
**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): May 20, 2022

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 7.01 – Regulation FD Disclosure.

On May 18, 2022, the US Food & Drug Administration (“FDA”) granted Sesen Bio, Inc.’s (the “Company”) request for a meeting to discuss the remaining outstanding items related to an additional Phase 3 clinical trial that the Company is evaluating for potential resubmission of its Biologics License Application (“BLA”) for Vicineum™ for the treatment of non-muscle invasive bladder cancer (“NMIBC”). The FDA has designated the meeting as a Type B meeting (the “Type B Meeting”), which is scheduled for July 11, 2022.

As the Company prepares for the Type B Meeting, and evaluates an additional Phase 3 clinical trial, it will continue the process to review strategic alternatives with the goal of maximizing shareholder value.

The information furnished in this Item 7.01 shall not be deemed to be “filed” for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of such section, nor shall such information be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS:

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, statements regarding an additional Phase 3 clinical trial that the Company is evaluating for potential resubmission of a BLA for Vicineum for the treatment of NMIBC and the Company’s plans to continue the process to review strategic alternatives with the goal of maximizing shareholder value, 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 request for a Type B Meeting may not occur within the anticipated timing, or at all, the risk that the Type B Meeting may not enable the Company to align with the FDA on the remaining outstanding items related to an additional Phase 3 clinical trial of Vicineum for the treatment of NMIBC, the risk that the Company may not continue its plans to conduct an additional Phase 3 clinical trial and pursue regulatory approval for Vicineum for the treatment of NMIBC in the US, the risk that an additional Phase 3 clinical trial of Vicineum for the treatment of NMIBC may fail to demonstrate safety and efficacy to the satisfaction of the FDA, or otherwise produce favorable results, the risk that the FDA may not approve the BLA for Vicineum for the treatment NMIBC if the Company resubmits the BLA at a future time, the risk that Vicineum for the treatment of 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, limit the commercial profile of its labeling, if approved, or result in significant negative consequences following any marketing approval, the risk that the Company may pursue one or more strategic alternatives instead of pursuing an additional Phase 3 clinical trial and the risk that the Company may not be successful in identifying one or more strategic alternatives or ultimately pursuing a strategic alternative that delivers the anticipated benefits or enhances shareholder value, 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: May 20, 2022

Sesen Bio, Inc.

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