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): February 25, 2022

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.

As previously announced, the Board of Directors (the "Board") of Sesen Bio, Inc. (the "Company") initiated an independent internal review conducted by outside counsel with the assistance of subject matter experts (the "Review"). The Review took place over the course of five months, involved full cooperation from the Company's management team, a review of more than 600,000 documents, and 39 interviews of current and former employees and consultants. It is now complete. As a result of the Review, the Board continues to fully support the Company's current management team and believes no changes or amendments relating to the Company's prior disclosures to the Securities and Exchange Commission ("SEC") or the Food and Drug Administration ("FDA") relating to Vicineum™, the Phase 3 VISTA trial for Vicineum for the treatment of BCG-unresponsive NMIBC, or the Company's Biologics License Application ("BLA") for Vicineum are warranted. The Company intends to work cooperatively with the FDA in preparing for an additional Phase 3 clinical trial for Vicineum.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS:

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, statements regarding the Board's continued support for the Company's current management team; the Board's belief that no changes or amendments relating to the Company's prior disclosures to the SEC or FDA relating to Vicineum, the Phase 3 VISTA trial or the Company's BLA for Vicineum are warranted; and the Company's intentions to work cooperatively with the FDA in preparing for an additional Phase 3 clinical trial for Vicineum. 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, including the impact of the completion of the Review, including any related investigations, reviews or proceedings, shareholder lawsuits or reputational harm; and the risk that the Company may not be able to reach agreement with the FDA on the protocol for an additional Phase 3 clinical trial for Vicineum, or other issues related to preparing for an additional Phase 3 clinical trial for Vicineum, including difficulties with clinical trial site selection and obtaining clinical trial materials and supplies, among other 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: February 25, 2022

Sesen Bio, Inc.

By: /s/ Jay S. Duker, M.D.
Jay S. Duker, M.D.
Chair of the Board of Directors