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): April 1, 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 31, 2021, Sesen Bio, Inc. (the "Company") received notice from the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA") that the CHMP has conditionally accepted the proprietary brand name VYSYNEUM™ for the Company's product candidate, oportuzumab monatox, in the European Union.

The name VYSYNEUM has identical pronunciation to the U.S. proprietary brand name VICINEUM™ and was developed in accordance with the criteria outlined in the EMA's *Guideline on the acceptability of names for human medicinal products*.

The Company believes VYSYNEUM is a brand name with strong marketing potential. Final approval of the VYSYNEUM brand name is conditional on EMA product approval.

The Marketing Authorization Application ("MAA") for VYSYNEUM is currently under review with the EMA with potential approval expected in early 2022.

As previously disclosed by the Company, in June 2020, the U.S. Food and Drug Administration ("FDA") conditionally accepted the proprietary brand name VICINEUM™ for oportuzumab monatox in the United States. Final approval of the VICINEUM brand name is conditional on FDA product approval.

The BLA for VICINEUM is currently under Priority Review with the FDA with a target Prescription Drug User Fee Act ("PDUFA") date of August 18, 2021 for a decision on approval.

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 expectations regarding the EMA's final approval of the VYSYNEUM brand name, expectations regarding the timing of the potential EMA approval of the MAA for VYSYNEUM, expectations regarding the FDA final approval of the VICINEUM brand name, and 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. 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, which include, without limitation, risks related to the EMA's review and approval of the MAA for VYSYNEUM and risks related to the FDA's review and approval of the BLA for VICINEUM. 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.

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: April 1, 2021

Sesen Bio, Inc.

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