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 19, 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 7.01 – Regulation FD Disclosure.

On the morning of October 19, 2021, the US Food & Drug Administration ("FDA") granted Sesen Bio, Inc.'s (the "Company") request for a Type A meeting to discuss the Chemistry, Manufacturing and Controls ("CMC") issues raised in the FDA's Complete Response Letter ("CRL") regarding the Company's Biologics License Application ("BLA") for Vicineum™ for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (the "CMC Type A Meeting"). The CMC Type A Meeting has been scheduled for October 29, 2021.

During the CMC Type A Meeting, the Company intends to align on a path forward with the FDA related to the CMC issues raised in the CRL.

The Company is also preparing for a separate Type A meeting to discuss the recommendations specific to additional clinical/statistical data and analyses that the FDA raised in the CRL (the "Clinical Type A Meeting"). The Company expects the Clinical Type A Meeting to occur later in the fourth quarter of 2021.

As previously disclosed, the Company intends to use the information from the CMC Type A Meeting and the Clinical Type A Meeting to synchronize the regulatory reviews of Vicineum for the treatment of BCG-unresponsive NMIBC in the US and the European Union. The Company looks forward to continuing to work collaboratively with regulators to determine the appropriate path forward.

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 the Company's plans to align on a path forward with the FDA regarding issues raised in the CRL, the Company's preparations for the CMC Type A Meeting and the Clinical Type A Meeting, the Company's expectation for the timing of the Clinical Type A meeting, the Company's plans to use information from the CMC Type A Meeting and Clinical Type A Meeting to synchronize the regulatory reviews of Vicineum for the treatment of BCG-unresponsive NMIBC in the US and the European Union, and the Company's expectation that providing additional information to the FDA will enable a determination of the appropriate path forward, 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 CMC Type A Meeting and the Clinical Type A Meeting may not occur within the anticipated timing, or at all, the risk that the CMC Type A Meeting and the Clinical Type A Meeting may not enable the Company to synchronize the regulatory reviews of Vicineum for the treatment of BCG-unresponsive NMIBC in the US and the European Union, the Company may not resume its plans to pursue regulatory approval for Vicineum for the treatment of BCG-unresponsive NMIBC in the US or the European Union, 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 the European Medicines Agency, or otherwise produce favorable results, 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 the European Commission may not approve the Company's marketing authorization application ("MAA") for Vicineum for the treatment of BCG-unresponsive NMIBC if the Company resubmits the MAA at a future time, 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 the European Commission, 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 19, 2021

Sesen Bio, Inc.

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