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): July 6, 2020

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 8.01 – Other Events.

On July 3, 2020, Sesen Bio, Inc. (the “Company”) received a product-specific pediatric waiver from the European Medicines Agency (“EMA”) for Vicineum™ (oportuzumab monatox), the Company's lead product candidate, which is currently in the follow-up stage of a Phase 3 registration trial for the treatment of high-risk, BCG-unresponsive non-muscle invasive bladder cancer.

As part of the regulatory process for the registration of new medicines with the EMA, pharmaceutical companies are required to provide a Pediatric Investigation Plan (“PIP”) that outlines the clinical development strategy for studying the investigational product in the pediatric population. In some instances, a waiver from required pediatric studies for certain conditions may be granted by the EMA when development of a medicine for use in children is not feasible or appropriate.

The PIP waiver from the EMA applies to Vicineum across all subsets of the pediatric population for the treatment of urothelial carcinoma. The receipt of the waiver will allow the Company to submit a Marketing Authorization Application (“MAA”) for Vicineum to the EMA without the requirement to conduct clinical studies in a pediatric population either pre-approval or post-approval.

As previously disclosed, the Company has received positive Scientific Advice from the Committee for Medicinal Products for Human Use (“CHMP”) of the EMA related to the clinical program and the chemistry, manufacturing and controls program for Vicineum in Europe. The PIP waiver is an important milestone in the regulatory process towards a potential MAA submission for Vicineum to the EMA, which is anticipated in early 2021, with potential approval anticipated in early 2022.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS:

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, expectations regarding the timing of the Company’s MAA submission for Vicineum and expectations regarding the timing of the potential EMA approval of the Vicineum MAA. These forward-looking statements 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, which include, without limitation, risks related to the EMA’s review and approval of the Vicineum MAA. 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.

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: July 6, 2020

Sesen Bio, Inc.

By: /s/ Thomas R. Cannell, D.V.M.

Thomas R. Cannell, D.V.M.

President and Chief Executive Officer