenses	143	103	268	213
Other expenses	300	82	366	263
Total personnel and other expenses	2,896	1,427	5,408	2,930
Total Research and Development	**$ 7,228**	**$ 4,562**	**$ 13,306**	**$ 13,429**

General and Administrative

General and administrative expenses consist primarily of salaries and related costs for personnel, including share-based compensation, 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, commercial market research and United States pre-launch market readiness. Future reporting periods may include selling costs pursuant to our commercialization strategy.

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 and future revenue levels. The fair value of contingent consideration is assessed at each balance sheet date and changes, if any, to the fair value are recognized in earnings (or loss) for the period.

Other Income (Expense), Net

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

Provision for Income Taxes

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 June 30, 2021 and 2020

	Three Months ended June 30,		Increase/(Decrease)	
	2021	2020	Dollars	Percentage
	(in thousands, except percentages)			
License and related revenue	$ 2,234	$ —	$ 2,234	—
Operating expenses:				
Research and development	$ 7,228	$ 4,562	$ 2,666	58 %
General and administrative	6,805	3,318	3,487	105 %
Change in fair value of contingent consideration	13,600	18,480	(4,880)	(26) %
Total operating expenses	27,633	26,360	1,273	5 %
(Loss) Income from operations	(25,399)	(26,360)	961	(4) %
Other (expense) income, net:				
Other (expense) income, net	(43)	16	(59)	(369) %
Net (Loss) Income and Comprehensive (Loss) Income Before Taxes	**$ (25,442)**	**$ (26,344)**	**$ 902**	**(3)%**
Provision for income taxes	$ —	$ —	$ —	—
Net (Loss) Income and Comprehensive (Loss) Income After Taxes	**$ (25,442)**	**$ (26,344)**	**$ 902**	**(3)%**

License and Related Revenue

Revenue for the three months ended June 30, 2021 was $2.2 million, which was due to clinical supply revenue resulting from the delivery of drug product to our OUS business development 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. We did not record any revenue for the three months ended June 30, 2020.

Research and Development

Research and development expenses were $7.2 million for the three months ended June 30, 2021 compared to $4.6 million for the three months ended June 30, 2020. The increase of $2.7 million was due to increased costs associated with technology transfer and manufacturing ($1.0 million), professional services in support of regulatory activity ($0.7 million), employee-related compensation ($0.7 million), and other increases ($0.3 million).

General and Administrative

General and administrative expenses were $6.8 million for the three months ended June 30, 2021 compared to $3.3 million for the three months ended June 30, 2020. The increase of $3.5 million was due primarily to increases in sales and marketing expense for Vicineum pre-commercial launch planning ($1.6 million), employee-related compensation driven by increased headcount as part of the commercial build ($1.3 million), and other increases for commercial launch preparation ($0.6 million).

Fair Value of Contingent Consideration

The non-cash change in fair value of contingent consideration was a $13.6 million loss for the three months ended June 30, 2021 compared to an $18.5 million loss for the three months ended June 30, 2020. The increase in the fair value of contingent consideration of $13.6 million for the three months ended June 30, 2021 was primarily attributable to decreased discount rates to future cash outflows related to the contingent payment obligations, and these discount rates continue to fluctuate each period. 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 17.9% of March 31, 2020, to 14.5% as of June 30, 2020 and from 7.4% as of March 31, 2021, to 6.6% as of June 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 14.7% as of March 31, 2020 to 13.2% as of June 30, 2020, and from 7.8% as of March 31, 2021 to 6.8% as of June 30, 2021.

The change in the fair value of contingent consideration was an $18.5 million loss for the three months ended June 30, 2020. This was primarily attributable to significant decreases in applicable discount rates, as a result of the extreme volatility of financial markets as global economies shut down in order to contain the spread of COVID-19.

Comparison of the Six Months ended June 30, 2021 and 2020

	Six Months ended June 30,		Increase/(Decrease)	
	2021	2020	Dollars	Percentage
	(in thousands, except percentages)			
License and related revenue	$ 6,544	$ —	$ 6,544	—
Operating expenses:				
Research and development	$ 13,306	$ 13,429	$ (123)	(1) %
General and administrative	12,098	6,766	5,332	79 %
Change in fair value of contingent consideration	61,760	(35,220)	96,980	(275) %
Total operating expenses	87,164	(15,025)	102,189	(680) %
(Loss) Income from operations	(80,620)	15,025	(95,645)	(637) %
Other (expense) income, net:				
Other (expense) income, net	(46)	195	(241)	(124) %
Net (Loss) Income and Comprehensive (Loss) Income Before Taxes	**$ (80,666)**	**$ 15,220**	**$ (95,886)**	**(630) %**
Provision for income taxes	$ (288)	$ —	$ (288)	—
Net (Loss) Income and Comprehensive (Loss) Income After Taxes	**$ (80,954)**	**$ 15,220**	**$ (96,174)**	**(632) %**

License and Related Revenue

Revenue for the six months ended June 30, 2021 was $6.5 million, which was due to achieving the IND milestone in China pursuant to the Qilu License Agreement, clinical supply revenue resulting from the delivery of drug product to 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. We did not record any revenue for the six months ended June 30, 2020.

Research and Development

Research and development expense was $13.3 million for the six months ended June 30, 2021 which was consistent with the $13.4 million expensed for the six months ended June 30, 2020

General and Administrative

General and administrative expenses were $12.1 million for the six months ended June 30, 2021 compared to $6.8 million for the six months ended June 30, 2020. The increase of $5.3 million was due primarily to increases in employee-related compensation driven by increased headcount as part of the commercial build ($2.1 million), sales and marketing expense for Vicineum pre-commercial launch planning ($1.7 million), legal fees related to regulatory and commercial launch support ($0.7 million), professional fees related to commercial launch preparation ($0.4 million), and other increases ($0.4 million).

Change in Fair Value of Contingent Consideration

The non-cash change in fair value of contingent consideration was a loss of $61.8 million for the six months ended June 30, 2021, compared to income of $35.2 million for the six months ended June 30, 2020. The increase in the fair value of contingent
consideration of $61.8 million for the six months ended June 30, 2021 was primarily attributable to changes in the competitive landscape, higher probability of regulatory success, expanded patient population, and to a lesser extent by the refinement of estimated launch timelines for Vicineum, if approved, in certain markets. In addition, the estimated fair value of contingent consideration is determined by applying appropriate discount rates to future cash outflows related to the contingent payment obligations. 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 fluctuated from 11.8% as of December 31, 2019 to 14.5% as of June 30, 2020 and from 8.4% as of December 31, 2020 to 6.6% as of June 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 13.2% as of June 30, 2020 and from 8.8% as of December 31, 2020, to 6.8% as of June 30, 2021.

The change in fair value of contingent consideration was a $35.2 million decrease for the six months ended June 30, 2020. The decrease in the fair value of contingent consideration of $35.2 million for the six months ended June 30, 2020 was primarily attributable to significant increases in applicable discount rates, as a result of the extreme volatility of financial markets as global economies shut down in order to contain the spread of COVID-19.

Other (Expense) Income, Net

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

Liquidity and Capital Resources

Overview

As of June 30, 2021, we had cash and cash equivalents of $151.0 million, net working capital of $156.3 million and an accumulated deficit of $396.9 million. We incurred negative cash flows from operating activities of $30.8 million for the year ended December 31, 2020 and $41.6 million for the six months ended June 30, 2021. 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 complete the follow-up stage of our ongoing Phase 3 VISTA Trial of Vicineum for the treatment of BCG-unresponsive NMIBC and seek marketing approval from the FDA and the EMA 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 its common stock from time to time for an aggregate sales price of up to an additional $50.0 million and $34.5 million, respectively. In June 2021, 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 Agreement and filed a prospectus supplement with the SEC in connection with the offer and sale of up to $100.0 million of our common stock pursuant to the Sale Agreement. In July 2021, we filed a prospectus supplement with the SEC in connection with the offer and sale of up to $100.0 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 over the coming months, 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 $136.8 million of net proceeds from the sale of 47.1 million shares of common stock at a weighted-average price of $2.99 per share during the six months ended June 30, 2021, including $64.3 million of net proceeds from the sale of 16.5 million shares of common stock at a weighted-average price of $4.02 per share during the three months ended June 30, 2021. We raised $8.0 million of net proceeds from the sale of 9.8 million shares of common stock at a weighted-average price of $0.75 per share during the six months ended June 30, 2020, including $4.8 million of net proceeds from the sale of 6.6 million shares of common stock at a weighted-average price of $0.69 per share during the three months ended June 30, 2020. Share issue costs, including sales agent commissions, related to the ATM Offering totaled $2.0 million and $4.2 million for the three and six months ended June 30, 2021 compared to $0.1 million and $0.2 million for the three and six months ended June 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.

We do not believe that our cash and cash equivalents of $151.0 million as of June 30, 2021 is sufficient to fund our current operating plan for at least twelve months after the issuance of our condensed consolidated financial statements. Based on our current operating plan, we anticipate having sufficient cash and cash equivalents to fund our operations through the second quarter of 2022; however, we have based this estimate on assumptions that may prove to be wrong, and our capital resources may be utilized faster than we currently expect. Given our history of significant losses, negative cash flows from operations, limited cash resources currently on hand, and dependence on our ability - about which there can be no certainty - to obtain additional financing to fund our operations after the current cash resources are exhausted, substantial doubt exists about our

ability to continue as a going concern. The condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q were prepared under the assumption that we will continue as a going concern and do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

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:

- complete our follow-up stage of our Phase 3 VISTA Trial for Vicineum for the treatment of BCG-unresponsive NMIBC;
- 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 cost and timing of any new clinical trials or studies of Vicineum for the treatment of BCG-unresponsive NMIBC;
- 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 six months ended June 30, 2021 and 2020 (in thousands):

	Six Months ended June 30,	
	2021	2020
Net Cash Used in Operating Activities	$ (41,616)	$ (18,326)
Net Cash Used in Investing Activities	(49)	(8)
Net Cash Provided by Financing Activities	137,312	7,954
Net Increase (Decrease) in Cash, Cash Equivalents and Restricted Cash	**$ 95,647**	**$ (10,380)**

Net Cash Used in Operating Activities

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

Net cash used in operating activities was $18.3 million for the six months ended June 30, 2020 and consisted primarily of net income of $15.2 million, adjusted for non-cash items, including share-based compensation of $0.9 million, a decrease in the fair value of contingent consideration of $35.2 million and a net increase in operating assets and liabilities of $0.7 million.

Net Cash Used in Investing Activities

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

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $137.3 million and $8.0 million for the six months ended June 30, 2021 and June 30, 2020, respectively, and consisted, primarily, of net proceeds from the sale of common stock under the ATM Offering and, with respect to the six months ended June 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. Based on the annual testing and quarterly reviews performed, we concluded that the carrying value of our intangible assets was not impaired as of June 30, 2021 and December 31, 2020.

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. Based on the annual testing and quarterly reviews performed, we concluded that there was no goodwill impairment as of June 30, 2021 and December 31, 2020.

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.

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 June 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 Qilu. 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 June 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 June 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.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors.

[During the six months ended June 30, 2021, 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.]

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

We did not issue any unregistered equity securities during the six months ended June 30, 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).
10.1	Amendment No. 2 to the Sesen Bio, Inc. 2014 Stock Incentive Plan. Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed May 3, 2021 (File No. 001-36296).
10.2	Amendment No. 1 to the Sesen Bio, Inc. 2014 Employee Stock Purchase Plan. Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed May 3, 2021 (File No. 001-36296).
10.3	Amendment No. 3 to the Open Market Sale AgreementSM, dated June 1, 2021, by and between Sesen Bio, Inc. and Jefferies LLC. Incorporated by reference to Exhibit 1.1 to our Current Report on Form 8-K filed on June 1, 2021 (File No. 001-36296).
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 June 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: August 9, 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 June 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: August 9, 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 June 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: August 9, 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 June 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: August 9, 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 June 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: August 9, 2021

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