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): August 8, 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 August 8, 2022, Sesen Bio, Inc. (the "Company") announced its financial results for the quarter ended June 30, 2022. 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
10.1	Press Release dated August 8, 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: August 8, 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 Second Quarter 2022 Financial Results and Business Update

Company continues to assess potential strategic alternatives with the goal of maximizing shareholder value

Strong balance sheet of $161 million in cash, cash equivalents and marketable securities as of June 30, 2022

CAMBRIDGE, Mass., Aug. 8, 2022 – Sesen Bio (Nasdaq: SESN) today reported operating results for the second quarter ended June 30, 2022. During the quarter, the Company paused clinical development of its lead asset, Vicineum™ for the treatment of non-muscle invasive bladder cancer (NMIBC), and turned its primary focus to the assessment of potential strategic alternatives with the goal of maximizing shareholder value, which it believes will be complete by the end of 2022.

Business Updates

- **On July 11, 2022, Sesen Bio participated in a Type B Meeting with the US Food and Drug Administration (FDA)**. During the meeting, the Company and the FDA discussed outstanding items related to the Company's proposed protocol and statistical analysis plan design elements for an additional Phase 3 clinical trial for Vicineum for the treatment of NMIBC, which the Company had been evaluating for potential resubmission of a Biologics License Application for Vicineum.

- **On July 15, 2022, the Company executed an asset purchase agreement (the "Roche Asset Purchase Agreement") with Roche for legacy Interleukin-6 (IL-6) antagonist antibody technology owned by Sesen Bio.** Pursuant to the Roche Asset Purchase Agreement, Roche purchased all patent rights and know-how related to the monoclonal antibody EBI-031 and all other IL-6 antagonist monoclonal antibody technology owned by Sesen Bio for up to $70 million. This includes a $40 million payment made by Roche to the Company upon execution of the Roche Asset Purchase Agreement, and an additional $30 million payable to Sesen Bio upon Roche's initiation of a Phase 3 clinical trial with EBI-031 for a defined indication if initiated prior to December 31, 2026.

  As a result of the Roche Asset Purchase Agreement, the Company's previous license agreement with Roche dated June 10, 2016 (the "Roche License Agreement") was terminated. Prior to the termination of the Roche License Agreement, the Company had received $50 million in upfront and milestone payments from Roche.

- **On July 18, 2022, Sesen Bio announced that it had made the strategic decision to voluntarily pause further development of Vicineum in the US.** The decision was based on a thorough reassessment of Vicineum following recent discussions with the FDA, which included feedback that had implications on the size, timeline, and costs of the required additional Phase 3 clinical trial for the treatment of NMIBC. The Company continues to believe that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with a larger infrastructure, and as such, intends to seek a partner that can execute further development

to realize the full potential of Vicineum.

As a result of this decision, the Company has turned its primary focus to the careful assessment of strategic alternatives with the goal of maximizing shareholder value. As previously disclosed, the Company is actively working with an investment bank in the assessment process, and believes it will be complete by the end of 2022.

- **On July 20, 2022, Sesen Bio announced the approval of a restructuring plan to reduce operating expenses and to better align its workforce with the needs of its business following the decision to pause further development of Vicineum in the US.** Execution of the restructuring plan is expected to be substantially complete by the end of the fourth quarter of 2022.

Second Quarter 2022 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were $161.2 million as of June 30, 2022, compared to $151.1 million as of June 30, 2021.
- **R&D Expenses:** Research and development expenses for the second quarter of 2022 were $29.9 million compared to $7.2 million for the same period in 2021. The increase of $22.7 million was primarily due to the expense of prepaid balances related to consumables and manufacturing reservations, as the balances were evaluated and deemed to have no future value ($25.2 million). This increase was partially offset by lower costs associated with manufacturing ($2.5 million).
- **G&A Expenses:** General and administrative expenses for the second quarter of 2022 were $15.6 million compared to $6.8 million for the same period in 2021. The increase of $8.8 million was primarily due to an increase in legal expense ($10.3 million). This increase was driven by the preliminary settlement of the securities and derivative litigation, net of expected insurance recovery ($8.6 million), related legal fees ($0.9 million), legal fees related to the internal review ($0.3 million), and other legal expenses ($0.5 million). This increase was partially offset by a decrease in marketing and commercial expenses, which were incurred in the second quarter of 2021 in preparation for potential commercial launch of Vicineum but were discontinued as a result of the Complete Response Letter from the FDA received in August 2021 ($1.5 million).
- **Non-Cash Related Expenses:**
  - Intangibles impairment charge for the second quarter of 2022 was $27.8 million. In light of assumption changes in market share for Vicineum and the Company's strategic decision to voluntarily pause further development of Vicineum in the US, the Company performed an interim impairment test for In-Process Research and Development (IPR&D) assets and goodwill. This resulted in the full impairment of IPR&D assets ($14.7 million) and goodwill ($13.1 million).
  - The change in the fair value of contingent consideration was a decrease of $37.3 million for the second quarter of 2022, compared to an increase of $13.6 million for the same period in 2021. This decrease was due to a change in projected net sales for Vicineum subject to contingent consideration liability, which was based upon projected net sales in the Greater China region in the second quarter of 2022 compared to projected net sales worldwide in the second quarter of 2021.
- **Income Tax Benefit:** Benefit from income tax was $3.9 million for the second quarter of 2022. In connection with the intangibles impairment charge for the second quarter of 2022, the Company

wrote-down the associated deferred tax liability by $4.0 million as a benefit. This was partially offset by $0.1 million in income tax paid to foreign jurisdictions pursuant to the Company's license agreement with Qilu Pharmaceutical. There was no tax benefit or provision in the second quarter of 2021.

- **Net Loss:** Net loss was $32.0 million, or $0.16 per basic and per diluted share, for the second quarter of 2022, compared to net loss of $25.4 million, or $0.15 per basic and diluted share, for the same period in 2021. The change was primarily attributable to increases in R&D and G&A expenses ($31.5 million), primarily driven by the reduction of prepaid balances related to consumables and manufacturing reservations and the preliminary settlements of the securities and derivative litigation. Additionally, license and related revenue recognized decreased ($2.2 million). This was partially offset by favorable changes in non-cash related expenses of $27.0 million (including tax benefit).

About Vicineum™

Vicineum, a locally administered fusion protein, 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 has completed 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. On July 18, 2022, Sesen Bio announced that it had made the strategic decision to voluntarily pause further development of Vicineum in the US. The decision was based on a thorough reassessment of Vicineum, which included the incremental development timeline and associated costs, following recent discussions with the FDA. The Company continues to believe that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with a larger infrastructure, and as such intends to seek a partner for further development of Vicineum while it continues to assess potential strategic alternatives with the goal of maximizing shareholder value. 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 therapies, 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 focused on targeted fusion protein therapeutics for the treatment of patients with cancer. The Company's lead program, Vicineum™, also known as oportuzumab monatox, has completed 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. The Company intends to seek a partner for further development of Vicineum while it continues to assess potential strategic alternatives with the goal of maximizing shareholder value. Sesen Bio retains worldwide rights to Vicineum with the exception of Greater China, for which the Company has partnered with Qilu Pharmaceutical 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. 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 identify and assess potential strategic alternatives and seek a partner for the further development of 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," "would," "should," "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 plans to continue to assess potential strategic alternatives with the goal of maximizing shareholder value, the Company's belief that such process will be complete by the end of 2022, the Company's intentions to seek a partner for the further development of Vicineum, any future payments from Roche to the Company pursuant to the Roche Asset Purchase Agreement, the Company's belief that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with larger infrastructure, the expected timing for incurring costs associated with the restructuring plan, and the impact of COVID-19 on the Company, including its ability to identify and assess potential strategic alternatives and seek a partner for the further development of 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 Company may not be successful in identifying one or more strategic alternatives or a partner for the further development of Vicineum, the risk that the Company may not ultimately be successful in seeking such a partner or pursuing a strategic alternative that delivers the anticipated benefits or enhances shareholder value within the anticipated timeframe or at all, the risk that the Company's assessment of strategic alternatives or its intentions to seek a partner for the further development of Vicineum may cause the Company's stock price to fluctuate significantly, the risk that the Company's assessment of strategic alternatives or its intentions to seek a partner for the further development of Vicineum may be time consuming and involve the dedication of significant resources and may require the Company to incur significant costs and expenses, the risk that the Company's assessment of strategic alternatives or its intentions to seek a partner for the further development of Vicineum could negatively impact the Company's ability to attract, retain and motivate key employees and expose the Company to potential litigation in connection with such intentions to seek a partner or the process of assessing strategic alternatives or any resulting transaction, the risk that the Company may not be entitled to or receive any future payments from Roche pursuant to the Roche Asset Purchase

Agreement, the risk that the Company may not be able to implement the restructuring plan as currently anticipated or within the timing currently anticipated, unanticipated difficulties with preserving capital, unanticipated difficulties in terminating certain contracts and arrangements pursuant to the restructuring plan, unanticipated charges not currently contemplated that may occur as a result of the restructuring plan, 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:
Erin Clark, Vice President, Corporate Strategy & Investor Relations
ir@sesenbio.com

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

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 72,090	$ 162,636
Short term marketable securities	69,454	
Accounts receivable	73	21,011
Other receivables	14,046	3,482
Prepaid expenses and other current assets	757	18,476
Total current assets	156,420	205,605
Non-current assets:		
Restricted cash	30	20
Marketable securities	19,641	-
Property and equipment, net	30	43
Intangible assets	-	14,700
Goodwill	-	13,064
Long term prepaid expenses	-	7,192
Other assets	42	123
Total non-current assets	19,743	35,142
Total Assets	$ 176,163	$ 240,747
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,667	$ 2,853
Accrued expenses	29,851	8,255
Other current liabilities	487	460
Total current liabilities	32,005	11,568
Non-current liabilities:		
Contingent consideration	1,800	52,000
Deferred tax liability	-	3,969
Deferred revenue	-	1,500
Total non-current liabilities	1,800	57,469
Total liabilities	33,805	69,037
Stockholders' Equity:		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized at June 30, 2022 and December 31, 2021; no shares issued and outstanding at June 30, 2022 and December 31, 2021	-	-
Common stock, $0.001 par value per share; 400,000,000 shares authorized at June 30, 2022 and December 31, 2021; 199,463,645 shares issued and outstanding at June 30, 2022 and December 31, 2021	199	199
Additional paid-in capital	491,464	487,768
Other comprehensive loss	(281)	-
Accumulated deficit	(349,024)	(316,257)
Total Stockholders' Equity	142,358	171,710
Total Liabilities and Stockholders' Equity	$ 176,163	$ 240,747

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue:				
License and related revenue	$ -	$ 2,234	$ -	$ 6,544
Total revenue	$ -	$ 2,234	$ -	$ 6,544
Operating expenses:				
Research and development	$ 29,944	$ 7,228	$ 34,705	$ 13,306
General and administrative	15,589	6,805	24,564	12,098
Intangibles impairment charge	27,764	-	27,764	-
Change in fair value of contingent consideration	(37,300)	13,600	(50,200)	61,760
Total operating expenses	$ 35,997	$ 27,633	$ 36,833	$ 87,164
Loss from Operations	$ (35,997)	$ (25,399)	$ (36,833)	$ (80,620)
Other income (expense), net	162	(43)	191	(46)
Loss Before Taxes	$ (35,835)	$ (25,442)	$ (36,642)	$ (80,666)
Benefit for income taxes	3,875	-	3,875	(288)
Net Loss After Taxes	$ (31,960)	$ (25,442)	$ (32,767)	$ (80,954)
Net loss attributable to common stockholders - basic and diluted	$ (31,960)	$ (25,442)	$ (32,767)	$ (80,954)
Net loss per common share - basic and diluted	$ (0.16)	$ (0.15)	$ (0.16)	$ (0.49)
Weighted-average common shares outstanding - basic and diluted	199,464	175,393	199,464	166,264

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net loss	$ 31,960	$ 25,442	$ 32,767	$ 80,954
Unrealized loss on marketable securities	(281)	-	(281)	-
Total comprehensive loss	$ 32,241	$ 25,442	$ 33,048	$ 80,954