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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**  
Pursuant to Section 13 OR 15 (d)  
of the Securities Exchange Act of 1934

**Date of Report (Date of earliest event reported): November 18, 2021**

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**SESEN BIO, INC.**  
(Exact name of registrant as specified in its charter)

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**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.)

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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:

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- 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 November 17, 2021, the US Food & Drug Administration (“FDA”) granted Sesen Bio, Inc.’s (the “Company”) request for a Type A meeting (the “Clinical Type A Meeting”) to discuss recommendations specific to additional clinical/statistical data and analyses 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 (“NMIBC”). The Clinical Type A Meeting has been scheduled for December 8, 2021 and follows the Type A Meeting held on October 29, 2021 during which the Company and the FDA reviewed issues related to Chemistry, Manufacturing and Controls (“CMC”) raised in the CRL (the “CMC Type A Meeting”).

As previously disclosed, the Company intends to use the information from both the upcoming Clinical Type A Meeting and the CMC 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 intentions to use information from both the upcoming Clinical Type A Meeting and the CMC 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 plans to continue to work collaboratively with regulators to determine 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 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.

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**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: November 18, 2021

Sesen Bio, Inc.

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