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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): August 20, 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 8.01 – Other Events.**

On August 20, 2021, Sesen Bio, Inc. (the “Company”) withdrew its marketing authorization application (“MAA”) to the European Medicines Agency (“EMA”) for Vysyneum™ for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (“NMIBC”).

Given that certain components in the EMA’s review are interrelated with elements of the US Food and Drug Administration’s (“FDA”) decision to issue a complete response letter regarding the Company’s Biologics License Application (“BLA”) for Vicineum™ for the treatment of BCG-unresponsive NMIBC, the Company is pausing its plans to pursue regulatory approval of Vysyneum in Europe until there is more clarity from the FDA on the next steps in the United States.

Sesen Bio plans to request a Type A meeting as soon as possible with the FDA to discuss next steps for the potential regulatory path forward for Vicineum in the US, and the Company expects this meeting to occur in the fourth quarter of this year.

The Company believes additional information from the FDA will equip the Company to better synchronize the regulatory reviews of Vicineum in the US and Europe. Sesen Bio is committed to the highest standards of ethics and integrity and continues to believe in the safety and efficacy data of Vicineum. The Company intends to work closely with the FDA to understand next steps.

#### **CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS:**

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, the Company’s plans to pause pursuing regulatory approval of Vysyneum in Europe until there is more clarity from the FDA on next steps in the US, the Company’s expectations regarding the timing for the FDA’s scheduling of a Type A meeting with the Company, the Company’s belief that additional information from the FDA at the Type A meeting will clarify the next steps for a potential regulatory path forward for Vicineum in the US and equip the Company to better synchronize the regulatory reviews of Vicineum in the US and Europe, the Company’s commitment to ethics and integrity, the Company’s belief in the safety and efficacy data of Vicineum and the Company’s intentions to work closely with the FDA to understand next steps for Vicineum, 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 FDA may not schedule a Type A meeting with the Company in the fourth quarter of this year, or at all, the risk that the Company may not resume its plans to pursue regulatory approval for Vicineum in the US, the risk that the Company may not resume its plans to pursue regulatory approval of Vysyneum in Europe upon receiving any clarity from the FDA, or at all, 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, 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.

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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: August 25, 2021

Sesen Bio, Inc.

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