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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15 (d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 8, 2018

SESEN BIO, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36296
(Commission
File Number)

26-2025616
(I.R.S. Employer
Identification No.)

245 First Street, Suite 1800
Cambridge, MA
(Address of principal executive offices)

02142
(Zip Code)

Registrant's telephone number, including area code: (617) 444-8550

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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.

Item 2.02 - Results of Operations and Financial Condition.

On November 8, 2018, Sesen Bio, Inc. (the “Company”) announced its financial results for the quarter ended September 30, 2018. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information provided under this Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 - Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 8, 2018.

SIGNATURE

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 hereunto duly authorized.

Date: November 14, 2018

Sesen Bio, Inc.

By: /s/ Richard F. Fitzgerald
Richard F. Fitzgerald
Chief Financial Officer, Secretary and Treasurer



Sesen Bio Reports Third Quarter 2018 Financial Results and Planned VISTA Trial Readouts

Company Expects to Report Six-Month Update from VISTA Trial in December 2018; On-Track to Report 12-Month VISTA Trial Data in Mid-2019

CAMBRIDGE, Mass., Nov. 8, 2018 – Sesen Bio, Inc. (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of people with cancer, today reported operating results for the third quarter ended September 30, 2018 and recent highlights from its development program for Vicinium® for patients with high-grade non-muscle invasive bladder cancer (NMIBC).

“2018 has been a year of focused execution for Sesen Bio, led by the advancement of the Phase 3 program for Vicinium for patients with NMIBC,” said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. “NMIBC is a devastating disease and there remains just one recommendation for patients who do not respond or become refractory to today’s standard-of-care treatment: complete bladder removal. Our goal is to help save this essential organ and provide a meaningful treatment option for patients with BCG-unresponsive NMIBC. Our Phase 3 registration clinical trial is well-designed and preliminary data reported earlier this year suggest that Vicinium is active and has a favorable safety profile, consistent with our Phase 2 experience. We look forward to assessing six-month data from the trial next month and twelve-month data in mid-2019. If the VISTA Trial is successful, we believe Vicinium could change the treatment outlook for patients with NMIBC, bringing us closer to achieving our mission of saving and renewing the lives of patients with cancer.”

Recent Highlights

- In September 2018, at the Global Congress on Bladder Cancer 2018, Sesen Bio presented a biomarker update from its Phase 3 VISTA Trial data showing that all screened patient samples expressed EpCAM, the molecular target of Vicinium.
- In October 2018, the company entered into an agreement with FUJIFILM Diosynth Biotechnologies U.S.A., Inc. to provide supply services in support of the manufacturing of Vicinium for the treatment of high-grade NMIBC. The Agreement facilitates a transfer of manufacturing technology from Sesen Bio to Fujifilm.

Upcoming Events

- Sesen Bio anticipates reporting six-month data from the ongoing Phase 3 VISTA Trial in December 2018. A conference call will be held to review the data, with details to follow.

Third Quarter 2018 Financial Results

- **Cash Position:** Cash and cash equivalents were \$57.9 million as of September 30, 2018, compared to \$11.3 million as of September 30, 2017.
-



- **Revenue:** There was no revenue for the three-month periods ended September 30, 2018 and 2017, respectively, as no revenue triggering milestones were achieved during either period under the company's license agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (Roche).
- **R&D Expenses:** Research and development expenses were \$3.4 million for the three months ended September 30, 2018, compared to \$3.6 million for the same period in 2017. The decrease was due primarily to a reduction in Vicinium-related development expenses.
- **G&A Expenses:** General and administrative expenses were \$3.8 million for the three months ended September 30, 2018, compared to \$1.6 million for the same period in 2017. The increase was due primarily to an increase in professional fees as well as higher personnel-related expenses.
- **Net Loss:** Net loss was \$14.0 million, or \$0.18 per share, for the three months ended September 30, 2018, compared to net loss of \$9.1 million, or \$0.37 per share, for the same period in 2017. The increase was due primarily to the change in the fair value of contingent consideration and increased general and administrative expenses.
- **Financial Guidance:** Based on current operating plans, Sesen Bio believes it will have capital sufficient to fund its current operating plans into 2020.

About Sesen Bio

Sesen Bio, Inc. is a late-stage clinical company advancing targeted fusion protein therapeutics for the treatment of people with cancer. The company's lead program, Vicinium[®], also known as VB4-845, is currently in a Phase 3 registration trial, the VISTA Trial, for the treatment of high-grade non-muscle invasive bladder cancer. Twelve-month data from the trial are anticipated in mid-2019. Vicinium incorporates a tumor-targeting antibody fragment and a protein cytotoxic payload into a single protein molecule designed to selectively and effectively kill cancer cells, while minimizing toxicity to non-cancerous bladder cells. For more information, please visit the company's website at www.sesenbio.com.

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation and conduct of clinical trials, the possibility that the three-month or six-month data of the Phase 3 VISTA Trial are not indicative of final clinical results and final clinical trial results may not be positive with regard to the safety or efficacy of Vicinium[®], our ability to successfully develop our product candidates and complete our planned clinical programs, our ability to obtain marketing approvals for our product candidates, expectations regarding our ongoing clinical trials, availability and timing of data from clinical trials, whether interim results from a clinical trial will be predictive of the final results of the trial or results of early clinical studies will be indicative of the results of future studies, the adequacy of any clinical models,



expectations regarding regulatory approvals, expectations regarding the adequacy of our existing capital resources to fund our operations into 2020 and other factors discussed in the “Risk Factors” section of the Company’s Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other reports filed with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company’s views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company’s views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company’s views as of any date subsequent to the date hereof.

###

Contacts:

Monique Allaire, THRUST Strategic Communications
monique@thrustsc.com
781-631-0759

Alicia Davis, THRUST Strategic Communications
alicia@thrustsc.com
910-620-3302



SESEN BIO, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 57,856	\$ 14,680
Prepaid expenses and other current assets	1,529	301
Total current assets	59,385	14,981
Property and equipment, net	365	522
Restricted cash	20	10
Intangible assets	46,400	46,400
Goodwill	13,064	13,064
Other assets	61	120
Total assets	\$ 119,295	\$ 75,097
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,391	\$ 907
Accrued expenses	5,170	3,813
Total current liabilities	6,561	4,720
Other liabilities	311	215
Deferred tax liability	12,528	12,528
Contingent consideration	49,500	39,600
Stockholders' equity:		
Common stock	77	35
Additional paid-in capital	229,585	170,330
Accumulated deficit	(179,267)	(152,331)
Total stockholders' equity	50,395	18,034
Total liabilities and stockholders' equity	\$ 119,295	\$ 75,097

SESEN BIO, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)
(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Total revenue	\$ -	\$ -	\$ -	\$ 425
Operating expenses:				
Research and development	3,372	3,619	9,406	9,402
General and administrative	3,825	1,631	8,128	6,085
Loss from change in fair value of contingent consideration	7,200	3,900	9,900	7,600
Total operating expenses	14,397	9,150	27,434	23,087
Loss from operations	(14,397)	(9,150)	(27,434)	(22,662)
Other income, net	382	45	498	180
Net loss and comprehensive loss	\$ (14,015)	\$ (9,105)	\$ (26,936)	\$ (22,482)
Net loss per share—basic and diluted	\$ (0.18)	\$ (0.37)	\$ (0.48)	\$ (0.91)
Weighted-average number of common shares used in net loss per share—basic and diluted	77,030	24,691	56,526	24,663

