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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, 2020**

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 117,171,636 shares of the registrant's common stock outstanding as of August 3, 2020.

SESEN BIO, INC.

Quarterly Report on Form 10-Q for the Quarterly Period ended June 30, 2020

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 37,741	$ 48,121
Prepaid expenses and other current assets	3,727	6,326
Total current assets	41,468	54,447
Restricted cash	20	20
Property and equipment, net of accumulated depreciation of $820 and $758, respectively	185	238
Intangible assets	46,400	46,400
Goodwill	13,064	13,064
Other assets	76	196
Total Assets	**$ 101,213**	**$ 114,365**
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 1,274	$ 1,902
Accrued expenses	4,866	6,169
Other current liabilities	373	446
Total current liabilities	6,513	8,517
Contingent consideration	84,800	120,020
Deferred tax liability	12,528	12,528
Total Liabilities	$ 103,841	$ 141,065
Commitments and contingencies		
Stockholders' Deficit:		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized at June 30, 2020 and December 31, 2019; no shares issued and outstanding at June 30, 2020 and December 31, 2019	—	—
Common stock, $0.001 par value per share; 200,000,000 shares authorized at June 30, 2020 and December 31, 2019; 116,627,653 and 106,801,409 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	116	107
Additional paid-in capital	275,560	266,717
Accumulated deficit	(278,304)	(293,524)
Total Stockholders' Deficit	(2,628)	(26,700)
Total Liabilities and Stockholders' Deficit	**$ 101,213**	**$ 114,365**

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

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

	Three Months ended June 30,		Six Months ended June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 4,562	$ 7,944	$ 13,429	$ 12,630
General and administrative	3,318	2,617	6,766	5,672
Change in fair value of contingent consideration	18,480	44,000	(35,220)	43,000
Total operating expenses	26,360	54,561	(15,025)	61,302
Income (Loss) from Operations	(26,360)	(54,561)	15,025	(61,302)
Other income (expense):				
Other income, net	16	226	195	487
Net Income (Loss) and Comprehensive Income (Loss)	**$ (26,344)**	**$ (54,335)**	**$ 15,220**	**$ (60,815)**
Net income (loss) per common share - basic	$ (0.24)	$ (0.67)	$ 0.13	$ (0.77)
Weighted-average common shares outstanding - basic	112,569	80,739	111,189	79,107
Net income (loss) per common share - diluted	$ (0.24)	$ (0.67)	$ 0.11	$ (0.77)
Weighted-average common shares outstanding - diluted	112,569	80,739	111,203	79,107

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 (Deficit)
	Shares	Amount			
Balance at December 31, 2019	106,801,409	$ 107	$ 266,717	$ (293,524)	$ (26,700)
Net income	—	—	—	41,564	41,564
Share-based compensation	—	—	407	—	407
Sales of common stock under 2014 ESPP	2,785	—	1	—	1
Issuance of common stock under ATM Offering, net of issuance costs of $0.1 million	3,187,359	3	3,176	—	3,179
Balance at March 31, 2020	**109,991,553**	**$ 110**	**$ 270,301**	**$ (251,960)**	**$ 18,451**
Net income	—	—	—	(26,344)	(26,344)
Share-based compensation	—	—	491	—	491
Issuance of common stock under ATM Offering, net of issuance costs of $0.1 million	6,636,100	6	4,768	—	4,774
Balance at June 30, 2020	**116,627,653**	**$ 116**	**$ 275,560**	**$ (278,304)**	**$ (2,628)**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2018	77,456,180	$ 77	$ 230,154	$ (186,024)	$ 44,207
Net loss	—	—	—	(6,480)	(6,480)
Share-based compensation	—	—	326	—	326
Sales of common stock under 2014 ESPP	8,601	—	7	—	7
Balance at March 31, 2019	**77,464,781**	**$ 77**	**$ 230,487**	**$ (192,504)**	**$ 38,060**
Net loss	—	—	—	(54,335)	(54,335)
Share-based compensation	—	—	356	—	356
Exercise of stock options	30,000	—	45	—	45
Exercise of common stock warrants	3,361,115	4	3,430	—	3,434
Issuance of common stock and common stock warrants, net of issuance costs of $2.2 million	20,410,000	20	27,789	—	27,809
Balance at June 30, 2019	**101,265,896**	**$ 101**	**$ 262,107**	**$ (246,839)**	**$ 15,369**

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,	
	2020	**2019**
Cash Flows from Operating Activities:		
Net income (loss)	$ 15,220	$ (60,815)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation	61	107
Share-based compensation	898	682
Change in fair value of contingent consideration	(35,220)	43,000
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	2,719	(1,487)
Accounts payable	(628)	809
Accrued expenses and other liabilities	(1,376)	961
Net Cash Used in Operating Activities	**(18,326)**	**(16,743)**
Cash Flows from Investing Activities:		
Net Cash Used in Investing Activities	**(8)**	**(43)**
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock under ATM Offering, net of issuance costs	7,953	—
Proceeds from sales of common stock under 2014 ESPP	1	7
Proceeds from exercises of stock options	—	45
Proceeds from the issuance of common stock and common stock warrants, net of issuance costs	—	27,809
Proceeds from the exercise of common stock warrants	—	3,434
Net Cash Provided by Financing Activities	**7,954**	**31,295**
Net Increase (Decrease) in Cash, Cash Equivalents and Restricted Cash	(10,380)	14,509
Cash, Cash Equivalents and Restricted Cash - Beginning of Period	48,141	50,442
Cash, Cash Equivalents and Restricted Cash - End of Period	**$ 37,761**	**$ 64,951**
Supplemental disclosure of non-cash operating activities:		
Right-of-use assets related to the adoption of ASC 842	—	$ 236
Cash paid for amounts included in the measurement of lease liabilities	$ 75	$ 76
Supplemental disclosure of non-cash investing activities:		
Fixed assets included in Accrued Expenses	—	$ 119
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 developing 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*. The Company has an ongoing single-arm, multi-center, open-label Phase 3 clinical trial of Vicineum as a monotherapy in patients with high-risk, bacillus Calmette-Guérin ("BCG")-unresponsive non-muscle invasive bladder cancer ("NMIBC") (the "VISTA Trial"). The VISTA Trial completed enrollment in April 2018 with a total of 133 patients, and in December 2019, the Company initiated submission of the Biologics License Application ("BLA") for Vicineum to the United States Food and Drug Administration ("FDA") under Rolling Review, which enables individual modules to be submitted and reviewed on an ongoing basis, rather than waiting for all sections to be completed before submission. The Company operates in one segment under the direction of its Chief Executive Officer (chief operating decision maker).

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, 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 $7.0 million payable upon the first sale of the Purchased Product in any one of certain specified European countries; (iii) a one-time milestone payment of $3.0 million payable upon the first sale of the Purchased Product in Japan; and (iv) quarterly earn-out payments equal to 2% of net sales of the Purchased Product during specified earn-out periods. Such earn-out payments are payable with respect to net sales in a country beginning on the date of the first sale in such country and ending on the earlier of (i) December 31, 2033 and (ii) fifteen years after the date of such sale, subject to early termination in certain circumstances if a biosimilar product is on the market in the applicable country (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 were previously employees or members of the Company's board of directors.

Liquidity and Going Concern

As of June 30, 2020, the Company had cash and cash equivalents of $37.7 million, net working capital of $35.0 million and an accumulated deficit of $278.3 million. The Company incurred negative cash flows from operating activities of $37.5 million for the year ended December 31, 2019 and $18.3 million for the six months ended June 30, 2020. Since its inception, the Company has received no revenue from sales of its products, and management anticipates that operating losses will continue for the foreseeable future as the Company continues its ongoing Phase 3 VISTA Trial for Vicineum for the treatment of high-risk NMIBC and seeks marketing approval from the FDA. 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, a License Agreement with F. Hoffmann-La Roche Ltd and Hoffman-La Roche Inc. (collectively, "Roche") (the "License Agreement with Roche") and, to a lesser extent, from a collaboration. See "Note 9. Stockholders' Equity" 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 high-risk NMIBC, and ultimately upon its ability to attain profitable operations. In order to commercialize its product candidates, including Vicineum for the treatment of high-risk 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 and market acceptance of its products. The successful discovery and development of product candidates, including Vicineum for the treatment of high-risk NMIBC, requires substantial working capital, and management expects to seek additional funds through equity or debt financings or through additional collaboration, licensing transactions or other sources. The Company may be unable to obtain equity or debt financings or enter into additional collaboration or licensing transactions at 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 and 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 or future commercialization efforts or grant rights to develop and market products or product candidates that management would otherwise prefer to develop and market.

The Company's management does not believe that its cash and cash equivalents of $37.7 million as of June 30, 2020 is 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, the ongoing COVID-19 pandemic 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 income (operations) and comprehensive income (loss), stockholders’ equity 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, 2020 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 16, 2020, 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; and going concern considerations.

Principles of Consolidation

The Company's 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, 2019.

4. RECENT ACCOUNTING PRONOUNCEMENTS

Adopted in 2020

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). ASU 2016-13 requires measurement and recognition of expected credit losses for financial assets held. The amendments in ASU 2016-13 eliminate the probable threshold for initial recognition of a credit loss in current GAAP and reflect an entity's current estimate of all expected credit losses. ASU 2016-13 is effective for annual and interim periods beginning January 1, 2020 and is to be applied using a modified retrospective transition method. The Company adopted this guidance effective January 1, 2020, and it did not have a material impact on the Company's financial position, results of operations or cash flows.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurements* ("ASU 2018-13"). ASU 2018-13 modifies fair value measurement disclosure requirements. ASU 2018-13 is effective for annual and interim periods beginning after December 15, 2019. The Company adopted this guidance effective January 1, 2020, and although it resulted in some additional footnote disclosures, it did not have a material impact on the Company's disclosures. For the new disclosures regarding our Level 3 instruments, please read Note 5, Fair Value Measurements and Financial Instruments, to these condensed consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* ("ASU 2018-15"). ASU 2018-15 requires a customer in a cloud computing arrangement that is a service contract to

follow the internal-use software guidance to determine which implementation costs to defer and recognize as an asset. The effective date for ASU 2018-15 is for annual and interim periods beginning after December 15, 2019. The amendments in this ASU should be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company adopted this guidance effective January 1, 2020, and it did not have a material impact on the Company's financial position, results of operations or cash flows.

Pending Adoption

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. Because the Company generates losses and pays no income taxes, it does not expect the adoption of ASU 2019-12 to have a material impact on the Company's 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 consolidated balance sheets approximated their fair values as of June 30, 2020 and December 31, 2019 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, 2020 and December 31, 2019 (in thousands):

	June 30, 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)	$ 31,339	$ 31,339	$ 31,339	$ —	$ —
Liabilities:					
Contingent consideration	$ 84,800	$ 84,800	$ —	$ —	$ 84,800

	December 31, 2019				
			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)	$ 31,146	$ 31,146	$ 31,146	$ —	$ —
Liabilities:					
Contingent consideration	$ 120,020	$ 120,020	$ —	$ —	$ 120,020

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, 2020.

Contingent Consideration

On September 20, 2016, the Company acquired Viventia through the issuance 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 following table sets forth a summary of the change in the fair value of the Company's contingent consideration liability, measured on a recurring basis at each reporting period, for the six months ended June 30, 2020 (in thousands):

Balance at December 31, 2019	**$**	**120,020**
Change in fair value of contingent consideration		(35,220)
Balance at June 30, 2020	**$**	**84,800**

The 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, and the level of commercial sales of Vicineum forecasted for the United States, Europe, Japan and other potential markets. There have been no changes to the valuation methods utilized during the six months ended June 30, 2020. Because of the business environment uncertainty created by the ongoing COVID-19 pandemic, management carefully reviewed as of June 30, 2020 all of the Company’s financial forecast assumptions related to probability, timing and anticipated level of commercial sales, which were used to determine the estimated fair value of contingent consideration, and updated its forecasts for commercial sales in the second quarter of 2020 to reflect certain changes within the current competitive landscape. However, given the evolving and uncertain nature of the COVID-19 pandemic, management will continue to closely monitor developments in order to timely determine if any financial forecast changes may be required. As of June 30, 2020, no financial forecast changes due to COVID-19 were currently required. Changes to probabilities of success, timing of certain milestones and achievements, and level of commercial sales could materially affect the valuation of contingent consideration.

However, the estimated fair value of contingent consideration is also determined by applying appropriate discount rates to future cash outflows related to the contingent payment obligations, and these discount rates have increased significantly as a result of the extreme volatility of financial markets as global economies shut down in order to contain the spread of COVID-19. 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 increased from 11.8% as of December 31, 2019 to 14.5% as of June 30, 2020. The discount rate applied to the 2% royalty due on forecasted Vicineum revenues is derived from the Company’s estimated weighted-average cost of capital (“WACC”), and this WACC-derived discount rate increased from 5.6% as of December 31, 2019 to 13.2% as of June 30, 2020. These significant increases in the applicable discount rates, in conjunction with changes to the competitive

landscape, resulted in a $35.2 million decrease in the estimated fair value of contingent consideration as of June 30, 2020. Changes to the discount rates could materially affect the valuation of the contingent consideration.

6. INTANGIBLE ASSETS AND GOODWILL

Intangible Assets

Intangible assets on the Company's consolidated balance sheet are the result of the Viventia Acquisition in September 2016. The following table sets forth the composition of intangible assets as of June 30, 2020 and December 31, 2019 (in thousands):

	June 30, 2020	December 31, 2019
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 consolidated balance sheet is the result of the Viventia Acquisition in September 2016. Goodwill had a carrying value of $13.1 million as of June 30, 2020 and December 31, 2019.

7. LEASES

On January 1, 2019, the Company adopted ASC Topic 842, *Leases* using the optional transition method. The Company's lease portfolio includes:

1. An operating lease for its 31,100 square foot facility in Winnipeg, Manitoba which consists of manufacturing, laboratory, warehouse and office space, under a five-year renewable lease through September 2020 with a right to renew the lease for one subsequent five-year term. The minimum monthly rent under this lease is $12,800 per month. In addition to rent expense, the Company expects to incur $12,500 per month in related operating expenses. Operating lease cost under this lease, including the related operating costs, was $72,000 and $148,000 for the three and six months ended June 30, 2020 and $71,000 and $146,000 for the three and six months ended June 30, 2019, respectively;
2. Short-term property leases for modular office space for 1) its current corporate headquarters in Cambridge, MA and 2) office space in Philadelphia, PA. The short-term leases renew every four to nine months and currently extend through March 2021. The minimum monthly rent for these office spaces is currently $21,400 per month, which is subject to change if and as the Company adds or deducts space to or from the leases. The Company recorded $65,000 and $131,000 in rent expense for the three and six months ended June 30, 2020 and $53,000 and $129,000 for the three and six months ended June 30, 2019, respectively, for these leases.

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 consolidated balance sheet. The short-term liability is recorded in other current liabilities on the Company's consolidated balance sheet. Operating lease cost is recognized on a straight-line basis over the lease term.

8. ACCRUED EXPENSES

The following table sets forth the composition of accrued expenses as of June 30, 2020 and December 31, 2019 (in thousands):

	June 30, 2020	December 31, 2019
Research and development	$ 3,100	$ 3,688
Payroll-related expenses	985	1,638
Severance to former Executives and other employees	66	378
Professional fees	692	378
Other	23	87
Total Accrued Expenses	**$ 4,866**	**$ 6,169**

Management Changes

On August 26, 2019, Richard Fitzgerald departed as the Company's Chief Financial Officer. In connection with his separation from the Company, Mr. Fitzgerald and the Company entered into a Separation Agreement and General Release dated as of September 9, 2019, pursuant to which the Company provided Mr. Fitzgerald with twelve months of separation payments and benefits. The Company recorded $0.3 million of expense, which will be paid through the normal payroll cycle through August 2020.

On August 2, 2019, Dennis Kim, M.D., MPH departed as the Company's Chief Medical Officer. In connection with his separation from the Company, Dr. Kim and the Company entered into a Separation Agreement and General Release dated as of August 2, 2019 (the “Kim Separation Agreement”), pursuant to which the Company provided Dr. Kim with six months of separation payments in the amount of $0.2 million. In addition, Dr. Kim and the Company entered into a Consulting Agreement dated as of August 3, 2019 (the "Kim Consulting Agreement"), pursuant to which the Company agreed to pay Dr. Kim $0.1 million in consulting fees and transition expenses over the following three months ended November 2, 2019. The Company recorded $0.3 million of expenses related to these agreements in 2019. The Kim Consulting Agreement payments were made in a lump sum when the agreement concluded in November 2019. The separation payments were paid through the normal payroll cycle through January 2020, when the Company concluded its obligations under the Kim Separation Agreement.

9. STOCKHOLDERS' EQUITY (DEFICIT)

Equity Financings

ATM Offering

In November 2019, the Company entered into an Open Market Sale Agreement [SM] (the "Sales Agreement") with Jefferies LLC ("Jefferies"), under which the Company may issue and sell shares of its common stock from time to time for an aggregate sales price of up to $35.0 million through Jefferies (the "ATM Offering"). Sales of common stock under the Sales Agreement are made by any method that is deemed to be an ATM offering as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended, including but not limited to sales made directly on or through the Nasdaq Global Market or any other existing trading market for the common stock. The Company has no obligation to sell any of its common stock and may at any time suspend offers under the Sales Agreement or terminate the Sales Agreement. Subject to the terms and conditions of the Sales 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. The Company incurred $0.2 million in legal, accounting and printing costs related to the commencement of the ATM Offering. For the six months ended June 30, 2020, the Company 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 under the ATM Offering, 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 $0.1 million and $0.2 million during the three and six months ended June 30, 2020, respectively.

June 2019 Financing

In June 2019, the Company raised $27.8 million of net proceeds from the sale of 20.4 million shares of common stock and accompanying warrants to purchase an additional 20.4 million shares of common stock in an underwritten public offering (the "June 2019 Financing"). The combined purchase price for each share of common stock and accompanying warrant was $1.47. Subject to certain ownership limitations, the warrants issued in the June 2019 Financing were exercisable immediately upon issuance at an exercise price of $1.47 per share, subject to adjustments as provided under the terms of such warrants, and had a one-year term expiring on June 21, 2020. As of June 30, 2020, all warrants issued in connection with the June 2019 financing have expired.

Preferred Stock

Pursuant to its Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation"), the Company is authorized to issue 5.0 million shares of "blank check" preferred stock, $0.001 par value per share, which enables its board of directors, from time to time, to create one or more series of preferred stock. Each series of preferred stock issued shall have the rights, preferences, privileges and restrictions as designated by the board of directors. The issuance of any series of preferred stock could affect, among other things, the dividend, voting and liquidation rights of the Company's common stock. The Company had no preferred stock issued and outstanding as of June 30, 2020 and December 31, 2019.

Common Stock

Pursuant to its Certificate of Incorporation, the Company is authorized to issue 200.0 million shares of common stock, $0.001 par value per share, of which 116.6 million and 106.8 million shares were issued and outstanding as of June 30, 2020 and December 31, 2019, respectively. In addition, the Company had reserved for issuance the following amounts of shares of its common stock for the purposes described below as of June 30, 2020 and December 31, 2019 (in thousands):

	June 30, 2020	December 31, 2019
Shares of common stock issued	116,628	106,801
Shares of common stock reserved for issuance for:		
Warrants	2,485	22,895
Stock options	9,990	6,236
Shares available for grant under 2014 Stock Incentive Plan	5,084	8,753
Shares available for sale under 2014 Employee Stock Purchase Plan	25	28
Total shares of common stock issued and reserved for issuance	**134,212**	**144,713**

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, 2020 (in thousands):

			Year-to-Date Warrant Activity				
Issued	**Exercise Price [1]**	**Expiration**	**December 31, 2019**	**Issued**	**(Exercised)**	**(Expired)**	**June 30, 2020**
Jun-2019	$1.47	Jun-2020	20,410	—	—	(20,410)	—
Mar-2018	$0.55*	Mar-2023	1,943	—	—	—	1,943
Nov-2017	$0.55*	Nov-2022	487	—	—	—	487
May-2015	$11.83	Nov-2024	28	—	—	—	28
Nov-2014	$11.04	Nov-2024	27	—	—	—	27
			22,895	**—**	**—**	**(20,410)**	**2,485**

[1] As of June 30, 2020.

* *Exercise price shown subject to further adjustment based on down round provision added by amendment.*

In March 2018, the Company raised $9.0 million of net proceeds from the sale of common stock in a registered direct public offering and the sale of warrants to purchase shares of the Company's common stock with an exercise price of $1.20 per share (the "2018 Warrants") in a concurrent private placement. On October 28, 2019, the Company entered into transactions with certain holders of its then outstanding 2018 Warrants to amend their warrants pursuant to a Warrant Amendment Agreement (the "2018 Warrant Amendment Agreements"). The 2018 Warrant Amendment Agreements reduced the exercise price of the warrants from $1.20 to the lesser of (a) $0.95 per share of common stock and (b) the exercise price as determined from time to

time, pursuant to the anti-dilution provisions in the 2018 Warrant Amendment Agreements. During the three months ended June 30, 2020, the anti-dilution provision was triggered; as such, the Company recognized a deemed dividend of approximately $0.1 million which reduced the income available to common stockholders for both the three and six months ended June 30, 2020. As of June 30, 2020, the exercise price of the 2018 Warrants was $0.55. As the Company has an accumulated deficit balance as of June 30, 2020, the deemed dividend was recorded as offsetting debit and credit entries to additional-paid-in capital for the period ended June 30, 2020. As there was no overall impact to additional paid-in capital, the amounts were not presented on the Statement of Stockholders' Equity (Deficit) for the period ended June 30, 2020.

10. EARNINGS (LOSS) PER SHARE

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

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

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

Accordingly, the Company applied the two-class method to calculate basic and diluted net earnings per share of common stock for the six months ended June 30, 2020. The two-class method was not applied for the three months ended June 30, 2020 and for the three and six months ended June 30, 2019 as the Company’s participating securities do not have any obligation to absorb net losses.

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(in thousands, except per share amounts)			
Basic Earnings (Loss) Per Share:				
Numerator:				
Net income (loss)	$ (26,344)	$ (54,335)	$ 15,220	$ (60,815)
Less: Deemed dividend	(147)	—	(147)	—
Less: Income attributable to participating securities - basic	—	—	(322)	—
Net income (loss) attributable to common stockholders - basic	$ (26,491)	$ (54,335)	$ 14,751	$ (60,815)
Denominator:				
Weighted average common shares outstanding - basic	112,569	80,739	111,189	79,107
Net income (loss) per share applicable to common stockholders - basic	$ (0.24)	$ (0.67)	$ 0.13	$ (0.77)
Dilutive Earnings (Loss) Per Share:				
Numerator:				
Net income (loss)	$ (26,344)	$ (54,335)	$ 15,220	$ (60,815)
Less: Deemed Dividend	(147)	—	(147)	—
Less: Income attributable to participating securities - diluted	—	—	(2,473)	
Net income (loss) attributable to common stockholders - diluted	$ (26,491)	$ (54,335)	$ 12,600	$ (60,815)
Denominator:				
Weighted average shares outstanding	112,569	80,739	111,189	79,107
Dilutive impact from:				
Stock options and employee stock purchase plan	—	—	14	—
Weighted average common shares outstanding for diluted	112,569	80,739	111,203	79,107
Net income (loss) per share applicable to common stockholders - diluted	$ (0.24)	$ (0.67)	$ 0.11	$ (0.77)

The following potentially dilutive securities outstanding as of June 30, 2020 and 2019 have been excluded from the denominator of the diluted income (loss) per share of common stock outstanding calculation as their effect is anti-dilutive (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Warrants	2,485	5,779	55	5,779
Stock options	9,990	26,307	9,989	26,307
	12,475	**32,086**	**10,044**	**32,086**

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 consolidated statements of income (operations) for the three and six months ended June 30, 2020 and 2019 (in thousands):

	Three Months ended June 30,		Six Months ended June 30,	
	2020	2019	2020	2019
Research and development	$ 91	$ 86	$ 171	$ 139
General and administrative	400	269	727	543
	$ 491	$ 355	$ 898	$ 682

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 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 7.7 million stock options outstanding under the 2014 Plan as of June 30, 2020. There were 5.1 million shares of common stock available for issuance under the 2014 Plan as of June 30, 2020.

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 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 0.1 million fully vested stock options outstanding under the 2009 Plan as of June 30, 2020.

Out-of-Plan Inducement Grants

From time to time, the Company has granted equity awards to its newly hired 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 executive's acceptance of employment with the Company. There were 2.2 million stock options outstanding which were granted as employment inducement awards outside of the 2014 Plan as of June 30, 2020.

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, 2020:

	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, 2019	6,236	$1.52	8.8	$ 358
Granted	3,754	$0.87		
Exercised	—	$0.00		
Canceled or forfeited	—	$0.00		
Outstanding at June 30, 2020	9,990	$1.27	9.0	$ —
Exercisable at June 30, 2020	2,866	$1.91	8.0	$ —

The Company recognized share-based compensation expense related to stock options of $0.5 million and $0.9 million for the three and six months ended June 30, 2020 and $0.4 million and $0.7 million for the three and six months ended June 30, 2019, respectively. As of June 30, 2020, there was $4.4 million of total unrecognized compensation cost related to non-vested stock options which the Company expects to recognize over a weighted-average period of 2.9 years. The weighted-average grant-date fair value of stock options granted during the six months ended June 30, 2020 was $0.55 per option. The total intrinsic value of stock options exercised during the six months ended June 30, 2020 was de minimus.

For the six months ended June 30, 2020 and 2019, 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, 2020	June 30, 2019
Fair value of common stock	$0.55	$0.63
Exercise price	$0.87	$0.93
Expected term (in years)	6.02	5.97
Risk-free interest rate	1.4	2.4
Expected volatility	71.3	78.0
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. 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 the Company's 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 Company's 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, 2020, there were approximately 25,000 shares of the Company's 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 75% 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

Vicineum 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 $0.75 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.

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, the Company may be obligated to pay up to €3.6 million in milestone payments for the first product candidate that achieves applicable clinical development milestones. Based on current clinical status, the Company anticipates that certain of these milestones may be triggered by Vicineum’s clinical development pathway. 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, which can be credited towards any royalty payment the Company owes to Micromet.

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.

Other License Agreements

License Agreement with Roche

In June 2016, the Company entered into the License Agreement with 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 "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 Licensed Intellectual Property that contains an IL-6 antagonist anti-IL monoclonal antibody ("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 $72.5 million in development milestones, $50.0 million in regulatory milestones and $75.0 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 $65.0 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 with Roche. Specifically, (i) Roche may exercise a buy-out option following the first dosing ("Initiation") in the first Phase 2 study for a Licensed Product until the day before Initiation of the first Phase 3 study for a Licensed Product, in which case Roche is required to pay the Company $135.0 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 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 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, $265.0 million, which amount would be reduced to $220.0 million if none of the Company's patent rights containing a composition of matter claim covering any compound or 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 Licensed Product, there is a period of 12 months where Roche is not conducting sufficient development activities with respect to the products made from the Licensed Intellectual Property.

14. RELATED PARTY TRANSACTIONS

The Company leases its facility in Winnipeg, Manitoba from an affiliate of Leslie L. Dan, a director of the Company until his retirement in July 2019. The Company paid $0.1 million and $0.1 million of rent for the three and six months ended June 30, 2020, respectively, and $0.1 million and $0.1 million of rent for the three and six months ended June 30, 2019, respectively. All payments include related operating expenses.

The Company pays fees under an intellectual property license agreement to Protoden Technologies Inc. ("Protoden"), a company owned by Clairmark, an affiliate of Mr. Dan. Pursuant to the agreement, the Company has an exclusive, perpetual, irrevocable and non-royalty bearing license, with the right to sublicense, to certain patents and technology to make, use and sell products that utilize such patents and technology. The annual fee is $0.1 million. Upon expiration of the term on December 31, 2024, the licenses granted to the Company will require no further payments to Protoden. For each of the six months ended June

30, 2020 and 2019, the Company paid $0.1 million under this agreement. The Company did not make payments under this agreement during the three months ended June 30, 2020 and 2019.

Mr. Dan was not deemed a related party during the three and six months ended June 30, 2020; as such, only payments made during the three and six months ended June 30, 2019 are considered payments to a related party.

15. SUBSEQUENT EVENTS

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”) ("Qilu License Agreement") pursuant to which the Company granted Qilu an exclusive, sublicensable, royalty-bearing license, under certain intellectual property owned or exclusively licensed by the Company, to develop, manufacture and commercialize Vicineum™ (the “Licensed Product”) for the treatment of NMIBC and other types of cancer (the “Field”) in China, Hong Kong, Macau and Taiwan (the “Territory”). 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 Territory. The Company retains development, manufacturing and commercialization rights with respect to Vicineum in the rest of the world.

In partial consideration for the rights granted by the Company, Qilu agreed to pay to the Company (i) a one-time upfront cash payment of $12 million payable within 45 business days of the execution date, subject to delivery by the Company of certain know-how and other documentation related to the Licensed Product to Qilu, and (ii) milestone payments totaling up to $23 million upon the achievement of certain technology transfer, development and regulatory milestones.

Qilu also agreed to pay the Company a 12% royalty based upon annual net sales of Licensed Products in the Territory. 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 Term”). 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 the Territory. 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 the Territory. A joint development committee will be established between the Company and Qilu to coordinate and review the development, manufacturing and commercialization plans with respect to the Licensed Products in the Territory. The Company and Qilu also agreed to negotiate in good faith 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 the Territory 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 for the Licensed Product.

The Qilu License Agreement 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. Upon expiration of the Qilu License Agreement, Qilu will have a fully paid-up, freely transferable, perpetual license to use the patent rights and know-how licensed from the Company to research, develop, have developed, manufacture, have manufactured, use, sell, offer for sale, import, export and otherwise commercialize the applicable Licensed Product in the Field in the Territory. Either party may terminate the Qilu License Agreement for the other party’s material breach following a cure period or upon certain insolvency events. If the Qilu License Agreement is terminated by Qilu for the Company’s material breach, the license granted to Qilu will become fully paid-up, royalty-free, and perpetual. Qilu may terminate the Qilu License Agreement at its sole discretion and without any penalty or liability for any reason or no reason upon 90 calendar days’ prior written notice to the Company. Qilu has the right to receive a refund of all amounts paid to the Company in the event the Qilu License Agreement is terminated under certain circumstances.

The Qilu License Agreement includes customary representations and warranties, covenants and indemnification obligations for a transaction of this nature.

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, 2019, included in our Annual Report on Form 10-K filed with the United States Securities and Exchange Commission ("SEC") on March 16, 2020. 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, 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. These statements 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.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "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 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 are subject to a number of risks, uncertainties and assumptions 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 which is produced through our proprietary one-step, microbial manufacturing process. We target tumor cell surface antigens with limited expression on normal cells. Binding of the target antigen by the TFPT allows for rapid internalization into the targeted cancer cell. We have designed our targeted proteins to overcome the fundamental efficacy and safety challenges inherent in existing antibody-drug conjugates ("ADCs") where a payload is chemically attached to a targeting antibody.

Our most advanced product candidate, Vicineum, also known as VB4-845, is a locally-administered targeted fusion protein composed of an anti-epithelial cell adhesion molecule ("EpCAM") antibody fragment tethered to a truncated form of *Pseudomonas exotoxin A* for the treatment of high-risk non-muscle invasive bladder cancer ("NMIBC"). On December 6, 2019, we initiated our Biologics License Application ("BLA") submission for Vicineum to the United States Food and Drug Administration ("FDA") under Rolling Review. "Rolling Review" of the BLA enables individual modules to be submitted and reviewed on an ongoing basis, rather than waiting for all sections to be completed before submission. The submission consisted of Modules 1, 2, 4 and 5, with information amendments to be submitted to these modules throughout 2020. We anticipate completing Module 3 (Chemistry, Manufacturing and Controls ("CMC")) to finalize the BLA submission by the end of 2020. We may experience disruptions as a result of the COVID-19 pandemic that may impact our expected timeline to finalize the BLA submission, including manufacturing activities of our contract manufacturers due to limitations on work and travel imposed or recommended by federal or state governments, employers and others.

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 high-risk, bacillus Calmette-Guérin ("BCG")-unresponsive NMIBC (the "VISTA Trial"). As of the May 29, 2019 data cutoff date, we reported 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. The results were consistent with the results observed in the previously completed Phase 1 and Phase 2 clinical trials of Vicineum for the treatment of high-risk 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.

As of the end of April 2020, all patients have completed treatment in the VISTA Trial. The primary endpoints of the VISTA Trial are 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") subject 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 subject who completed the induction phase.*

Pooled Cohorts 1 and 2 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 subject 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 subject 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.

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 high-risk 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

In August 2018, we received Fast Track designation from the FDA for Vicineum for the treatment of high-risk NMIBC.

In May 2019, we met with the FDA for a Type C meeting for CMC and reached agreement with the FDA on the analytical comparability plan to be used to assess comparability between the drug supply used in clinical trials and the potential commercial drug supply to be produced by Fujifilm. We also confirmed with the FDA that, subject to final comparability data to be provided in the BLA submission, no additional clinical trials were deemed necessary to establish comparability.

In June 2019, we met with the FDA for a Type B Pre-BLA meeting regarding the approval pathway for Vicineum for the treatment of patients with high-risk, BCG-unresponsive NMIBC. At the meeting, we reached alignment with the FDA on an accelerated approval pathway for Vicineum along with Rolling Review. The FDA also indicated that the clinical data, nonclinical data, clinical pharmacology data, and the safety database were sufficient to support a BLA submission, and that no additional clinical trials were necessary for a BLA submission. Per the official FDA minutes received post-meeting, the FDA stated that the pre-licensing inspection may be completed at the time of process performance qualification manufacturing, which we believe will benefit the overall review timeline for the BLA. In addition, the FDA communicated that they expect that a meeting with the FDA's Oncologic Drugs Advisory Committee ("ODAC") will be required as part of the accelerated approval pathway. If Vicineum receives marketing approval for treatment of NMIBC, a post-marketing confirmatory trial will also be required.

In November 2019, we met with the FDA for a Type C meeting to discuss the details of a post-marketing confirmatory trial for Vicineum for the treatment of high-risk NMIBC. At that meeting, we reached agreement with the FDA that the post-marketing confirmatory trial for Vicineum will enroll BCG-refractory patients who have received less-than-adequate BCG, which is especially important in light of the ongoing BCG shortage. This represents a broader patient population than the BCG-intolerant population originally proposed. We anticipate that, if Vicineum is approved by the FDA, the initial indication will be for BCG-unresponsive patients who have received adequate BCG. If the post-marketing confirmatory trial is successful, it could result in an expanded label to include this additional population of patients who have received less-than-adequate BCG.

On December 4, 2019, we met with the FDA for a Type B pre-BLA meeting for CMC. At that meeting, we reached agreement with the FDA on the final content for Module 3 (CMC) of the BLA.

On December 6, 2019, we initiated our BLA submission for Vicineum to the FDA under Rolling Review. The submission consisted of Modules 1, 2, 4 and 5, with information amendments to be submitted to these modules throughout 2020. We anticipate completing Module 3 (CMC) to finalize the BLA submission in the second half of 2020.

On May 7, 2020, we received clinical Scientific Advice from the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA") stating that the Committee agreed that our nonclinical, clinical pharmacology and safety database are all sufficient to support a marketing authorization application ("MAA"). Furthermore, additional clinical trials were not requested by the CHMP in support of the MAA submission for Vicineum for the treatment of high-risk NMIBC. Based on the guidance received, we expect to submit the MAA for Vicineum for the treatment of high-risk NMIBC to the EMA in early 2021, with potential approval anticipated in early 2022. We expect to receive Scientific Advice from the CHMP on the CMC program for Vicineum at a later date.

On May 29, 2020, we received CMC Scientific Advice from the CHMP of the EMA, stating that the committee agreed that our comparability plan provides a strong analytical package, and no additional clinical trials to establish comparability are deemed necessary at this time. Furthermore, the CHMP agreed to accept the Good Manufacturing Practice ("GMP") inspections conducted by the FDA and will therefore not conduct an independent inspection of the manufacturing facilities.

On June 17, 2020, we were informed that the FDA has conditionally accepted the proprietary brand name VICINEUM™ for our product candidate, oportuzumab monatox. The name VICINEUM was developed in compliance with the FDA's final Guidance for Industry, Contents of a Complete Submission for the Evaluation of Proprietary Names and the FDA's draft Guidance for Industry, Best Practices in Developing Proprietary Name for Drugs. We believe VICINEUM is a proprietary

name with strong marketing potential that is also consistent with FDA's goal of preventing medication errors and potential harm to the public by ensuring that only appropriate proprietary names are approved for use. Final approval of the VICINEUM brand name is conditional on FDA approval of our product candidate, oportuzumab monatox. Based upon FDA feedback, we withdrew our previously submitted proposed brand name, VICINIUM®, from consideration due to potential for confusion with ammonium derivatives products with the "-ium" suffix as established by the United States Adopted Names Council.

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 GMP ("cGMP") run was completed at Fujifilm and all quality acceptance criteria were met. This supports 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 high-risk NMIBC. 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 has been completed and all quality acceptance criteria were met. In addition, the bulk drug substance from the Fujifilm pre-PPQ batch has been used to manufacture the first drug product PPQ batch by Baxter Oncology GmbH. Full quality release testing of the first drug product PPQ batch has been completed and is currently undergoing standard quality assurance review. On August 4, 2020, we completed validation studies for the drug substance PPQ batches. We also received the interim certificate of analysis to ship drug substance to Baxter to complete the next drug product PPQ run. Based on this progress, we expect to complete the manufacturing of the full drug product PPQ campaign for Vicineum in late-September 2020.

Joint Development

In June 2017, we entered into a Cooperative Research and Development Agreement ("CRADA") with the National Cancer Institute ("NCI") for the development of Vicineum in combination with AstraZeneca's immune checkpoint inhibitor durvalumab for the treatment of NMIBC. Under the terms of the CRADA, the NCI will conduct a Phase 1 clinical trial in patients with high-risk NMIBC to evaluate the safety, efficacy and biological correlates of Vicineum in combination with durvalumab. This Phase 1 clinical trial is open and is actively recruiting patients.

Vicineum has also been evaluated for the treatment of squamous cell carcinoma of the head and neck ("SCCHN"). Vicineum for the treatment of SCCHN had previously been designated as Proxinium™ to indicate its different fill volume and vial size as well as its different route for local administration via intratumoral injection. In addition to our locally-administered TFPTs, our pipeline also includes systemically-administered TFPTs that are built around our proprietary de-immunized variant of the plant-derived cytotoxin bouganin ("deBouganin"). One of these product candidates, VB6-845d, is a TFPT consisting of an EpCAM-targeting fragment antigen binding domain ("Fab") genetically linked to deBouganin, a novel plant derived cytotoxic payload that we have optimized for minimal immunogenic potential and is administered by intravenous infusion. We have deferred further development of Vicineum for the treatment of SCCHN and of VB6-845d in order to focus our efforts and our resources on our ongoing development of Vicineum for the treatment of high-risk NMIBC. We are also exploring collaborations for Vicineum for the treatment of SCCHN and for VB6-845d.

We maintain global development, marketing and commercialization rights for all of our TFPT-based product candidates. We intend to explore various commercialization strategies to market our approved products. If we obtain regulatory approval for Vicineum for the treatment of high-risk NMIBC, we intend to build a North American specialty urology sales force to market the product in the United States and Canada. Outside the United States and Canada, we will seek commercialization partners with urology expertise. We also own or exclusively license worldwide intellectual property rights for all of our TFPT-based product candidates, covering our key patents with protection into 2036.

License Agreement with Roche

In June 2016, we entered into a License Agreement with F. Hoffman-La Roche Ltd. and Hoffman-La Roche Inc. (collectively, "Roche") (the "License Agreement with Roche"), pursuant to which we granted Roche an exclusive, worldwide license, including the right to sublicense, to our patent rights and know-how related to our monoclonal antibody EBI-031 and all other IL-6 anti-IL antagonist monoclonal antibody technology owned by us (collectively, the "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 Licensed Intellectual Property that contains an IL-6 antagonist anti-IL monoclonal antibody ("Licensed Product") and pursue ongoing patent prosecution, at its cost. At the time of the License Agreement with Roche, EBI-031, which was derived using our previous AMP-Rx platform, was in pre-clinical development as an intravitreal injection for diabetic macular edema and uveitis.

Through June 30, 2020, we have received a total of $30.0 million in payments pursuant to the License Agreement with Roche, including a $7.5 million upfront payment in August 2016 and a $22.5 million milestone payment in September 2016 as a result of the investigational new drug ("IND") application for EBI-031 becoming effective. We are also entitled to receive up to an

additional $240.0 million upon the achievement of other specified regulatory, development and commercial milestones, as well as 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.

Liquidity and Going Concern

As of June 30, 2020, we had cash and cash equivalents of $37.7 million, net working capital (current assets less current liabilities) of $35.0 million and an accumulated deficit of $278.3 million. We incurred negative cash flows from operating activities of $37.5 million for the year ended December 31, 2019 and $18.3 million for the six months ended June 30, 2020. Since our inception, we have received no revenue from sales of our products, and we anticipate that operating losses will continue for the foreseeable future as we continue our ongoing Phase 3 VISTA Trial of Vicineum for the treatment of high-risk NMIBC and seek marketing approval from the FDA. 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, our License Agreement with Roche 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 our product candidates, including Vicineum for the treatment of high-risk NMIBC, and ultimately upon our ability to attain profitable operations. In order to commercialize our product candidates, including Vicineum for the treatment of high-risk 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 high-risk NMIBC, requires substantial working capital, and we expect to seek additional funds through equity or debt financings or through additional collaboration, licensing transactions or other sources. We may be unable to obtain equity or debt financings or enter into additional collaboration 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 and 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.

In December 2019, an outbreak of a novel strain of coronavirus ("COVID-19") was identified in Wuhan, China. This virus continues to spread globally, has been declared a pandemic by the World Health Organization and has spread to over 200 countries and territories, including the United States disproportionately. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to businesses and capital markets around the world. 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 $37.7 million as of June 30, 2020 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, and including the net proceeds of the $12 million upfront payment from our exclusive license agreement with Qilu Pharmaceutical Co. Ltd. ("Qilu") (the "Qilu License Agreement"), which we expect to receive by the end of 2020, we anticipate having sufficient cash and cash equivalents to fund our operations into the second quarter of 2021; 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, the ongoing COVID-19 pandemic 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

Research and Development

Research and development expenses consist primarily of costs incurred for the development of Vicineum for the treatment of high-risk 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; and
- expenses associated with regulatory activities.

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 high-risk 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 high-risk NMIBC compared to alternative treatments, including any standard of care;
- the market acceptance of Vicineum for the treatment of high-risk 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 high-risk NMIBC could mean a significant change in the costs and timing associated with the development of Vicineum for the treatment of high-risk NMIBC. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials or other testing beyond those that we currently contemplate will be required for the completion of clinical development of Vicineum for the treatment of high-risk 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 high-risk 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, and costs related to manufacturing or purchasing clinical trial materials and technology transfer, 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 high-risk NMIBC and other expenses by category. We have deferred further development of Vicineum for the treatment of SCCHN and VB6-845d in order to focus our efforts and our resources on our

ongoing development of Vicineum for the treatment of high-risk NMIBC. We expect our research and development expenses for Vicineum for the treatment of high-risk NMIBC will continue to increase during subsequent periods.

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,	
	2020	2019	2020	2019
Programs:				
Vicineum for the treatment of high-risk NMIBC	$ 3,135	$ 6,010	$ 10,499	$ 8,372
Total direct program expenses	3,135	6,010	10,499	8,372
Personnel and other expenses:				
Employee and contractor-related expenses	1,207	1,347	2,374	3,057
Platform-related lab expenses	35	132	80	413
Facility expenses	103	115	213	226
Other expenses	82	340	263	562
Total personnel and other expenses	1,427	1,934	2,930	4,258
Total Research and Development	**$ 4,562**	**$ 7,944**	**$ 13,429**	**$ 12,630**

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, patent, consulting and accounting services, commercial market research and United States pre-launch market readiness.

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

Other Income, Net

Other income, net consists primarily of interest income earned on cash and cash equivalents.

Our Results of Operations

Comparison of the Three Months ended June 30, 2020 and 2019

	Three Months ended June 30,		Increase/(Decrease)	
	2020	2019	Dollars	Percentage
	(in thousands, except percentages)			
Operating expenses:				
Research and development	$ 4,562	$ 7,944	$ (3,382)	(43) %
General and administrative	3,318	2,617	701	27 %
Change in fair value of contingent consideration	18,480	44,000	(25,520)	(58) %
Total operating expenses	26,360	54,561	(28,201)	(52) %
Income (Loss) from Operations	(26,360)	(54,561)	28,201	(52) %
Other income (expense):				
Other income, net	16	226	(210)	(93) %
Net Income (Loss) and Comprehensive Income (Loss)	**$ (26,344)**	**$ (54,335)**	**$ 27,991**	**(52) %**

Research and Development

Research and development expenses were $4.6 million for the three months ended June 30, 2020 compared to $7.9 million for the three months ended June 30, 2019. The decrease of $3.4 million was due primarily to decreased costs associated with technology transfer and manufacturing scale-up for commercial supply and timing of procurement of manufacturing consumables, in addition to lower employee compensation and lower clinical trial expenses as a result of our Phase 3 VISTA Trial winding down.

General and Administrative

General and administrative expenses were $3.3 million for the three months ended June 30, 2020 compared to $2.6 million for the three months ended June 30, 2019. The increase of $0.7 million was due primarily to increases in employee compensation, and legal and insurance costs, which were partially offset by reduced audit and professional fees.

Change in Fair Value of Contingent Consideration

The non-cash change in fair value of contingent consideration was an $18.5 million loss for the three months ended June 30, 2020 compared to a $44.0 million loss for the three months ended June 30, 2019. The increase in the fair value of contingent consideration of $18.5 million for the three months ended June 30, 2020 was attributable in part to changes in the competitive landscape for Vicineum. In addition, the estimated fair value of contingent consideration is also determined by applying appropriate discount rates to future cash outflows related to the contingent payment obligations, and these discount rates continue to remain high as a result of the extreme volatility of financial markets as global economies shut down in order to contain the spread of COVID-19. 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 increased from 11.8% as of December 31, 2019, to 17.9% of March 31, 2020 and then decreased to 14.5% as of June 30, 2020. The discount rate applied to the 2% royalty due on forecasted Vicineum revenues is derived from our estimated weighted-average cost of capital ("WACC"), and this WACC-derived discount rate increased from 5.6% as of December 31, 2019, to 14.7% as of March 31, 2020 and then decreased to 13.2% as of June 30, 2020. Therefore, the quarterly decrease in the applicable discount rates, as well as the change to the competitive landscape for Vicineum in the second quarter fo 2020, resulted in the $18.5 million increase in the estimated fair value of contingent consideration for the three months ended June 30, 2020.

The change in the fair value of contingent consideration was a $44.0 million loss for the three months ended June 30, 2019. During the quarter ended June 30, 2019, the Company reassessed the total addressable global market for NMIBC and determined that both the global market size and estimated potential Vicineum commercial net sales within the global NMIBC market were likely higher than the Company’s previous estimates. Specific drivers of the increased revenue estimates include the expectation that Vicineum could achieve peak market penetration earlier than previously estimated, and the expectation that Vicineum sales outside the United States could be two to three times the expected sales volumes in the United States. As contingent consideration incorporates a royalty rate of 2% on all commercial net sales reported through December 2033, an increase in expected future net sales correlates to an increase in the fair value of the Company’s potential contingent consideration. Accordingly, the Company’s contingent consideration at June 30, 2019 was adjusted to reflect the Company’s updated view of the NMIBC market and Vicineum’s potential sales volumes in that market. The loss in the three months ended

June 30, 2019 was therefore due to changes in assumptions related to increases in projected sales volumes in both the US and OUS markets compared to prior estimates.

Changes in forecast assumptions, including the probability of regulatory approvals and Vicineum pricing and sales volumes, as well as changes in the discount rates utilized based on prevailing market conditions, could result in materially different fair value estimates.

Other Income, Net

Other income, net was de minimus for the three months ended June 30, 2020 compared to $0.2 million for the three months ended June 30, 2019. The change of $0.2 million was due to lower interest income on lower cash balances used to fund current operations.

Comparison of the Six Months ended June 30, 2020 and 2019

	Six Months ended June 30,		Increase/(Decrease)	
	2020	2019	Dollars	Percentage
	(in thousands, except percentages)			
Operating expenses:				
Research and development	$ 13,429	$ 12,630	$ 799	6 %
General and administrative	6,766	5,672	1,094	19 %
Change in fair value of contingent consideration	(35,220)	43,000	(78,220)	(182) %
Total operating expenses	(15,025)	61,302	(76,327)	(125) %
Income (Loss) from Operations	15,025	(61,302)	76,327	(125) %
Other income (expense):				
Other income, net	195	487	(292)	(60) %
Net Income (Loss) and Comprehensive Income (Loss)	**$ 15,220**	**$ (60,815)**	**$ 76,035**	**(125) %**

Research and Development

Research and development expenses were $13.4 million for the six months ended June 30, 2020 compared to $12.6 million for the six months ended June 30, 2019. The increase of $0.8 million was due primarily to increased costs associated with technology transfer and manufacturing scale-up for commercial supply, timing of procurement of manufacturing consumables and professional fees in support of regulatory activities, partially offset by lower employee compensation and lower clinical trial expenses as a result of our Phase 3 VISTA Trial winding down.

General and Administrative

General and administrative expenses were $6.8 million for the six months ended June 30, 2020 compared to $5.7 million for the six months ended June 30, 2019. The increase of $1.1 million was due primarily to increases in employee compensation, and legal and insurance costs, which were partially offset by reduced professional fees and market research.

Change in Fair Value of Contingent Consideration

The non-cash change in fair value of contingent consideration was income of $35.2 million for the six months ended June 30, 2020 compared to a $43.0 million loss for the six months ended June 30, 2019. The decrease in the fair value of contingent consideration of $35.2 million for the six months ended June 30, 2020 was attributable to changes to the current competitive landscape offset by significantly higher discount rates as a result of financial market conditions as of June 30, 2020. The estimated fair value of contingent consideration are determined by applying appropriate discount rates to future cash outflows related to the contingent payment obligations, and these discount rates have increased significantly as a result of the extreme volatility of financial markets as global economies shut down in order to contain the spread of COVID-19. 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 increased from 11.8% as of December 31, 2019 to 14.5% as of June 30, 2020. The discount rate applied to the 2% royalty due on forecasted Vicineum revenues is derived from our estimated WACC, and this WACC-derived discount rate increased from 5.6% as of December 31, 2019 to 13.2% as of June 30, 2020. These increases in the applicable discount rates contributed significantly to the $35.2 million decrease in the estimated fair value of contingent consideration for the six months ended June 30, 2020.

The change in fair value of contingent consideration was a $43.0 million loss for the six months ended June 30, 2019. During the quarter ended June 30, 2019, the Company reassessed the total addressable global market for NMIBC and determined that both the global market size and estimated potential Vicineum commercial net sales within the global NMIBC market were likely higher than the Company's previous estimates. Specific drivers of the increased revenue estimates include the expectation that Vicineum could achieve peak market penetration earlier than previously estimated, and the expectation that Vicineum sales outside the United States could be two to three times the expected sales volumes in the United States. As contingent consideration incorporates a royalty rate of 2% on all commercial net sales reported through December 2033, an increase in expected future net sales correlates to an increase in the fair value of the Company's potential contingent consideration. Accordingly, the Company's contingent consideration at June 30, 2019 was adjusted to reflect the Company's updated view of the NMIBC market and Vicineum's potential sales volumes in that market. The loss in the six months ended June 30, 2019 was therefore due to changes in assumptions related to increases in projected sales volumes in both the US and OUS markets compared to prior estimates.

Changes in forecast assumptions, including the probability of regulatory approvals and Vicineum pricing and sales volumes, as well as changes in the discount rates utilized based on prevailing market conditions, could result in materially different fair value estimates.

Other Income, Net

Other income, net was $0.2 million for the six months ended June 30, 2020 compared to $0.5 million for the six months ended June 30, 2019. The decrease of $0.3 million was due primarily to lower interest income on lower cash balances used to fund current operations.

Liquidity and Capital Resources

Overview

As of June 30, 2020, we had cash and cash equivalents of $37.7 million, net working capital of $35.0 million and an accumulated deficit of $278.3 million. We incurred negative cash flows from operating activities of $37.5 million for the year ended December 31, 2019 and $18.3 million for the six months ended June 30, 2020. Since our inception, we have received no revenue from sales of our products, and we anticipate that operating losses will continue for the foreseeable future as we continue our ongoing Phase 3 VISTA Trial of Vicineum for the treatment of high-risk NMIBC and seek marketing approval from the FDA. 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 License Agreement with Roche and, to a lesser extent, from a collaboration.

In November 2019, we entered into an Open Market Sale Agreement [SM] (the "Sales Agreement") with Jefferies LLC ("Jefferies"), under which we may issue and sell shares of our common stock from time to time for an aggregate sales price of up to $35.0 million through Jefferies (the "ATM Offering"). Sales of common stock under the Sales Agreement are made by any method that is deemed to be an ATM offering as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended, including but not limited to sales made directly on or through the Nasdaq Global Market or any other existing trading market for our common stock. We have no obligation to sell any of our common stock and may at any time suspend offers under the Sales Agreement or terminate the Sales Agreement. Subject to the terms and conditions of the Sales 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. We incurred $0.2 million in legal, accounting and printing costs related to the commencement of the ATM Offering. For the six months ended June 30, 2020, we raised $8 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 under the ATM Offering, 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 $0.1 million and $0.2 million during the three and six months ended June 30, 2020, respectively.

In December 2019, an outbreak of COVID-19 was identified in Wuhan, China. This virus continues to spread globally, has been declared a pandemic by the World Health Organization and has spread to over 200 countries and territories, including the United States disproportionately. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to businesses and capital markets around the world. 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 $37.7 million as of June 30, 2020 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, and including the net proceeds of the $12 million upfront payment from the Qilu License Agreement which we expect to receive by the end of 2020, we anticipate having sufficient cash and cash equivalents to fund our operations into the second quarter of 2021; 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, the impact of the ongoing COVID-19 pandemic on the capital markets 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.

Nasdaq Notice

On March 2, 2020, we received written notice (the "Notice") from The Nasdaq Stock Market, LLC ("Nasdaq") indicating that we are not in compliance with the $1.00 minimum bid price requirement for continued listing on The Nasdaq Global Market, as set forth in Nasdaq Listing Rule 5450(a)(1).

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we had a period of 180 calendar days, or until August 31, 2020, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our common stock must meet or exceed $1.00 per share for a minimum of ten consecutive business days during this 180-day period.

On April 17, 2020, we received written notice from Nasdaq that the 180-day grace period to regain compliance with the $1.00 minimum bid price requirement has been extended in response to the COVID-19 pandemic and related extraordinary market conditions. As a result of this extension, we now have until November 12, 2020, to regain compliance with the minimum bid price requirement.

If we are not in compliance by November 12, 2020, we may be afforded a second 180 calendar day period to regain compliance. To qualify, we would be required to apply to have our common stock listed on the Nasdaq Capital Market and meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, except for the minimum bid price requirement, and will need to provide written notice to Nasdaq of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. If we do not qualify for the second compliance period or we fail to regain compliance during the second 180-day period, then Nasdaq will notify us of its determination to delist the common stock, at which point we would have an opportunity to appeal the delisting determination to a Nasdaq hearings panel.

We intend to monitor the closing bid price of our common stock and may, if appropriate, consider implementing available options to regain compliance with the minimum bid price requirement under the Nasdaq Listing Rules, including effecting a reverse stock split.

Funding Requirements

Our future success is dependent on our ability to develop our product candidates, including Vicineum for the treatment of high-risk NMIBC, and ultimately upon our ability to attain profitable operations. In order to commercialize our product candidates, including Vicineum for the treatment of high-risk 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 high-risk NMIBC, requires substantial working capital, and we expect to seek additional funds through equity or debt financings or through additional collaboration, licensing transactions or other sources. We may be unable to obtain equity or debt financings or enter into additional collaboration 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:

- continue our Phase 3 VISTA Trial for Vicineum for the treatment of high-risk NMIBC;
- seek marketing approvals for Vicineum for the treatment of high-risk NMIBC;

- establish 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 high-risk 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 high-risk NMIBC 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 high-risk NMIBC and our other product candidates;
- the cost and timing of any new clinical trials or studies of Vicineum for the treatment of high-risk NMIBC;
- the ongoing COVID-19 pandemic and its impact on our business;
- our ability to establish 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 sales, marketing and distribution capabilities for Vicineum for the treatment of high-risk 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 and comparable foreign regulatory authorities for Vicineum for the treatment of high-risk NMIBC, including the potential for the FDA or comparable foreign regulatory authorities, including Health Canada, 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 the License Agreement with Roche;
- the effect of competing technological and market developments; and
- the revenue, if any, received from commercial sales of Vicineum for the treatment of high-risk 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 and 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. 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 and 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, 2020 and 2019 (in thousands):

	Six Months ended June 30,	
	2020	2019
Net Cash Used in Operating Activities	$ (18,326)	$ (16,743)
Net Cash Used in Investing Activities	(8)	(43)
Net Cash Provided by Financing Activities	7,954	31,295
Net Increase (Decrease) in Cash, Cash Equivalents and Restricted Cash	**$ (10,380)**	**$ 14,509**

Net Cash Used in Operating Activities

Net cash used in operating activities was $18.3 million for the six months ended June 30, 2020 and consisted primarily of a 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 operating activities was $16.7 million for the six months ended June 30, 2019 and consisted primarily of a net loss of $60.8 million, adjusted for non-cash items, including share-based compensation of $0.7 million, a decrease in the fair value of contingent consideration of $43.0 million and a net increase in operating assets and liabilities of $0.3 million.

Net Cash Used in Investing Activities

Net cash used in investing activities was de minimis during each of the six months ended June 30, 2020 and 2019.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $8.0 million for the six months ended June 30, 2020 and consisted of net proceeds from the sale of common stock under the ATM Offering and sales of common stock under our 2014 ESPP.

Net cash provided by financing activities for the six months ended June 30, 2019 consisted primarily of (i) approximately $28 million in net proceeds from the June 2019 Financing, and (ii) $3.4 million in net proceeds from the exercise of warrants to purchase our common stock.

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; 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 high-risk 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, 2020 and December 31, 2019.

Goodwill

Goodwill on our consolidated balance sheet 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, 2020 and December 31, 2019.

Contingent Consideration

Contingent consideration on our consolidated balance sheet is the result of the 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 ("NOL") and research and development credit ("R&D 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, 2020 and December 31, 2019, we did not have any uncertain tax positions.

Research and Development Costs

Research and development activities are expensed in the period incurred. Research and development expenses consist of both internal and external costs associated with all basic research activities, clinical development activities and technical efforts required to develop a product candidate. Internal research and development consist primarily of personnel costs, including

salaries, benefits and share-based compensation, facilities leases, research-related overhead, pre-approval regulatory and clinical trial costs, manufacturing and other contracted services, license fees and other external costs.

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

Recently Issued Accounting Standards

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

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, 2020.

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 six months ended June 30, 2020, 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, 2020, other than as set forth below, there were no material changes to the "Risk Factors" included in our Annual Report on Form 10-K for the year ended December 31, 2019. 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.

The COVID-19 coronavirus could adversely impact our business.

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, the COVID-19 coronavirus has spread to multiple countries, including the United States, and has caused significant disruptions around the world. We may experience disruptions as a result of the COVID-19 pandemic that could severely impact our business, including:

- difficulties in raising additional capital needed to commercialize Vicineum for the treatment of high-risk NMIBC due to the slowing of our economy and near term and/or long term negative effects of the pandemic on the financial, banking and capital markets;
- delays in necessary interactions with regulators and other important agencies and contractors due to limitations in employee resources, travel restrictions or forced furlough of government employees;
- interruption of key business activities due to illness and/or quarantine of key individuals and delays associated with recruiting, hiring and training new temporary or permanent replacements for such key individuals, both internally and at our third party service providers;
- changes in local regulations as part of a response to the COVID-19 coronavirus outbreak that may require us to change the ways in which operate, which may result in unexpected costs;
- interruption of key commercialization, manufacturing, and related activities due to limitations on work and travel imposed or recommended by federal or state governments, employers and others; and
- delays or difficulties related to any future clinical trials that may be required, including delays in clinical trial sites receiving the supplies and materials needed to conduct clinical trials, difficulties in recruiting clinical site investigators and clinical site staff and difficulties in enrolling patients or treating patients in active trials.

The global outbreak of the COVID-19 coronavirus continues to rapidly evolve. The extent to which the COVID-19 coronavirus may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the virus. The full impact of the COVID-19 pandemic on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected time frame, will depend on future developments, including the duration and spread of the pandemic and related restrictions on travel and transports, and shelter-in-place, social distancing, and similar measures, all of which are uncertain and difficult to predict. The broad-based business and economic disruptions caused by the pandemic could materially affect our business condition, results of operations and cash flows, including our ability to raise additional capital.

The price of our common stock may fluctuate substantially.

The stock market in general has recently experienced relatively large price and volume fluctuations, particularly in response to the COVID-19 pandemic. If the market for stocks in our industry, or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business condition, results of operations and cash flows. In particular, the market prices of securities of smaller biotechnology companies have experienced dramatic fluctuations that often have been unrelated or disproportionate to the operating results of these companies. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock. In addition, price volatility may increase if the trading volume of our common stock declines.

We will depend on Qilu for the development and commercialization of Vicineum in the greater China region.

On July 30, 2020 we entered into the Qilu License Agreement with Qilu. Under the terms of the Qilu License Agreement, Qilu has an exclusive license to manufacture, develop and commercialize Vicineum in the greater China region, including mainland

China, Hong Kong, Macau and Taiwan. The timing and amount of any milestone and royalty payments we may receive under the Qilu License Agreement will depend in part on Qilu's efforts. We will also depend on Qilu to comply with all applicable laws relative to the manufacturing, development and commercialization of Vicineum in the greater China region. We do not control the individual efforts of Qilu, and any failure by Qilu to devote sufficient time and effort to the manufacture, development and commercialization of Vicineum could have a material adverse impact on our financial results and operations, such as by a failure of Qilu to meet its obligations to us, including for future milestone and royalty payments. In addition, if Qilu were to violate, or was alleged to have violated, any laws or regulations during the performance of its obligations for us, it is possible that we could suffer financial and reputational harm or other negative outcomes, including possible legal consequences.

Any termination, breach or expiration of the Qilu License Agreement could have a material adverse effect on our financial position by reducing or eliminating the potential for us to receive milestones and royalties. In such an event, we may be required to devote additional efforts and to incur additional costs associated with pursuing the manufacture, development and commercialization of Vicineum in greater China. If we breach our obligations under the Qilu License Agreement and are unable to cure such breach, Qilu may terminate the Qilu License Agreement and retain all rights to manufacture, develop and commercialize Vicineum in the greater China region with no obligation to make any additional milestone or royalty payments. Qilu has the right to receive a refund of all amounts paid to the Company in the event the Qilu License Agreement is terminated under certain circumstances. In addition, the royalty rate is subject to reduction under certain circumstances, including when there is no valid claim of a licensed patent for Vicineum in a particular region or no data or regulatory exclusivity for Viceneum in a particular region.

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, 2020.

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	Amended and Restated By-laws of Eleven Biotherapeutics, Inc. Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed on April 16, 2015 (File No. 001-36296).
3.3	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).
3.4	Amendment to 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	Amended and Restated Investors' Rights Agreement of Eleven Biotherapeutics, Inc. Incorporated by reference to Exhibit 4.2 to our Registration Statement on Form S-1 filed on December 30, 2013 (Reg. No. 333-193131).
4.3	Registration Rights Agreement, dated as of September 20, 2016 by and among Eleven Biotherapeutics, Inc. and the shareholders named therein. Incorporated herein by reference to Exhibit 4.1 to our Current Report on Form 8-K filed on September 21, 2016 (File No. 001-36296).
4.4	Form of Warrant to Purchase Common Stock, by and between Eleven Biotherapeutics, Inc. and the persons party thereto. Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed on December 1, 2014 (File No. 001-36296).
4.5	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).
4.6	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).
4.7	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).
4.8	Form of Warrant, Incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed with the SEC on June 19, 2019 (File No. 001-36296).
10.1	Open Market Sale Agreement SM, dated November 2019, by and between Sesen Bio, Inc. and Jeffries LLC. Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on November 29, 2019 (File No. 001-36296).
31.1*	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of the Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Interactive Data File (Form 10-Q for the Quarterly Period ended June 30, 2020 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 10, 2020

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, 2020 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 10, 2020

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, 2020 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 10, 2020

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, 2020 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 10, 2020

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, 2020 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 10, 2020

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