
**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): December 15, 2020

SESEN BIO, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36296
(Commission
File Number)

26-2025616
(I.R.S. Employer
Identification No.)

245 First Street, Suite 1800
Cambridge, MA
(Address of principal executive offices)

02142
(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 December 14, 2020, Sesen Bio, Inc. (the “Company”) had its second of two successful meetings with the assigned Rapporteurs, following the first meeting on November 2, 2020, to discuss the upcoming marketing authorization application (“MAA”) for Vicineum™, the Company’s lead product candidate.¹

The Rapporteurs are members of the European Medicines Agency’s (“EMA”) Committee for Medicinal Products for Human Use (“CHMP”) who jointly coordinate the CHMP’s evaluation of the Company’s planned MAA. During the meetings, the Company received guidance on the contents of the MAA, further refining the path to potential approval in Europe.

The successful meetings with the Rapporteurs are the final material step in completing all pre-submission activities for the MAA for Vicineum, which the Company expects to submit to the EMA in early 2021.

The Company also remains on track to submit its Biologics License Application to the United States Food and Drug Administration (“FDA”) later this month and has been in close contact with the FDA to discuss the timing of the pre-license inspection.

¹The 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 going through the tradename approval process in Europe 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, expectations regarding the timing of the Company’s planned MAA submission for Vicineum, expectations regarding the potential EMA approval of the planned Vicineum MAA, expectations regarding the timing of completion of the Company’s BLA submission for Vicineum, and expectations regarding the tradename approvals for the Company’s product candidate, oportuzumab monatox, in the United States and Europe. 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.

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: December 15, 2020

Sesen Bio, Inc.

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