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): February 28, 2022

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 February 28, 2022, Sesen Bio, Inc. (the "Company") announced its financial results for the quarter and year ended December 31, 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 February 28, 2022
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: February 28, 2022

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 Fourth Quarter and Full-Year 2021 Financial Results and **Anticipated Regulatory Path Forward for the Company's Lead Product Candidate, Vicineum™**

Participated in productive CMC and Clinical Type A Meetings with the FDA in the fourth quarter

Type C Meeting with the FDA planned for March 28, 2022

Strong balance sheet with $163M in cash and cash equivalents as of December 31, 2021 expected to fund current operating plan into 2024

CAMBRIDGE, Mass., Feb. 28, 2022 – 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 fourth quarter and full year ended December 31, 2021. During the fourth quarter, the Company worked with the US Food and Drug Administration (FDA) to identify an anticipated regulatory path toward potential resubmission of a Biologics License Application (BLA) for the Company's lead program, Vicineum™ for the treatment of non-muscle invasive carcinoma in situ (CIS) of the bladder in patients previously treated with adequate or less than adequate bacillus Calmette-Guérin (BCG).[1]

"Our interactions with the FDA during the fourth quarter provided us further clarity on the steps required to resubmit a BLA for Vicineum and to bring a therapy to market that we believe has the potential to save and improve the lives of patients," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "We have bolstered our team's expertise in order to carry out that mission, and we look forward to executing our strategic priorities leading into, and coming out of, our upcoming Type C Meeting in March."

US Regulatory Update

- On October 29, 2021, Sesen Bio participated in a productive Chemistry, Manufacturing and Controls (CMC) Type A Meeting with the FDA. Following the meeting, the Company believes it has a clear understanding of what additional information regarding CMC is required for potential resubmission of a BLA. Other key takeaways from the meeting include the FDA confirming that:
    - Vicineum manufactured using the proposed commercial process is comparable to Vicineum used in prior clinical trials.
    - Sesen Bio can utilize Vicineum manufactured during process validation for any future clinical trials needed to address issues raised in the Complete Response Letter (CRL) regarding the BLA for Vicineum for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC), and that any of these future trials can proceed while addressing CMC issues raised in the CRL.

- On December 8, 2021, Sesen Bio participated in a productive Clinical Type A Meeting with the FDA. Following the meeting, the Company announced that it plans to conduct an additional Phase 3 clinical trial for potential resubmission of a BLA. Other key takeaways from the meeting include:

- The trial design may include a randomized clinical trial assessing the safety and efficacy of Vicineum compared to investigators' choice of intravesical chemotherapy.
- The trial may include both patients who have received adequate BCG and patients who have received less than adequate BCG.

The anticipated randomized trial design is aligned with guidance the Company has received from the European Medicines Agency, which may help to coordinate the regulatory paths forward for Vicineum in the US and the European Union. The Company was also encouraged by the FDA to submit the final results from the Phase 3 VISTA trial for Vicineum for the treatment of BCG-unresponsive NMIBC with a BLA resubmission.

- **On January 7, 2022, the FDA granted Sesen Bio's request for a Type C Meeting to** discuss the study protocol for an additional Phase 3 clinical trial that the Company plans to conduct for potential resubmission of a BLA for Vicineum for the treatment of non-muscle invasive carcinoma in situ (CIS) of the bladder in patients previously treated with adequate or less than adequate BCG. The Type C Meeting has been scheduled for March 28, 2022.

Other Business Updates

- On January 6, 2022, Sesen Bio disclosed that it achieved a $20 million milestone **payment pursuant to the Company's exclusive license agreement** (Roche License Agreement) with Roche for legacy Interleukin-6 (IL-6) antagonist antibody technology owned by Sesen Bio. Following this milestone payment, Sesen Bio has cumulatively received $50 million in upfront and milestone payments, with an additional $220 million in potential future milestone payments remaining under the Roche License Agreement.

- On February 25, 2022, the Board of Directors (Board) of Sesen Bio disclosed the completion of an independent internal review conducted by outside counsel with the assistance of subject matter experts (Review). The Review took place over the course of five months, involved full cooperation from the Company's management team, a review of more than 600,000 documents, and 39 interviews of current and former employees and consultants. As a result of the Review, the Board continues to fully support the Company's current management team and believes no changes or amendments relating to the Company's prior disclosures to the Securities and Exchange Commission (SEC) or FDA relating to Vicineum, the Phase 3 VISTA trial for Vicineum for the treatment of BCG-unresponsive NMIBC, or the Company's BLA for Vicineum are warranted. The Company intends to work cooperatively with the FDA in preparing for an additional Phase 3 clinical trial for Vicineum.

Fourth Quarter and Full-Year 2021 Financial Results

- Cash Position: Cash, cash equivalents and restricted cash were $162.6 million as of December 31, 2021, compared to $55.4 million as of December 31, 2020. The increase of $107.2 million was due primarily to net proceeds from at-the-market (ATM) offerings.
- R&D Expenses: Research and development expenses for the fourth quarter of 2021 were $7.0 million compared to $5.6 million for the same period in 2020. For the year ended December 31, 2021, research and development expenses were $25.3 million compared to $29.2 million for the same period in 2020. The full year decrease of $3.9 million was due primarily to lower costs associated with technology transfer and manufacturing ($7.4

million). This was partially offset by increases in employee-related compensation driven by increased headcount and the retention program implemented after receipt of the CRL in August 2021 ($2.1 million), regulatory and clinical consulting fees ($1.0 million) and certain other R&D expenses, none of which were individually material ($0.5 million).

- G&A Expenses: General and administrative expenses for the fourth quarter of 2021 were $8.6 million compared to $3.4 million for the same period in 2020. For the year ended December 31, 2021, general and administrative expenses were $29.4 million compared to $14.3 million for the same period in 2020. The full year increase of $15.1 million was due primarily to increases in employee-related compensation ($5.0 million), legal costs ($4.8 million), and marketing and commercial expenses driven by preparation for the commercial launch prior to receipt of the CRL ($4.1 million). Additionally, accounting services ($0.4 million), insurance expenses ($0.4 million), information technology expenses ($0.3 million) and other G&A expenses, none of which were individually material ($0.1 million), contributed to the increase.
- Restructuring Charge: Restructuring expenses were $5.5 million for the year ended December 31, 2021 compared to no restructuring expenses for the year ended December 31, 2020. The increase was due to one-time costs associated with the Restructuring Plan implemented in response to the CRL for severance and other employee-related costs ($2.8 million) and the termination of certain contracts ($2.7 million).
- Non-Cash Related Expenses:
    - Intangibles impairment charge for the year ended December 31, 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 $56.8 million for the year ended December 31, 2021 compared to a decrease of $11.2 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 $8.3 million for the year ended December 31, 2021 compared to $1.4 million tax expense for the same period in 2020. In connection with the intangibles impairment charge in 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 $8.9 million, or $0.04 per basic and per diluted share, for the fourth quarter of 2021, compared to net loss of $15.0 million, or $0.11 per basic and diluted share, for the same period in 2020. For the year ended December 31, 2021, net loss was $0.3 million, or $0.00 per share, compared to net loss of $22.5 million, or $0.19 per share, for the same period in 2020. The full year decrease of $22.2 million in net loss was due primarily to the $20 million milestone achieved by Roche initiating a Phase II clinical study pursuant to the Roche License Agreement.

[1]As per the 2018 FDA guidance on NMIBC, adequate BCG is defined as at least one of the following: (i) at least five of six doses of an initial induction course plus at least two of three doses of maintenance therapy or (ii) at least five of six doses of an initial induction course plus at least two of six doses of a second induction course.

About Vicineum™

Vicineum, a locally administered fusion protein, is Sesen Bio's lead product candidate being developed for the treatment of non-muscle invasive carcinoma in situ (CIS) of the bladder in patients previously treated with adequate or less than adequate BCG. 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 non-muscle invasive bladder cancer (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 clinical trial in the US for the treatment of BCG-unresponsive NMIBC. In February 2021, the FDA accepted the Company's Biologics License Application (BLA) file for Vicineum for the treatment of BCG-unresponsive NMIBC, granted Priority Review for the BLA and set a Prescription Drug User Fee Act (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. After meeting with the FDA, the Company plans to conduct an additional Phase 3 clinical trial for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG in connection with the potential resubmission of a BLA. 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 clinical 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, granted Priority Review for the BLA and set a PDUFA date of August 18, 2021. On August 13, 2021, the Company received a CRL from the FDA regarding its BLA for Vicineum. After meeting with the FDA, the Company plans to conduct an additional Phase 3 clinical trial for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG in connection with the potential resubmission of a BLA. 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 non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG. 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 its operations as a result of COVID-19, however, the Company is not able to quantify or predict with certainty the overall scope of potential impacts to its business, including, but not limited to, its ability to conduct an additional Phase 3 clinical trial for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, its ability to raise capital and, if approved, its ability to 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 anticipated regulatory path forward for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, the Company's belief that it has further clarity on the steps required to resubmit a BLA for Vicineum and to bring a therapy to market that it believes has the potential to save and improve the lives of patients, the Company's belief that it has a clear understanding of what additional information regarding CMC is required for potential resubmission of a BLA, the Company's ability to use Vicineum manufactured during process validation for any future clinical trials needed to address issues raised in the CRL regarding the BLA for Vicineum, the ability for future trials for Vicineum to proceed while the Company addresses CMC issues raised in the CRL, the Company's plans to conduct an additional Phase 3 clinical trial for potential resubmission of a BLA for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, the Company's belief that the trial design for an additional Phase 3 clinical trial may include the following elements: a randomized clinical trial assessing the safety and efficacy of Vicineum compared to investigators' choice of intravesical chemotherapy and inclusion of both patients who have received adequate BCG and patients who have received less-than-adequate BCG, the Company's expectation that the anticipated randomized trial design is aligned with guidance the Company has received from the European Medicines Agency (EMA), which may help to coordinate the regulatory paths forward for Vicineum in the US and the European Union, the Company's expectations to hold a Type C Meeting with the FDA to discuss study protocol for an additional Phase 3 clinical trial, any future payments to the Company pursuant to the Roche License Agreement including any future milestone payments and royalty payments, the Board's continued support for the Company's current management team, the Board's belief that no changes or amendments relating to the Company's prior disclosures to the SEC or FDA relating to Vicineum, the Phase 3 VISTA trial or the Company's BLA for Vicineum are warranted, the Company's intentions to work cooperatively with the FDA in preparing for an additional Phase 3 clinical trial for Vicineum, the impact of COVID-19 on the Company, including its ability to conduct an additional Phase 3 clinical trial for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, its ability to raise capital, and, if approved, its ability to commercialize Vicineum. 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 Type C Meeting may not enable the Company to align with the FDA on the protocol for an additional Phase 3 clinical trial of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously

treated with adequate or less than adequate BCG, the occurrence of any event, change or other circumstances that could give rise to the termination of the Roche License Agreement, the risk that the Company may not resume its plans to pursue regulatory approval for Vicineum in the US or the European Union, the impact of the completion of the Review, including any related investigations, reviews or proceedings, shareholder lawsuits or reputational harm, the risk that the Company may not be able to reach agreement with the FDA on the protocol for an additional Phase 3 clinical trial for Vicineum, or other issues related to preparing for an additional Phase 3 clinical trial for Vicineum, including difficulties with clinical trial site selection and obtaining clinical trial materials and supplies, the risk that clinical trials of Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG, including the additional 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 a BLA for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG if the Company resubmits a BLA at a future time, the risk that the European Commission may not approve the marketing authorization application (MAA) for Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG if the Company resubmits a MAA at a future time, the risk that Vicineum for the treatment of non-muscle invasive CIS of the bladder in patients previously treated with adequate or less than adequate BCG 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, 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:
Zane Goodwin, Senior Director, Corporate Development
ir@sesenbio.com

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

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 162,636	$ 52,389
Accounts receivable	21,011	-
Other receivables	3,482	-
Prepaid expenses and other current assets	18,476	7,478
Restricted cash	-	3,000
Total current assets	205,605	62,867
Non-current assets:		
Restricted cash	20	20
Property and equipment, net	43	123
Intangible assets	14,700	46,400
Goodwill	13,064	13,064
Long term prepaid expenses	7,192	-
Other assets	123	349
Total non-current assets	35,142	$ 59,956
Total Assets	$ 240,747	$ 122,823
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,853	$ 3,102
Accrued expenses	8,255	3,973
Deferred revenue	-	1,500
Contingent consideration	-	8,985
Other current liabilities	460	489
Total current liabilities	11,568	18,049
Non-current liabilities:		
Contingent consideration, net of current portion	52,000	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	57,469	114,001
Total liabilities	69,037	132,050
Stockholders' Equity (Deficit):		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized at December 31, 2021 and 2020; no shares issued and outstanding at December 31, 2021 and 2020	-	-
Common stock, $0.001 par value per share; 400,000,000 and 200,000,000 shares authorized at December 31, 2021 and 2020; 199,463,645 and 140,449,647 shares issued and outstanding at December 31, 2021 and 2020, respectively	199	140
Additional paid-in capital	487,768	306,554
Accumulated deficit	(316,257)	(315,921)
Total Stockholders' Equity (Deficit)	171,710	(9,227)
Total Liabilities and Stockholders' Equity	$ 240,747	$ 122,823

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

	Three Months ended December 31,		Twelve Months ended December	
	2021	2020	2021	2020
Revenue:				
License and related revenue	$ 20,000	$ -	$ 26,544	$ 11,236
Total revenue	20,000	-	26,544	11,236
Operating expenses:				
Research and development	7,039	5,566	25,312	29,191
General and administrative	8,597	3,421	29,393	14,302
Restructuring charge	6	-	5,528	-
Intangibles impairment charge		-	31,700	-
Change in fair value of contingent consideration	(4,600)	5,640	(56,840)	(11,180)
Total operating expenses	11,042	14,627	35,093	32,313
Income (Loss) from Operations	8,958	(14,627)	(8,549)	(21,077)
Other income (expense), net	(15)	(69)	(60)	125
Income (Loss) Before Taxes	8,944	(14,696)	(8,609)	(20,952)
Benefit (provision) for income taxes	-	(313)	8,273	(1,445)
Net Income (Loss) and Comprehensive Income (Loss) After Taxes	$ 8,944	$ (15,009)	$ (336)	$ (22,397)
Deemed dividend on adjustment of exercise price of certain warrants	$ -	$ -	$ -	$ (147)
Net income (loss) attributable to common stockholders - basic	$ 8,944	$ (15,009)	$ (336)	$ (22,544)
Net income (loss) attributable to common stockholders - diluted	$ 8,944	$ (15,009)	$ (336)	$ (22,544)
Net income (loss) per common share - basic	$ 0.04	$ (0.11)	$ (0.00)	$ (0.19)
Weighted-average common shares outstanding - basic	199,464	131,522	182,323	118,221
Net income (loss) per common share - diluted	$ 0.04	$ (0.11)	$ (0.00)	$ (0.19)
Weighted-average common shares outstanding - diluted	199,464	131,522	182,323	118,221