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 30, 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 30, 2021, Sesen Bio, Inc. (the "Company") provided a regulatory update for Vicineum™ for the four largest global markets in terms of commercial opportunity for the treatment of BCG-unresponsive non-muscle invasive bladder cancer ("NMIBC"):

United States:
The Company will be participating in a Late-Cycle Meeting with the U.S. Food and Drug Administration ("FDA") to discuss the Biologics License Application ("BLA") for Vicineum on June 1, 2021. The Late-Cycle Meeting will be held between members of the FDA review team and the Company to discuss the status of the review and is intended to share information and plan for the rest of the review.

In February 2021, the Company received notice from the FDA that the BLA for Vicineum was accepted for filing and granted Priority Review with a target Prescription Drug User Fee Act ("PDUFA") date of August 18, 2021 for a decision on the BLA.

Europe:
The Company received notice on March 25, 2021 from the European Medicines Agency ("EMA") that the Company's Marketing Authorization Application ("MAA") for Vicineum was found to be valid and that the review procedure has officially started. The Company remains on-track for potential approval of Vicineum in Europe in early 2022. Additionally, the Company has completed the tradename approval process with the EMA[1] and anticipates an official decision on the proprietary brand name in Europe from the EMA in the next few weeks.

China:
The Company received notice on March 19, 2021 from its partner, Qilu Pharmaceutical, that the Investigational New Drug ("IND") application for Vicineum for the treatment of BCG-unresponsive NMIBC submitted to the Center for Drug Evaluation ("CDE") of the China National Medical Products Administration ("NMPA") was approved, thereby triggering a $3M milestone payment to the Company.

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 with the first patient enrolled in the trial expected in the next one-to-two months. 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.

Middle East and North Africa ("MENA"):
The Company continues to work closely with its partner, Hikma Pharmaceuticals, to submit marketing authorization applications for Vicineum in 2021 in four key markets in the region: the Kingdom of Saudi Arabia, Jordan, Morocco and Egypt. These four markets represent a significant opportunity in the MENA region, as Saudi Arabia, Jordan and Morocco have some of the most advanced healthcare systems in the region while Egypt is the second largest economy in Africa. The Company anticipates the first wave of potential country approvals for Vicineum in the MENA region as early as 2022.

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[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. The Company is currently awaiting a tradename decision from the EMA for oportuzumab monatox.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS:

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, statements related to 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 PDUFA date of August 18, 2021, statements related to expectations regarding the final approval of the tradename for oportuzumab monatox by the EMA if at all, statements related to the timing of approval of the MAA by the EMA if at all, 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 the 2022 with potential approval in China in 2023, the Company's expectations regarding its partnership with Hikma Pharmaceuticals to commercialize Vicineum in the MENA markets, and statements related to the first wave of potential country approvals in the MENA as early as 2022. 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.
expectations.

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 30, 2021

Sesen Bio, Inc.

By: /s/ Thomas R. Cannell, D.V.M.
Thomas R. Cannell, D.V.M.
President and Chief Executive Officer