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

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**FORM 8-K**

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

**Date of Report (Date of earliest event reported): July 18, 2022**

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

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**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.)

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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:

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- 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 July 18, 2022, Sesen Bio, Inc. (the “Company”) announced that it has made the strategic decision to voluntarily pause further development in the US of its lead asset, Vicineum™. The decision was based on a thorough reassessment of Vicineum, which included the incremental development timeline and associated costs for an additional Phase 3 clinical trial for the treatment of non-muscle invasive bladder cancer, following recent discussions with the US Food & Drug Administration. This decision enables the Company to conserve cash while it continues to assess potential strategic alternatives with the goal of maximizing shareholder value. Additionally, the Company intends to seek a partner for the further development of Vicineum. 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 June 30, 2022, the Company had approximately \$161.2 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 June 30, 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 continue to assess potential strategic alternatives with the goal of maximizing shareholder value and the Company’s intentions to seek a partner for the further development of Vicineum, 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 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 be disruptive to the Company’s business operations or 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, 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.

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<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release dated July 18, 2022</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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: July 18, 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 Announces Strategic Decision to Pause Clinical Development of Vicineum™ in the US

*Company intends to seek a partner for further development of Vicineum*

*Sesen Bio continues to focus on the assessment of potential strategic alternatives*

**CAMBRIDGE, Mass., Jul. 18, 2022** – Sesen Bio (Nasdaq: [SESN](#)) today announced that it has made the strategic decision to voluntarily pause further development in the US of its lead asset, Vicineum. The decision was based on a thorough reassessment of Vicineum, which included the incremental development timeline and associated costs for an additional Phase 3 clinical trial for the treatment of non-muscle invasive bladder cancer (NMIBC), following recent discussions with the US Food & Drug Administration (FDA). This decision enables Sesen Bio to conserve cash while it continues to assess potential strategic alternatives with the goal of maximizing shareholder value. Additionally, the Company intends to seek a partner for the further development of Vicineum.

“We have had four productive meetings with the FDA since August 2021 and we believe we have a full understanding of the FDA’s evolving position and guidance on the following variables: accelerated versus standard approval, single-arm versus randomized controlled trials, comparative versus non-comparative efficacy endpoints, and adequate versus less-than-adequate BCG patient populations,” said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. “We have also recently observed an evolution of the current treatment paradigm in NMIBC, with substantial uptake of intravesical chemotherapy (monotherapy and combination therapy) during the ongoing BCG shortage. In assessing the impact of the regulatory and commercial landscape, we have made the decision to pause the clinical development of Vicineum.”

Dr. Cannell continued, “We continue to believe that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with larger infrastructure, and as such, we intend to find a partner that can execute further development to realize the full potential of Vicineum. We now turn our primary focus to the careful assessment of strategic alternatives, which we hope to have complete by the end of the year.”

As of June 30, 2022, the Company had \$161.2 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 June 30, 2022.

### **About Vicineum™**

Vicineum, a locally administered fusion protein, is Sesen Bio’s lead product candidate 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

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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 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. 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. 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, 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. For more information, please visit the Company's website at [www.sesensbio.com](http://www.sesensbio.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, seek a partner for the further development of Vicineum or raise capital. Sesen Bio remains committed to the health and safety of patients, caregivers and employees.

#### **Cautionary Note on Forward-Looking Statements**

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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 ability to conserve cash while it continues to assess potential strategic alternatives with the goal of maximizing shareholder value, the Company's intentions to seek a partner for the further development of Vicineum, the Company's belief that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with larger infrastructure, the Company's expectation that it will complete its assessment of potential strategic alternatives by the end of the year, and the impact of COVID-19 on the Company, including its ability to identify and assess potential strategic alternatives, seek a partner for the further development of Vicineum or raise capital. 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 be disruptive to the Company's business operations or 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, 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](mailto:ir@sesenbio.com)

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