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 20, 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.

As previously disclosed, 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") in order to pause its plans to pursue regulatory approval of Vysyneum in the European Union until there is more clarity from the US Food and Drug Administration ("FDA") on next steps for Vicineum™ in the United States. [1]

On the morning of October 20, 2021, the EMA issued its Withdrawal Assessment Report relating to the Company's MAA for Vysyneum, as is consistent with the EMA's standard practice when an MAA is withdrawn. The Assessment Report reflects the initial assessment and corresponding questions from the EMA and identifies major objections in the areas of Quality, Good Clinical Practice, Efficacy and Safety.

The Day 120 questions to which Sesen Bio was in the process of responding when it withdrew its MAA for Vysyneum covered these objections. At the time Sesen Bio withdrew its MAA for Vysyneum, initial responses to the EMA were expected in the first quarter of 2022.

Due to the high concordance between FDA and European Commission approvals, the Company believes that the probability of success of future approval in the European Union for Vysyneum increases if FDA approval for Vicineum has already been obtained. As previously disclosed, Sesen Bio intends to use information from its CMC Type A Meeting, which has been scheduled for October 29, 2021, and the Clinical Type A Meeting anticipated to occur later in the fourth quarter to determine the appropriate path forward with regulators.

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.

[1] Vysyneum is the proprietary brand name that was conditionally approved by the EMA for oportuzumab monatox in the European Union.

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 belief that there is a path to approval for Vysyneum in the European Union, the Company's belief that the probability of success of future approval in the European Union for Vysyneum increases if FDA approval for Vicineum has been obtained, and the Company's expectations regarding the CMC Type A Meeting and Clinical Type A Meeting to determine the path forward with regulators 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 Company may not be able to determine a path forward for Vicineum for the treatment of BCG-unresponsive NMIBC in either the US or the European Union, or both, 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 or the European Union, 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 MAA for Vysyneum for the treatment of BCG-unresponsive NMIBC if the Company resubmits the MAA 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 the EMA, or both, 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 the European Commission, or both, 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 20, 2021

Sesen Bio, Inc.

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