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): May 3, 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.

The information set forth in the second paragraph of Item 8.01 of this Current Report on Form 8-K is incorporated herein by reference.

Item 8.01 – Other Events.

On May 3, 2022, Sesen Bio, Inc., (the "Company") announced that it has initiated a process to review strategic alternatives with the goal of maximizing shareholder value. Potential strategic alternatives to be explored and evaluated during the review process may include the sale of the Company, a merger, acquisition or other business combination, a strategic partnership with one or more parties, or the licensing, sale or divestiture of some of the Company's proprietary technologies. Pending any decision to undertake any strategic alternative, the Company is continuing its development activities in accordance with its existing business strategy. A copy of the press release issued in connection with the announcement is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

As of March 31, 2022, the Company had $169.8 million in cash and cash equivalents, no outstanding debt and less than 0.2 million outstanding warrants. These amounts are preliminary and are subject to change upon completion of the Company's financial statements for the quarterly period ended March 31, 2022.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS:

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, statements regarding the Company's plans to review strategic alternatives with the goal of maximizing shareholder value, which may include the sale of the Company, a merger, acquisition or other business combination, a strategic partnership with one or more parties, or the licensing, sale or divestiture of some of the Company's proprietary technologies and the Company's plans to continue its development activities in accordance with its existing business strategy, which are based on the Company's current expectations and inherently involve significant risks and uncertainties. The Company's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, including the risk that the Company may not be successful in identifying one or more strategic alternatives or ultimately pursuing a strategic alternative that delivers the anticipated benefits or enhances shareholder value, the risk that the Company's exploration and evaluation of strategic alternatives or the public announcement thereof may be disruptive to the Company's business operations or cause the Company's stock price to fluctuate significantly, the risk that the Company's exploration and evaluation of strategic alternatives 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 exploration and evaluation of strategic alternatives could divert the attention of the Company's management and its board of directors from the existing business operations, negatively impact the Company's ability to attract, retain and motivate key employees, and expose the Company to potential litigation in connection with the process of exploring strategic alternatives or any resulting transaction, among other risks and uncertainties. A further description of the risks and uncertainties relating to the business of the Company is contained in the Company's most recent annual report on Form 10-K and the Company's quarterly reports on Form 10-Q, as well as any amendments thereto reflected in subsequent filings with the Securities and Exchange Commission. The Company undertakes no duty or obligation to update any forward-looking statements contained in this report as a result of new information, future events or changes in its expectations.

Item 9.01 - Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated May 3, 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: May 3, 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 Provides Strategic Update

CAMBRIDGE, Mass., May 3, 2022 – Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today announced that it has initiated a process to review strategic alternatives with the goal of maximizing shareholder value. Potential strategic alternatives to be explored and evaluated during the review process may include the sale of the Company, a merger, acquisition or other business combination, a strategic partnership with one or more parties, or the licensing, sale or divestiture of some of the Company's proprietary technologies. Pending any decision to undertake any strategic alternative, the Company is continuing its development activities in accordance with its existing business strategy.

"Our strong cash position provides us the opportunity to carefully consider a wide range of potential strategic alternatives designed to maximize shareholder value," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "As we assess potential external strategic alternatives, we continue to seek to create value through the development of Vicineum for the treatment of non-muscle invasive bladder cancer. We plan to request a meeting with the FDA in the coming weeks to align on the remaining outstanding items related to an additional Phase 3 clinical trial."

As of March 31, 2022, the Company had $169.8 million in cash and cash equivalents, no outstanding debt and fewer than 0.2 million outstanding warrants. These amounts are preliminary and are subject to change upon completion of the Company's financial statements for the quarterly period ended March 31, 2022.

About Vicineum™

Vicineum, a locally administered fusion protein, is Sesen Bio's lead product candidate being developed for the treatment of 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 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 NMIBC in connection with the potential resubmission of a BLA. The Company plans to request a meeting with the FDA in the coming

weeks to align on the remaining outstanding items related to the additional Phase 3 clinical trial. 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 NMIBC in connection with the potential resubmission of a BLA. The Company plans to request a meeting with the FDA in the coming weeks to align on the remaining outstanding items related to the additional Phase 3 clinical trial. 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 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 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 NMIBC, 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," "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 explore and evaluate potential strategic alternatives, which may include the sale of the Company, a merger, acquisition or other business combination, a strategic partnership with one or more parties, or the licensing, sale or divestiture of some of the Company's proprietary technologies, the Company's plans to continue its

development activities with its existing business strategy, the Company's plans to carefully consider a wide range of potential strategic alternatives designed to maximize shareholder value, the Company's plans to continue to seek to create value through the development of Vicineum for the treatment of NMIBC as it assesses potential external strategic alternatives, 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 NMIBC, 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 Company may not be successful in identifying one or more strategic alternatives or ultimately pursuing a strategic alternative that delivers the anticipated benefits or enhances shareholder value, the risk that the Company's exploration and evaluation of strategic alternatives or the public announcement thereof may be disruptive to the Company's business operations or cause the Company's stock price to fluctuate significantly, the risk that the Company's exploration and evaluation of strategic alternatives 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 exploration and evaluation of strategic alternatives could divert the attention of the Company's management and its board of directors from the existing business operations, negatively impact the Company's ability to attract, retain and motivate key employees, and expose the Company to potential litigation in connection with the process of exploring strategic alternatives or any resulting transaction, the risk that the Company may not resume its plans to pursue regulatory approval for Vicineum for the treatment of NMIBC, the risk that the Company may not be able to align with the FDA on the remaining outstanding items related to the additional Phase 3 clinical trial for Vicineum for the treatment of NMIBC, or other issues related to preparing for the 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 NMIBC, 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 European Medicines Agency, or otherwise produce favorable results, 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