
**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): June 18, 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 June 17, 2020, the U.S. Food and Drug Administration (“FDA”) informed Sesen Bio, Inc. (the “Company”) that the FDA has conditionally accepted the proprietary brand name VICINEUM™ for the Company’s product candidate, oportuzumab monatox.

The name VICINEUM was developed in compliance with the FDA’s final *Guidance for Industry, Contents of a Complete Submission for the Evaluation of Proprietary Names* and the FDA’s draft *Guidance for Industry, Best Practices in Developing Proprietary Name for Drugs*. The Company believes VICINEUM is a proprietary name with strong marketing potential that is also consistent with FDA’s goal of preventing medication errors and potential harm to the public by ensuring that only appropriate proprietary names are approved for use. Final approval of the VICINEUM brand name is conditional on FDA approval of the Company’s product candidate, oportuzumab monatox.

Based upon FDA feedback, the Company withdrew its previously submitted proposed brand name, VICINIUM®, from consideration due to potential for confusion with ammonium derivatives products with the “-ium” suffix as established by the United States Adopted Names Council.

VICINEUM is currently in the follow-up stage of a Phase 3 registration trial for the treatment of high-risk, BCG-unresponsive non-muscle invasive bladder cancer. In December 2019, the Company initiated the Biologics License Application (“BLA”) submission for VICINEUM to the FDA under Rolling Review. The Company expects to complete the VICINEUM BLA submission in the second half of 2020 and anticipates potential approval in first half of 2021.

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 final approval of the VICINEUM brand name, expectations regarding the timing of completion of the Company’s BLA submission for VICINEUM and expectations regarding the timing of the potential FDA approval of the VICINEUM BLA. 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 FDA’s review and approval of the VICINEUM BLA. 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: June 18, 2020

Sesen Bio, Inc.

By: /s/ Thomas R. Cannell, D.V.M.

Thomas R. Cannell, D.V.M.

President and Chief Executive Officer