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): January 13, 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 January 13, 2021, Sesen Bio, Inc. (the "Company") issued a press release announcing that the Investigational New Drug application for Vicineum™ submitted by the Company's partner in China, Qilu Pharmaceutical Co., Ltd., was accepted for review by the China National Medical Products Administration.

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 January 13, 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: January 13, 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 and Qilu Pharmaceutical Announce IND Application for Vicineum™ Accepted for Review by the National Medical Products Administration in China

Clinical trial expected to be initiated shortly after NMPA approval of the IND

Sesen Bio to receive $3M milestone payment upon IND approval

CAMBRIDGE, Mass., Jan 13, 2021 – Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today reported that the Investigational New Drug (IND) application submitted to the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) by the Company's partner in China, Qilu Pharmaceutical, was accepted for review. If the IND is approved, Qilu will be authorized to conduct the proposed clinical trial to assess the efficacy and safety of Vicineum™ in patients with non-muscle invasive bladder cancer (NMIBC) in Greater China. The Company's lead program, Vicineum, also known as VB4-845, is currently in the follow-up stage of a Phase 3 registration trial in the United States (US) for the treatment of high-risk, bacillus Calmette-Guérin (BCG)-unresponsive NMIBC. In December 2020, the Company completed the Biologics License Application (BLA) submission for Vicineum to the FDA.

"The IND submission and acceptance for review by the NMPA for Vicineum in China is a significant milestone for Sesen Bio and our mission of saving and improving the lives of patients with cancer around the world. This accomplishment further highlights the productive collaboration we have with our partner Qilu Pharmaceutical" said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "Vicineum is a highly differentiated and potentially best-in-class therapeutic for the treatment of NMIBC. Given the positive Phase 3 trial results achieved in the US and the highly experienced clinical oncology team at Qilu Pharmaceutical, we are optimistic on the prospects for a successful trial. We look forward to continuing to work with Qilu Pharmaceutical and the NMPA to develop and commercialize Vicineum in China."

The proposed open-label, single-arm, multi-center bridging trial will evaluate the efficacy and safety of Vicineum in approximately 53 patients with carcinoma in situ (CIS) with or without papillary disease, high-grade Ta papillary disease or T1 papillary disease of any grade. Patients will be required to have failed previous treatment with BCG for inclusion in the trial. The primary endpoints are the complete response rate (for CIS patients) and the recurrence-free rate (for papillary patients) at 6 months, with the complete response rate and the recurrence-free rate at 3 months, safety and tolerability as the secondary endpoints.

Upon approval of the IND application by the NMPA, expected in the first half of 2021, Sesen Bio is entitled to receive a $3M milestone payment from Qilu Pharmaceutical, the first of $23M in potential milestone payments. China represents a large potential market for Vicineum, with peak year sales estimated at $155-418M. Furthermore, due to more limited use of BCG in China

compared to the US, there is a major opportunity to transform the treatment paradigm of NMIBC in China and save and improve the lives of patients with cancer.

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 December 2020, Sesen Bio completed the BLA submission for Vicineum to the FDA. 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 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 December 2020, the Company completed the BLA submission for Vicineum to the FDA. 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 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 Company's ability to successfully develop its product candidates and complete its planned clinical programs, expectations regarding the initiation of Qilu Pharmaceutical's clinical trial, expectations regarding the proposed clinical trial, expectations regarding the potential market opportunity for Vicineum in Greater China, expectations regarding the potential approval of the IND application by the NMPA in the first half of 2021, expectations regarding the timing and amounts of any milestone payments due under the Company's license agreement with Qilu Pharmaceutical, expectations regarding the opportunity to transform the treatment paradigm of NMIBC 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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