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, 2021

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

Delaware	**001-36296**	**26-2025616**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

245 First Street, Suite 1800 **Cambridge, MA**	**02142**
(Address of principal executive offices)	**(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))

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

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, 2021, Sesen Bio, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2021. 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.

Exhibit No.	Description
99.1	Press Release dated November 8, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 8, 2021

Sesen Bio, Inc.

By: /s/ Thomas R. Cannell, D.V.M.
Thomas R. Cannell, D.V.M.
President and Chief Executive Officer

Sesen Bio Reports Third Quarter 2021 Financial Results and Business Update

Participated in productive CMC Type A Meeting with the FDA

Maintained strong balance sheet with $175M in cash and cash equivalents as of September 30, 2021

CAMBRIDGE, Mass., Nov. 8, 2021 – Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today reported operating results for the third quarter ended September 30, 2021. During the quarter, the Company continued to work on its path forward to address chemistry, manufacturing, and controls (CMC) and clinical issues identified by the US Food & Drug Administration (FDA) in its Complete Response Letter (CRL) regarding the Company's Biologics License Application (BLA) for the Company's lead program, Vicineum™ for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC).

"Our team is making progress in advancing our dialogue with the FDA as we work toward potential resolution of the issues raised in the CRL for Vicineum, as demonstrated by our recent CMC Type A Meeting with the agency," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "We remain dedicated to saving and improving the lives of patients, and we look forward to continuing to work collaboratively with the FDA in our upcoming Clinical Type A Meeting, expected later this year, to carry our mission into the next stage of the regulatory process and beyond."

Regulatory Update

US:

- On August 13, 2021, Sesen Bio announced that it had received a CRL from the FDA **regarding its BLA for the Company's lead program, Vicineum for the treatment of** BCG-unresponsive NMIBC. The FDA determined that it could not approve the BLA for Vicineum in its present form and provided recommendations specific to additional clinical/statistical data and analyses, in addition to CMC issues pertaining to a recent pre-approval inspection and product quality.

- On October 29, 2021, Sesen Bio participated in a productive CMC Type A Meeting with the FDA (CMC Type A Meeting). The purpose of the meeting was to discuss questions related to CMC raised in the CRL. During the meeting, the Company and the FDA reviewed issues related to CMC to be further discussed during the review of the BLA for Vicineum upon potential resubmission. Key takeaways from the meeting include:
    - The FDA confirmed that Vicineum manufactured using the proposed commercial process is comparable to Vicineum used in prior clinical trials.
    - The FDA confirmed that Sesen Bio can utilize Vicineum manufactured during process validation for any potential future clinical trials needed to address issues raised in the CRL, and that these potential trials can proceed while addressing CMC issues.

- The Company believes it has a clear understanding of the path forward regarding CMC for resubmission of the BLA.

Sesen Bio is preparing for a separate Type A Meeting to discuss the recommendations specific to additional clinical/statistical data and analyses that the FDA raised in the CRL (Clinical Type A Meeting), which the Company expects to occur later this year. As previously disclosed, the Company anticipates needing to conduct an additional clinical trial with 90-100 patients, and will provide further guidance after the Clinical Type A Meeting.

The Company intends to use the information from the CMC Type A Meeting and the Clinical Type A Meeting to synchronize the regulatory reviews of Vicineum for the treatment of BCG-unresponsive NMIBC in the US and the European Union.

European Union:

- On August 20, 2021, Sesen Bio withdrew its marketing authorization application **(MAA) to the European Medicines Agency (EMA) for Vysyneum™**[1] for the treatment of BCG-unresponsive NMIBC. Given that certain components in the EMA's review are interrelated with elements of the FDA's decision to issue a CRL for Vicineum, the Company decided to pause its plans to pursue regulatory approval of Vysyneum in the European Union until there is more clarity from the FDA on next steps in the United States.

Other Business Updates

- On August 30, 2021, Sesen Bio approved a restructuring plan to reduce operating expenses, to better align its workforce with the needs of its business following receipt of the CRL from the FDA for Vicineum, and to better position the Company to execute on next steps as they are determined. The Company expects the plan to decrease its annual cash costs by approximately $5.7 million.

- The Company also implemented a program designed to retain employees as the Company continues to work toward the potential resolution of the issues detailed in the CRL. This retention program applies to all current employees except for the Chief Executive Officer.

Third Quarter 2021 Financial Results

- Cash Position: Cash, cash equivalents and restricted cash were $175.3 million as of September 30, 2021, compared to $55.4 million as of December 31, 2020.
- R&D Expenses: Research and development expenses for the third quarter of 2021 were $5.0 million compared to $10.2 million for the same period in 2020. The decrease of $5.2 million was primarily due to lower costs associated with technology transfer and manufacturing ($6.3 million), partially offset by increased license fees related to a milestone payment to the University of Zurich triggered by the completion of the BLA review by the FDA ($0.5 million), regulatory fees triggered by withdrawal of the Company's MAA to the EMA for Vysyneum ($0.3 million), and regulatory consultant fees ($0.2 million).
- G&A Expenses: General and administrative expenses for the third quarter of 2021 were $8.7 million compared to $4.1 million for the same period in 2020. The increase of $4.6 million was due to increases in sales and marketing expense for Vicineum pre-commercial

launch planning ($2.4 million), employee-related compensation driven by increased headcount as part of the commercial build ($1.3 million), and professional fees for accounting services ($0.2 million). The majority of these expenses were incurred prior to receipt of the CRL in August 2021. Additionally, an increase in legal fees was driven primarily by legal proceedings and the on-going independent review related to Vicineum ($0.9 million). Such increase was partially offset by certain other decreases in G&A expenses, none of which were individually material ($0.2 million).

- Restructuring Charges: Restructuring charges for the third quarter of 2021 were $5.5 million, which were due to one-time costs of approximately $2.7 million associated with the termination of certain contracts, and severance and other employee-related costs of approximately $2.8 million.
- Non-Cash Related Expenses:
    - Intangibles impairment charge for the third quarter of 2021 was $31.7 million. In light of the CRL, the Company performed an interim impairment test for In-Process Research and Development (IPR&D) assets, which resulted in the decrease in fair value of Vicineum's US rights.
    - The change in fair value of contingent consideration was a decrease of $114.0 million compared to an increase of $18.4 million for the same period in 2020. This was primarily due to management's assessment of a lower probability of regulatory success and a refinement of timelines given the CRL.
- Income Tax Benefit (Provision): Benefit from income tax was $8.6 million compared to $1.1 million tax expense for the same period in 2020. In connection with the intangibles impairment charge for the third quarter of 2021, the Company wrote-down the associated deferred tax liability by $8.6 million as a benefit.
- Net Income (Loss): Net income was $71.7 million, or $0.36 per basic and $0.36 per diluted share, for the third quarter of 2021, compared to net loss of $22.6 million, or $0.19 per basic and diluted share, for the same period in 2020. The change was primarily attributable to favorable changes in non-cash related expenses ($110.4 million, including tax benefit), offset by restructuring charges ($5.5 million) and lower license revenue recognized ($11.2 million).

[1] Vysyneum is the proprietary brand name that was conditionally approved by the EMA for oportuzumab monatox in the European Union.

About Vicineum™

Vicineum, a locally administered fusion protein, is Sesen Bio's lead product candidate being developed for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC). Vicineum is comprised of a recombinant fusion protein that targets epithelial cell adhesion molecule (EpCAM) antigens on the surface of tumor cells to deliver a potent protein payload, Pseudomonas Exotoxin A. Vicineum is constructed with a stable, genetically engineered peptide tether to ensure the payload remains attached to the antibody binding fragment until it is internalized by the cancer cell. This fusion protein design is believed to decrease the risk of toxicity to healthy tissues, thereby improving its safety. In prior clinical trials conducted by Sesen Bio, EpCAM has been shown to be overexpressed in NMIBC cells with minimal to no EpCAM expression observed on normal bladder cells. Sesen Bio is currently in the follow-up stage of a Phase 3 registration trial in the US for the treatment of BCG-unresponsive NMIBC. In February 2021, the FDA accepted the Company's BLA file for Vicineum for the treatment of BCG-unresponsive NMIBC and granted the application Priority Review with a target PDUFA date of August 18, 2021. On August 13, 2021, the Company received a Complete Response Letter (CRL) from the FDA regarding its BLA for Vicineum.

Additionally, Sesen Bio believes that cancer cell-killing properties of Vicineum promote an anti-tumor immune response that may potentially combine well with immuno-oncology drugs, such as checkpoint inhibitors. For this reason, the activity of Vicineum in BCG-unresponsive NMIBC is also being explored at the US National Cancer Institute in combination with AstraZeneca's immune checkpoint inhibitor durvalumab.

About Sesen Bio

Sesen Bio, Inc. is a late-stage clinical company advancing targeted fusion protein therapeutics for the treatment of patients with cancer. The Company's lead program, Vicineum™, also known as oportuzumab monatox, is currently in the follow-up stage of a Phase 3 registration trial for the treatment of BCG-unresponsive NMIBC. In February 2021, the FDA accepted the Company's BLA file for Vicineum for the treatment of BCG-unresponsive NMIBC and granted the application Priority Review with a target PDUFA date of August 18, 2021. On August 13, 2021, the Company received a CRL from the FDA regarding its BLA for Vicineum. Sesen Bio retains worldwide rights to Vicineum with the exception of Greater China, the Middle East and North Africa (MENA) and Turkey, for which the Company has partnered with Qilu Pharmaceutical, Hikma Pharmaceuticals and Eczacibasi Pharmaceuticals Marketing (EIP), respectively, for commercialization. Vicineum is a locally administered targeted fusion protein composed of an anti-EpCAM antibody fragment tethered to a truncated form of Pseudomonas Exotoxin A, which is being developed for the treatment of BCG-unresponsive NMIBC. For more information, please visit the Company's website at www.sesenbio.com.

COVID-19 Pandemic Potential Impact

Sesen Bio continues to monitor the rapidly evolving environment regarding the potential impact of the COVID-19 pandemic on the Company. The Company has not yet experienced any disruptions to our operations as a result of COVID-19, however, we are not able to quantify or predict with certainty the overall scope of potential impacts to our business, including, but not limited to, our ability to raise capital and, if approved, commercialize Vicineum. Sesen Bio remains committed to the health and safety of patients, caregivers and employees.

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," "expect," "intend," "may," "plan," "predict," "target," "potential," "will," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. For example, statements regarding the Company's ability to work towards potential resolution of the issues raised in the CRL for Vicineum, the Company's ability to improve the lives of patients by bringing new treatment options to market, the outcome and timing of the Company's Clinical Type A Meeting with the FDA to discuss Vicineum, the Company's intentions to use additional information from the CMC Type A Meeting and Clinical Type A Meeting to better synchronize the regulatory reviews of Vicineum in the US and in the European Union, the Company's ability to utilize Vicineum manufactured during process validation for any potential clinical trials needed to address issues raised in the CRL, and that any such potential clinical trials can proceed while addressing CMC issues, the Company's belief that it has a clear understanding of the path forward regarding CMC for resubmission of the BLA for Vicineum, the Company's expectations that it will need to conduct an additional clinical trial for Vicineum with 90-100 patients, the Company's plans to provide further guidance after the Clinical Type A Meeting, the Company's expectation that the restructuring plan will better position the Company to execute on next steps as they are determined, the Company's expectations to decrease annual cash costs as a result of

the restructuring plan, the Company's expectations regarding the ability of outside counsel and other experts to work expeditiously to conduct their review, determine the nature and scope of any issues identified, and advise on next steps, the impact of COVID-19 on the Company, including its ability to raise capital, and, if approved, its ability to commercialize Vicineum for the treatment of BCG-unresponsive NMIBC. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the risk that the FDA may not schedule the Clinical Type A Meeting with the Company within the currently expected timing, or at all, the risk that the Company may not be able to determine a path forward for the development of Vicineum for the treatment of BCG-unresponsive NMIBC, the risk that the Company may not resume its plans to pursue regulatory approval for Vicineum in the US or in the European Union, the risk that clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC, including any clinical trial needed to address issues raised in the CRL, may fail to demonstrate safety and efficacy to the satisfaction of the FDA or the EMA, or otherwise produce favorable results, the risk that the FDA may not approve the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC if the Company resubmits the BLA at a future time, the risk that the European Commission may not approve the Company's MAA for Vicineum for the treatment of BCG-unresponsive NMIBC if the Company resubmits the MAA at a future time, the risk that Vicineum for the treatment of BCG-unresponsive NMIBC may cause undesirable side effects, serious adverse events or have other properties that could delay or halt clinical trials, delay or prevent its regulatory approval by the FDA or the European Commission, limit the commercial profile of its labeling, if approved, or result in significant negative consequences following any marketing approval, the risk that the restructuring plan may not achieve its intended purposes, including positioning the Company to execute on next steps as they are determined, the risk that the Company's internal review may identify misconduct or other improper activities by the Company's employees or third-parties involved in the Company's clinical or regulatory activities related to Vicineum, 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.

Investors and Media Contact:
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SESEN BIO, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)
(Unaudited)

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

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

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