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): November 1, 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 8.01 – Other Events.

On November 1, 2021, Sesen Bio, Inc. (the "Company") issued a press release announcing that on October 29, 2021 it participated in a productive Type A Meeting with the U.S. Food and Drug Administration ("FDA"). The purpose of the meeting was to discuss questions related to Chemistry, Manufacturing and Controls raised in the FDA's Complete Response Letter regarding the Company's Biologics License Application for Vicineum™ for the treatment of BCG-unresponsive non-muscle invasive bladder cancer.

A copy of the press release is attached as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01 - Financial Statements and Exhibits.
(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated November 1, 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: November 1, 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 Announces Productive CMC Type A Meeting with the FDA

Vicineum™ manufactured using the proposed commercial process is comparable to Vicineum used in prior clinical trials

CAMBRIDGE, Mass., Nov. 1, 2021 – Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today announced that on October 29, 2021, the Company participated in a productive Type A Meeting with the US Food and Drug Administration (FDA). The purpose of the meeting was to discuss questions related to Chemistry, Manufacturing and Controls (CMC) raised in the FDA's Complete Response Letter (CRL) regarding the Company's Biologics License Application (BLA) for Vicineum for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (CMC Type A Meeting).

During the CMC Type A Meeting, the Company and the FDA reviewed issues related to CMC to be further discussed during the review of the BLA for Vicineum upon potential resubmission. The Company believes it has a clear understanding of what additional information regarding CMC is required for resubmission of the BLA.

Additionally, although not an issue raised in the CRL, the FDA confirmed that Vicineum manufactured using the proposed commercial process is comparable to Vicineum used in prior clinical trials. The FDA also confirmed that Sesen Bio can utilize Vicineum manufactured during process validation for any potential future clinical trials needed to address issues raised in the CRL, and that these potential trials can proceed while addressing CMC issues.

"We are pleased by the collaborative dialogue with the FDA during our CMC Type A Meeting," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "Our team looks forward to continued progress as we prepare for the Clinical Type A Meeting, and we remain committed to working diligently to fulfill our mission of saving and improving the lives of patients by bringing new treatment options to market."

As previously disclosed, Sesen Bio is preparing for a separate Type A Meeting to discuss the recommendations specific to additional clinical/statistical data and analyses that the FDA raised in the CRL (Clinical Type A Meeting), which the Company expects to occur later this year. The Company intends to use the information from the CMC Type A Meeting and the Clinical Type A Meeting to synchronize the regulatory reviews of Vicineum for the treatment of BCG-unresponsive NMIBC in the US and the European Union.

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 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 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 belief that it has a clear understanding of what additional information regarding CMC is required for resubmission of the BLA for Vicineum, the Company's ability to utilize Vicineum manufactured during process validation for any potential clinical trials needed

to address issues raised in the CRL, and that any such potential clinical trials can proceed while addressing CMC issues, the Company's continued progress while it prepares for the Clinical Type A Meeting expected later this year, the Company's commitment to working diligently to fulfil its mission of saving and improving the lives of patients by bringing new treatment options to market, the Company's intentions to use additional information from the CMC Type A Meeting and Clinical Type A Meeting to synchronize the regulatory reviews of Vicineum in the US and in the European Union, 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 the Clinical Type A Meeting with the Company within the currently expected timing, or at all, the risk that the Company may not be able to determine a path forward for the development of Vicineum for the treatment of BCG-unresponsive NMIBC after any such Clinical Type A Meeting or in the future, the risk that the Company may not resume its plans to pursue regulatory approval for Vicineum in the US or in the European Union, the risk that clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC, including any 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 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 European Commission may not approve the Company's 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 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.

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