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): October 12, 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 7.01 – Regulation FD Disclosure.

On October 12, 2021, Sesen Bio, Inc. (the "Company") issued a press release announcing the expansion of its chemistry, manufacturing, and control ("CMC") and clinical development teams with the hiring of Eun Jang as Senior Director, Analytical Sciences, and Chèrie Kaefring as Director, Clinical Operations. The addition of these new team members demonstrates Sesen Bio's strong commitment to and continued focus on the development of Vicineum™ for the treatment of BCG-unresponsive non-muscle invasive bladder cancer ("NMIBC").

The information furnished in this Item 7.01, including the press release attached as Exhibit 99.1, shall not be deemed to be "filed" for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of such section, nor shall such information be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

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 commitment to and continued focus on the development of Vicineum for the treatment of BCG-unresponsive NMIBC, 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 resume its plans to pursue regulatory approval for Vicineum for the treatment of BCG-unresponsive NMIBC in the US or Europe, the risk that clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC may fail to demonstrate safety and efficacy to the satisfaction of the FDA or the European Medicines Agency ("EMA"), or otherwise produce favorable results, the risk that the FDA may not approve the Biologics License Application ("BLA") for Vicineum for the treatment of BCG-unresponsive NMIBC if the Company resubmits the BLA at a future time, the risk that the EMA may not approve the Company's marketing authorization application ("MAA") for Vicineum for the treatment of BCG-unresponsive NMIBC if the Company resubmits the MAA at a future time, and 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 EMA, limit the commercial profile of its labeling, if approved, or result in significant negative consequences following any marketing approval, 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 October 12, 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: October 12, 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 Expands CMC and Clinical Teams

CAMBRIDGE, Mass., Oct. 12, 2021 – Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today announced the expansion of its chemistry, manufacturing, and control (CMC) and clinical development teams with the hiring of Eun Jang as Senior Director, Analytical Sciences, and Chèrie Kaefring as Director, Clinical Operations. The addition of these new team members demonstrates Sesen Bio's strong commitment to and continued focus on the development of Vicineum™ for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC).

"I am delighted to welcome Eun and Chèrie to Sesen Bio to further strengthen our capabilities across our CMC and clinical teams," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "Their deep clinical and analytical expertise is the right match for our CMC and clinical needs as we chart our path forward in consultation with regulators. I am confident Eun and Chèrie will each make valuable contributions to Sesen Bio and to our mission of saving and improving the lives of patients."

These hirings come as Sesen Bio is preparing for CMC and clinical Type A meetings with the US Food and Drug Administration (FDA) for Vicineum™. The Company has submitted a request for the CMC Type A meeting, which is anticipated to occur at the end of October, and expects the clinical Type A meeting to occur later in the fourth quarter of 2021.

In connection with these hirings, non-statutory stock options were or will be granted. Under such grants, a combined total of up to 122,500 shares of Sesen Bio common stock are purchasable upon vesting of the stock options within each option's ten-year term. Each of the stock options vests over a four-year period, with one quarter of the underlying shares vesting on the first anniversary of the date of grant, and an additional 6.25% of the underlying shares vesting at the end of each successive three-month period following the one-year anniversary of the date of grant, subject in each case to the employee's continued service with Sesen Bio.

Ms. Jang's non-statutory stock option was granted on October 11, 2021 and Ms. Kaefring's non-statutory stock option will be granted on October 25, 2021, and each such stock option has an exercise price equal to the closing price per share of Sesen Bio's common stock on The Nasdaq Global Market on the date of the grant. These options are being granted outside of the Company's 2014 Stock Incentive Plan and as a material inducement to employment in accordance with Nasdaq Listing Rule 5635(c)(4).

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 immunooncology 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 non-muscle invasive bladder cancer (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. 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 expectations, commitment to and continued focus on development of Vicineum for the treatment of BCG-unresponsive NMIBC, the Company's preparations for CMC and clinical Type A meetings with the FDA to discuss next steps for Vicineum for the treatment of BCG-unresponsive NMIBC, the Company's expectations regarding the timing of the CMC Type A meeting, the Company's expectations regarding the timing of the clinical Type A meeting with the FDA to discuss Vicineum for the treatment of BCG-unresponsive NMIBC, 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 Type A meetings with the Company within the currently expected timing, or at all, the risk that the Company may not resume its plans to pursue regulatory approval for Vicineum in the US or Europe, the risk that clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC may fail to demonstrate safety and efficacy to the satisfaction of the FDA or the European Medicines Agency (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 EMA may not approve the Company's marketing authorization application (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 EMA, 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.

Contact:
Erin Clark, Vice President, Corporate Strategy & Investor Relations
ir@sesenbio.com