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 3, 2020

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.

Analytical Comparability

As of December 2, 2020, Sesen Bio, Inc. (the "Company") has received and analyzed all of the analytical comparability test results from the commercial-scale drug substance and drug product process performance qualification ("PPQ") batches of Vicineum™, the Company's lead product candidate. As previously disclosed, the Company has partnered with FUJIFILM Diosynth Biotechnologies U.S.A., Inc. and Baxter Oncology GmbH for the manufacturing process and technology transfer of Vicineum.

For analytical comparability, the Company conducted testing across four categories: release testing, biophysical characterization, forced degradation studies, and stability studies. This approach is in alignment with requirements of the United States Food and Drug Administration ("FDA"), the European Medicines Agency and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. The test results for product intended for commercial use were found to be highly comparable to the Company's clinical supply of Vicineum.

Based on these results, the Company is optimistic that the FDA will determine that the commercial supply of Vicineum is comparable to the clinical supply of Vicineum, and that no additional clinical trials are warranted.

The comparability data from the PPQ campaigns for drug substance and drug product are the final material components of the Company's Biologics License Application ("BLA") for Vicineum, which the Company expects to submit to the FDA later this month.

PPQ Campaign Release Testing

On November 23, 2020, the Company completed the assessment of the release testing results of the final of three drug product PPQ batches of Vicineum and all quality acceptance criteria were met. The satisfaction of the quality acceptance criteria supports the Company's ability to release Vicineum for supply, sale or export.

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 timing of completion of the Company's BLA submission for Vicineum, expectations regarding the FDA's assessment of the comparability of the commercial supply and clinical supply of Vicineum, and expectations that no additional clinical trials are warranted. 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 3, 2020

Sesen Bio, Inc.

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