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 26, 2020

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 October 26, 2020, Sesen Bio, Inc. (the "Company") issued a press release announcing that the Company has completed a successful pre-submission meeting with the European Medicines Agency for Vicineum™, the Company's lead product candidate, confirming the pathway to the Company's planned marketing authorization application ("MAA") submission for Vicineum in early 2021.

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

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS:

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, expectations regarding the timing of the Company's planned MAA submission for Vicineum. These forward-looking statements 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. 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 SEC. 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 26, 2020

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 26, 2020

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 Successful Pre-Submission Meeting with the European Medicines Agency for Vicineum™

Meeting outcome confirms the Company's pathway to a planned MAA submission for Vicineum in early 2021 with anticipated approval in early 2022

CAMBRIDGE, Mass., October 26, 2020 – 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 completed a successful pre-submission meeting with the European Medicines Agency ("EMA") for Vicineum[1] for the treatment of BCG-unresponsive non-muscle invasive bladder cancer ("NMIBC") in Europe.

During the meeting, the EMA addressed product-specific, legal, regulatory and scientific topics related to Vicineum. The information and insights gained from the meeting will help to facilitate the validation of the Marketing Authorization Application ("MAA") and support a smooth evaluation. The agency also provided guidance on various administrative topics which helps to clarify the regulatory path forward.

"We are very pleased to be managing the regulatory process with the EMA efficiently and effectively despite the pandemic. We have conducted productive virtual interactions allowing us to stay on track for regulatory filings in Europe," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "Europe represents one of the largest regions in terms of unmet need for patients with NMIBC, and we appreciate the agency's guidance and confidence in Sesen Bio to pursue an MAA submission for approval of Vicineum."

This successful pre-submission meeting with the EMA follows the critical milestone of written notice from the EMA that Vicineum has received confirmation of eligibility to file an MAA under the agency's centralized procedure. Confirmation of eligibility was given in response to the submission of a letter of intent, which notified the EMA that Sesen intended to file an MAA.

The success of the pre-submission meeting, in addition to the receipt of centralized procedure eligibility confirmation from the EMA, are significant milestones toward the Company's regulatory path forward in Europe and reaffirms the Company's intent to complete all necessary pre-submission activities with the EMA by the end of 2020.

[1]The proprietary brand name, Vicineum is a corporate trademark which has been conditionally approved by the FDA. Final approval of the Vicineum brand name is conditional on FDA approval of the Company's product candidate, oportuzumab monatox. Sesen Bio is currently going through the tradename approval process in Europe for oportuzumab monatox.

About Vicineum™

Vicineum, a locally administered fusion protein, is Sesen Bio's lead product candidate currently in the follow-up stage of a Phase 3 registration trial for the treatment of high-risk, BCG-unresponsive NMIBC. In December 2019, the Company initiated the Biologics License Applictation ("BLA") submission for Vicineum to the FDA under Rolling Review. 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 until it is internalized by the cancer cell, which 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 conducting the Phase 3 VISTA trial, designed to support the registration of Vicineum for the treatment of high-risk NMIBC in patients who have previously received a minimum of two courses of bacillus Calmette-Guérin ("BCG") and whose disease is now BCG-unresponsive. 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. 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 Non-Muscle Invasive Bladder Cancer

There are approximately 440,000 new cases of bladder cancer each year globally, and approximately 80 percent of patients have non-muscle invasive bladder cancer ("NMIBC"). In NMIBC, cancer cells are in the lining of the bladder or have grown into the lumen of the bladder but have not spread into muscle or other tissue. NMIBC primarily affects men and is associated with carcinogen exposure. Initial treatment includes surgical resection; however, there is a high rate of recurrence and more than 60 percent of all patients diagnosed with NMIBC will receive bacillus Calmette-Guérin ("BCG") immunotherapy. While BCG is effective in many patients, challenges with tolerability have been observed and many patients will experience recurrence of disease. Additionally, there is an ongoing chronic, global shortage of BCG, which puts a tremendous pressure on doctors, patients and the FDA. If BCG is not effective or a patient can longer receive BCG, the recommended option for treatment is radical cystectomy, the complete removal of the bladder.

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 VB4-845, is currently in a Phase 3 registration trial for the treatment of high-risk, BCG-unresponsive non-muscle invasive bladder cancer (NMIBC). In December 2019, the Company initiated the BLA submission for Vicineum to the FDA under Rolling Review. 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 the treatment of high-risk NMIBC. For more information, please visit the company's website at www.sesenbio.com.

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," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-

looking statements as a result of various important factors, including: our ability to successfully develop our product candidates and complete our planned clinical programs, expectations regarding the timing of the submission of our MAA for Vicineum to the EMA, expectations regarding the timing of potential approval of our MAA submission by the EMA, expectations regarding the projected market opportunity for Vicineum, expectations regarding the completion of all necessary pre-submission activities with the EMA, our expectations regarding approval of the Vicineum brand name, our ability to obtain marketing approvals for our product candidates, 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:
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