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): September 17, 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** **(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 September 17, 2021, the European Medicines Agency ("EMA") published a letter discussing certain Questions and Answers related to the withdrawal of Sesen Bio, Inc.'s (the "Company") marketing authorization application ("MAA") for Vysyneum™ for the treatment of BCG-unresponsive non-muscle invasive bladder cancer ("NMIBC") per the EMA's standard practice and outlining the EMA's concerns with Vysyneum based on its initial review of the MAA. A copy of the EMA's letter is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

As previously disclosed, the Company had received the Day 80 and Day 120 List of Outstanding Issues from the EMA and was in the process of preparing responses, which were due back to the EMA in early 2022, before voluntarily withdrawing its MAA on August 20, 2021. The Company determined to withdraw the MAA following feedback received from the US Food and Drug Administration ("FDA") regarding its Biologics License Application for Vicineum™ for the treatment of BCG-unresponsive NMIBC and while it waits for additional feedback from the FDA, which the Company expects to receive at chemistry, manufacturing and controls and clinical Type A meetings anticipated 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 for the treatment of BCG-unresponsive NMIBC in the US and Europe. The Company intends to work closely with the FDA to understand next steps.

Sesen Bio is committed to the highest standards of ethics and integrity and continues to believe in the safety and efficacy data of Vicineum. Consistent with our commitment to scientific integrity and thoroughness, the Company has voluntarily engaged outside counsel and other experts to conduct a review focusing on the conduct of, and data generated from, the clinical trials of Vicineum, and the overall safety and effectiveness of Vicineum. The Company expects outside counsel and other experts to work expeditiously to conduct the review, determine the nature and scope of any issues identified, and advise on any related disclosures.

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 expectations that it will receive additional feedback from the FDA regarding next steps for Vicineum for the treatment of BCG-unresponsive NMIBC in the US, the Company's expectations regarding the timing for the FDA's scheduling of Type A meetings with the Company, the Company's belief that additional information from the FDA at the Type A meetings 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 intentions to work closely with the FDA to understand next steps for Vicineum, the Company's commitment to ethics and integrity, the Company's belief in the safety and efficacy data of Vicineum, and the Company's internal review of the conduct of, and data generated from, the clinical trials for Vicineum, and the overall quality, safety and effectiveness of 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 Type A meetings 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 additional feedback 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, the risk that the EMA may not approve the MAA for Vysyneum for the treatment of BCG-unresponsive NMIBC if the MAA is submitted at a future time, and the risk that the Company's internal review may uncover misconduct or other improper activities by the Company's employees or third-parties involved in the Company's clinical or regulatory activities related to Vicineum, 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.

Item 9.01 - Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Questions & Answers published by the European Medicines Agency on September 17, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: September 17, 2021

Sesen Bio, Inc.

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

17 September 2021
EMA/508191/2021
EMEA/H/C/005730

Withdrawal of application for the marketing authorisation of Oportuzumab monatox DLRC Pharma Services (oportuzumab monatox)

DLRC Pharma Services withdrew its application for a marketing authorisation of Oportuzumab monatox DLRC Pharma Services for the treatment and prevention of recurrence of cancer of the bladder and the prevention of recurrence of papillary tumours.

The company withdrew the application on 20 August 2021.

What is Oportuzumab monatox DLRC Pharma Services and what was it intended to be used for?

Oportuzumab monatox DLRC Pharma Services was developed as a medicine for two types of bladder cancer. It was to be used for the treatment and prevention of recurrence of carcinoma-in-situ (CIS) of the urinary bladder and for the prevention of recurrence of high-grade Ta and/or T1 papillary tumours. It was to be used in patients who had undergone surgery to remove the cancer (transurethral resection) and whose cancer had not responded to BCG immunotherapy (a type of cancer treatment).

Oportuzumab monatox DLRC Pharma Services contains the active substance oportuzumab monatox and was to be injected directly into the bladder.

How does Oportuzumab monatox DLRC Pharma Services work?

Oportuzumab monatox DLRC Pharma Services consists of a fragment of an antibody (a type of protein) which is attached to a cytotoxic (cell-killing) substance. The antibody has been designed to attach to a target found on cancer cells (EpCAM), allowing the medicine to enter the cancer cell. Once the medicine is inside, the cytotoxic substance is expected to kill the cell. The medicine was also expected to trigger an immune response against the cancer cells.

What did the company present to support its application?

The company presented results from a study in 133 patients with CIS of the urinary bladder or papillary tumours (high-grade Ta or any grade T1) whose cancer did not respond to BCG

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immunotherapy. The main measures of effectiveness were the absence of signs of cancer cells (complete response) after 3 months and the duration of this response. Oportuzumab monatox DLRC Pharma Services was not compared with other medicines or placebo (a dummy treatment).

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the initial information from the company and had prepared questions for the company. The company had not responded to the questions at the time of the withdrawal.

What did the Agency recommend at that time?

Based on the review of the data, at the time of the withdrawal, the Agency had major concerns and its provisional opinion was that Oportuzumab monatox DLRC Pharma Services could not have been authorised for the treatment and prevention of recurrence of carcinoma-in-situ of the urinary bladder or for the prevention of recurrence of papillary tumours.

The Agency had concerns about the quality, safety and effectiveness of the medicine. In terms of quality, several processes were used for manufacturing the medicine, which raised questions about the measure of the medicine activity across the various processes used. Further information was also needed about compliance with good manufacturing practices and the presence of potential impurities. In terms of effectiveness, the Agency considered that the patient population involved in the main study was not compatible with the targeted indication. Also, major changes to the study design were carried out while the study was ongoing, raising issues for the interpretation of the results, and the choice of the main measures of effectiveness was not deemed appropriate. Further to that, there were doubts about the clinical relevance of the reported results on effectiveness. Finally, in terms of safety, some data seemed contradictory and had to be further explained.

Therefore, at the time of the withdrawal, the Agency had major concerns about the reliability of the data and concluded that the medicine could not have been authorised based on the data from the company.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of the application, the company stated that they withdrew their application following feedback received from the US FDA on an application for oportuzumab monatox submitted in the United States.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that this withdrawal will have no impact on patients in clinical trials using Oportuzumab monatox DLRC Pharma Services.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.