
**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): October 6, 2020¹

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 September 29, 2020, Sesen Bio Inc. (the “Company”) received notice from the European Medicines Agency (“EMA”) that it has appointed the Rapporteur and Co-Rapporteur for the Company’s marketing authorization application (“MAA”) currently in preparation for Vicineum™ (oportuzumab monatox), the Company’s lead product candidate. The Rapporteur and Co-Rapporteur are members of EMA’s Committee for Human Medicinal Products (the “CHMP”) and will jointly coordinate CHMP’s evaluation of the Company’s planned MAA for Vicineum.

Additionally, the Company’s pre-submission meeting with the EMA has been tentatively scheduled for October 23, 2020. The pre-submission meeting is a critical milestone in the preparation of a MAA and provides the Company with an opportunity to review key elements of the Company’s planned MAA submission with the EMA and discuss next steps.

The assignment of the Rapporteurs and the scheduling of the pre-submission meeting are pivotal mandatory steps in the regulatory process toward a potential MAA submission for Vicineum to the EMA.

The Company expects to complete all necessary pre-submission activities with the EMA by the end of 2020, and anticipates filing the MAA in early 2021, with potential approval anticipated in early 2022.

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 pre-submission meeting with the EMA, expectations regarding the completion of all pre-submission activities with the EMA, expectations regarding the timing of the Company’s planned MAA submission for Vicineum and expectations regarding the timing of the potential EMA approval of the planned Vicineum MAA. 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: October 6, 2020

Sesen Bio, Inc.

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