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): February 16, 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 February 16, 2021, Sesen Bio, Inc. (the "Company") announced that the U.S. Food and Drug Administration ("FDA") has accepted for filing the Company's Biologic License Application ("BLA") for Vicineum™, for the treatment of BCG-unresponsive non-muscle invasive bladder cancer, and granted the application Priority Review. With Priority Review, the anticipated target Prescription Drug User Fee Act ("PDUFA") date for a decision on the BLA is August 18, 2021. In addition, the FDA stated that it is not currently planning to hold an advisory committee meeting to discuss the BLA for Vicineum.

A copy of the press release is being filed 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 February 16, 2021

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: February 16, 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 FDA Acceptance and Priority Review of its Biologics License Application for Vicineum™

FDA stated it is not currently planning to hold an advisory committee meeting

Potential for Vicineum to be a best-in-class treatment with projected peak revenue of $1B-$3B globally, $400M-$900M in the US

Company to hold conference call at 8am ET

CAMBRIDGE, Mass., February 16, 2021 – Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, announced today that the U.S. Food and Drug Administration (FDA) accepted for filing the Company's Biologics License Application (BLA) for Vicineum for the treatment of high-risk, BCG-unresponsive non-muscle invasive bladder cancer (NMIBC), and granted the application Priority Review. In addition, the FDA stated that it is not currently planning to hold an advisory committee meeting to discuss the BLA for Vicineum.

The FDA grants Priority Review for medicines that treat a serious condition and, if approved, would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of such serious condition. Priority Review designation shortens the review period goal from the standard ten months to six months from the filing acceptance of the BLA. With Priority Review, the anticipated target Prescription Drug User Fee Act (PDUFA) date for a decision on the BLA is August 18, 2021.

"We have been meeting with the FDA regularly for the past two years on the application for Vicineum," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "We understand the FDA's position and guidance very clearly and have found the review process to be collaborative and engaging. With these critical FDA decisions, we have reached an inflection point for the Company. In addition to a clear regulatory path forward, we have continued to strengthen our balance sheet in preparation for the potential launch of a product we believe represents a significant advancement over available therapies. We remain focused on the patient and our mission to save and improve lives and expect to continue to make progress around the world in the coming months."

In the next one to two months, the Company expects to submit its Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for Vicineum for the treatment of high-risk, BCG-unresponsive NMIBC and receive an update from the Company's partner, Qilu Pharmaceutical, regarding the possible approval of the Investigational New Drug (IND) application for Vicineum in China by the Center for Drug Evaluation (CDE).

Conference Call and Webcast Information

Dr. Thomas Cannell Presided and CEO of Sesen Bio will host a conference call and webcast today at 8:00 AM ET. To participate in the conference call, please dial (844) 831-3025 (domestic) or (315) 625-6887 (international) and refer to conference ID 1290313. The webcast can be accessed in the Investor Relations section of the Company's website at

www.sesenbio.com. The replay of the webcast will be available in the investor section of the Company's website at www.sesenbio.com for 60 days following the call.

About Vicineum™

Vicineum, a locally administered fusion protein, is Sesen Bio's lead product candidate being developed for the treatment of high-risk 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 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 in the follow-up stage of a Phase 3 registration trial in the US 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. In February 2021, the FDA accepted for filing the Company's BLA for Vicineum for the treatment of high-risk, BCG-unresponsive NMIBC and granted the application Priority Review with a PDUFA date of August 18, 2021. 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 high-risk, 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 VB4-845, is currently in the follow-up stage of a Phase 3 registration trial for the treatment of high-risk, BCG-unresponsive non-muscle invasive bladder cancer (NMIBC). In February 2021, the FDA accepted for filing the Company's BLA for Vicineum for the treatment of high-risk, BCG-unresponsive NMIBC and granted the application Priority Review with a PDUFA date of August 18, 2021. Sesen Bio retains worldwide rights to Vicineum with the exception of Greater China and the Middle East and North Africa (MENA), for which the Company has partnered with Qilu Pharmaceutical and Hikma Pharmaceuticals, 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 the treatment of high-risk 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 our 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," "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: the timing for the FDA's decision on the Company's BLA for Vicineum for the treatment of high-risk, BCG unresponsive NMIBC based on the FDA granting the BLA Priority Review, including the anticipated PDUFA date of August 18, 2021 and the need for an advisory meeting on the BLA, the Company's ability to commercialize Vicineum for the treatment of high-risk, BCG unresponsive NMIBC, the Company's belief that Vicineum represents a significant advancement over available therapies, regulatory and partnering progress over the coming months, the timing to submit the Company's MAA for Vicineum to the EMA and to receive an update regarding the IND for Vicineum by the CDE in China, 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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