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): March 22, 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 March 22, 2021, Sesen Bio, Inc. (the "Company") issued a press release announcing that the Investigational New Drug ("IND") application for Vicineum™ for the treatment of BCG-unresponsive non-muscle invasive bladder cancer ("NMIBC") submitted to the Center for Drug Evaluation of the China National Medical Products Administration by the Company's partner in China, Qilu Pharmaceutical, was approved ahead of the original timeline of April 2021.

With approval of the IND, Qilu Pharmaceutical is authorized to conduct the proposed clinical trial to assess the efficacy and safety of Vicineum in patients with BCG-unresponsive NMIBC in China, at the sole cost of Qilu Pharmaceutical. Assuming a successful trial, Qilu Pharmaceutical anticipates submission of the product market application for Vicineum in 2022 with potential approval in China expected in 2023.

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, the Company's expectation for Qilu Pharmaceutical to conduct the proposed clinical trial for Vicineum in patients with BCG-unresponsive NMIBC at the sole cost to Qilu Pharmaceutical and, if such trial is successful, the anticipated submission of the product market application for Vicineum in 2022 with potential approval in China in 2023. 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 March 22, 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: March 22, 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 Approval of IND Application in China for Vicineum™

IND approval triggers $3 million milestone payment to Sesen Bio

Product market application expected to be submitted to the National Medical Products Administration in 2022 with potential approval in 2023

CAMBRIDGE, Mass., March 22, 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 the Investigational New Drug (IND) application for Vicineum for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) 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 approved ahead of the original timeline of April 2021.

With approval of the IND, Qilu Pharmaceutical is authorized to conduct the proposed clinical trial to assess the efficacy and safety of Vicineum in patients with BCG-unresponsive NMIBC in China, at the sole cost of Qilu Pharmaceutical. Assuming a successful trial, Qilu Pharmaceutical anticipates submission of the product market application for Vicineum in 2022 with potential approval in China expected in 2023.

"The approval of the IND for Vicineum in China represents a significant milestone in realizing our mission to save and improve the lives of patients globally," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "Due to more limited use of BCG in China compared to the US, there is an opportunity to transform the treatment paradigm of NMIBC in China. The approval of the IND ahead of the original timeline underscores the strong collaboration between Sesen Bio and our partner, Qilu Pharmaceutical. Given the highly experienced clinical oncology team at Qilu Pharmaceutical, and the Phase 3 trial results achieved in the US, we are optimistic on the prospects for a successful trial and expeditious submission. We look forward to continuing to work with Qilu Pharmaceutical and the NMPA to bring this potentially best-in-class treatment to patients in China."

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. Additionally, the Company anticipates Qilu Pharmaceutical will become a key strategic partner for global supply of Vicineum and the manufacturing technology transfer to Qilu Pharmaceutical is on track to be completed in mid-2021. The completion of the manufacturing technology transfer triggers an additional $2M milestone payment.

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 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 BCG-unresponsive NMIBC. In February 2021, the FDA accepted for filing the Company's BLA for Vicineum for the treatment of 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. 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 VB4-845, 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 for filing the Company's BLA for Vicineum for the treatment of 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 BCG-unresponsive NMIBC. For more information, please visit the company's website at www.sesenbio.com.

About Qilu Pharmaceutical

Qilu Pharmaceutical is a leading vertically integrated pharmaceutical company focused on discovering, developing, manufacturing and commercializing innovative medicines. With a diverse pipeline of novel therapeutics, 10 manufacturing sites and more than 23000 employees worldwide, Qilu is dedicated to transforming scientific innovation by internal R&D across 5 R&D platforms based in the US (Seattle WA, Boston MA, San Francisco CA) and China (Shanghai, Jinan), and external partnership globally into healthcare solutions to address unmet medical needs. To date, Qilu has launched 200+ products with 30+ products "First to launch" in China and 3 products "D181 launch" in US. To learn more about Qilu, please visit http://en.qilu-pharma.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 submission and potential approval of the product market application for Vicineum for the treatment of BCG-unresponsive NMIBC to the National Medical Products Administration, the timing and results of any clinical trial for Vicineum in China, the receipt by the Company of any milestone payments from Qilu Pharmaceutical, the ability of Vicineum to transform the treatment paradigm of NMIBC in China and become a best-in-class treatment for patients in China, the size of the potential market for Vicineum in China, the Company's estimates for peak year sales in China, the prospect of Qilu Pharmaceutical becoming a key strategic partner for the global supply of Vicineum for the treatment of BCG-unresponsive NMIBC, the timing for completion of the manufacturing technology transfer with Qilu Pharmaceutical, the timing for the FDA's decision on the Company's BLA for Vicineum for the treatment of BCG-unresponsive NMIBC based on the FDA granting the BLA Priority Review, the PDUFA date of August 18, 2021 and the need for an advisory meeting on the BLA, 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, and other factors discussed in the "Risk Factors" section of the Company's Annual Report on Form 10-K, 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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