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): July 20, 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 July 20, 2021, Sesen Bio, Inc. (the "Company") issued a press release with the Company's partner in Greater China, Qilu Pharmaceutical, announcing that the first patient has been enrolled in China in the clinical trial to assess the efficacy and safety of Vicineum™ in patients with BCG-unresponsive non-muscle invasive bladder cancer ("NMIBC").

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

In the US, the Company believes it remains on track for an FDA decision on its Biologics License Application for Vicineum[1] by the target PDUFA date of August 18, 2021.

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 beliefs regarding the timing for the U.S. Food and Drug Administration's decision on the Company's Biologics License Application for Vicineum for the treatment of BCG-unresponsive NMIBC. 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, including the risk that the FDA may not approve the BLA for Vicineum on or before the target PDUFA date, or at all, among other 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.

[1] For the treatment of BCG-unresponsive NMIBC

Item 9.01 - Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated July 20, 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: July 20, 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 Enrollment of First Patient in **Clinical Trial for Vicineum™ in China**

Anticipated submission of product market application for Vicineum in China in 2022, with potential approval in 2023

CAMBRIDGE, Mass., Jul. 20, 2021 – Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, and its partner in Greater China, Qilu Pharmaceutical, announced today that the first patient has been enrolled in China in the clinical trial to assess the efficacy and safety of Vicineum in patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC). The milestone comes only four months after the Investigational New Drug (IND) application for Vicineum was approved by the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA), which triggered a $3M milestone payment from Qilu Pharmaceutical, the first of $23M in potential milestone payments to Sesen Bio.

"The enrollment of the first patient in the clinical trial in China is 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. "Qilu Pharmaceutical has strong clinical and regulatory experience, and we are encouraged by the speed in which Qilu Pharmaceutical is moving forward with its clinical and regulatory efforts. We look forward to working closely with Qilu Pharmaceutical in the coming months as we continue to make progress in bringing Vicineum to market in China."

"We continue to believe in the differentiated clinical profile of Vicineum and its potential to address a significant unmet need in the treatment of BCG-unresponsive NMIBC in the Greater China region," said Oliver Kong, M.D., chief medical officer and corporate vice president of Qilu Pharmaceutical. "We look forward to completing enrollment of the trial, and to working with the NMPA to potentially bring Vicineum to market to make a meaningful impact on the lives of patients."

The 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 six months, with the complete response rate and the recurrence-free rate at three months, safety and tolerability as the secondary endpoints. Based on the partnership agreement between Sesen Bio and Qilu Pharmaceutical, the trial is being run at the sole cost of Qilu Pharmaceutical.

Assuming a successful trial, Qilu Pharmaceutical anticipates submission of the product market application for Vicineum in China in 2022, with potential approval expected in 2023. Sesen Bio

believes China represents a large potential market for Vicineum, with unadjusted peak year sales estimated at $155M-$418M.

In the US, the Company believes it remains on track for an FDA decision on its Biologics License Application for Vicineum by the target PDUFA date of August 18, 2021.

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 target 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 oportuzumab monatox, 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 target 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, which is being developed 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 23,000 employees worldwide, Qilu Pharmaceutical 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 Pharmaceutical has launched 200+ products with 30+ products "First to launch" in China and 3 products "D181 launch" in US.

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," "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 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 and the target PDUFA date of August 18, 2021, the timing and receipt by the Company of any milestone payments from Qilu Pharmaceutical, the timing and ability of Qilu Pharmaceutical to bring Vicineum to market in China, the timing and results of any clinical trial for Vicineum in China, the timing for submission and potential approval of the product market application for Vicineum for the treatment of BCG-unresponsive NMIBC to the NMPA, the size of the potential market for Vicineum in China, 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 Qilu may not be successful in its clinical or regulatory efforts for Vicineum for the treatment of BCG-unresponsive NMIBC in China, the risk that the Company and Qilu may not be successful in bringing Vicineum to market in China, the potential market for Vicineum in China may be significantly smaller than estimated by the Company, the risk that the FDA may not approve the BLA for Vicineum within the anticipated timing, or at all, 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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