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 27, 2021

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

On the morning of October 27, 2021, the U.S. Food and Drug Administration (“FDA”) published a Warning Letter issued to a former study investigator in Sesen Bio, Inc.’s (the “Company”) Phase 3 VISTA trial for Vicineum™ arising from a 2021 FDA inspection related to the review of the Company’s Biologics License Application (“BLA”) for Vicineum for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (“NMIBC”). Sesen Bio discontinued use of the clinical site and the study investigator over four years ago when the Company learned of professional misconduct by the study investigator that was unrelated to the Phase 3 VISTA trial.

The FDA Warning Letter indicates that the study investigator did not comply with applicable statutory requirements and applicable regulations regarding conduct of clinical investigations. The study investigator operated a clinical site that was previously part of the VISTA trial, which was closed by the Company on May 26, 2017. The study investigator's medical license was temporarily suspended on May 29, 2017 due to inaccurate recordkeeping, which was unassociated with Sesen Bio and the patients in the VISTA trial. The Company notified the FDA of the misconduct at that time.

When the clinical site was closed, five patients had completed treatment and were in post-treatment follow-up. There was no evidence found that patients were harmed by the study investigator’s actions. The Company included the corresponding patient data from the clinical site in its BLA submission to the FDA, which were thoroughly analyzed and discussed during the BLA review.

The Company did not receive any Warning Letters or Discipline Review Letters during the FDA’s review of the BLA for Vicineum from the Company’s initiation of the submission of its BLA under rolling review in December 2019 through the Company’s receipt of a Complete Response Letter from the FDA in August 2021. Sesen Bio looks forward to continuing to work collaboratively with regulators to determine the appropriate path forward 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 Company’s plans to continuing to work collaboratively with regulators to determine the appropriate path forward for Vicineum, which 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, including the risk that the Company may not be able to determine a path forward for Vicineum for the treatment of BCG-unresponsive NMIBC, the risk that the Company may not resume its plans to pursue regulatory approval for Vicineum for the treatment of BCG-unresponsive NMIBC in the US, the risk that the FDA may not approve the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC if the Company resubmits the BLA at a future time, the risk that clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC may fail to demonstrate safety and efficacy to the satisfaction of the FDA, or otherwise produce favorable results, and the risk that Vicineum for the treatment of BCG-unresponsive NMIBC may cause undesirable side effects, serious adverse events or have other properties that could delay or halt clinical trials, delay or prevent its regulatory approval by the FDA, or limit the commercial profile of its labeling, if approved, or result in significant negative consequences following any marketing approval, 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 Securities and Exchange Commission. 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 27, 2021

Sesen Bio, Inc.

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