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): January 6, 2022

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.

On January 6, 2022, Sesen Bio, Inc. ("Sesen Bio" or the "Company") disclosed that it will receive a $20 million milestone payment pursuant to the Company's exclusive license agreement with F. Hoffmann-La Roche Ltd and Hoffman-La Roche Inc. ("Roche") (the "Roche License Agreement"). Following this payment, Sesen Bio will have cumulatively received $50 million in upfront and milestone payments, with an additional $220 million in potential future milestone payments remaining under the Roche License Agreement. Upon receipt of the $20 million milestone payment from Roche, the Company currently expects that its cash and cash equivalents will be sufficient to fund its current operating plan into 2024. The Company plans to provide a further update on the Roche License Agreement in its Form 10-K for FY2021.

As previously disclosed, the Company entered into the Roche License Agreement in June 2016, pursuant to which the Company granted Roche an exclusive, worldwide license to develop and commercialize EBI-031 and all other Interleukin-6 ("IL-6") antagonist antibody technology owned by Sesen Bio. EBI-031 is a humanized monoclonal antibody that potently binds IL-6 and inhibits all known forms of IL-6 cytokine signaling, currently being developed by Roche for the potential treatment of ocular diseases. In addition to the milestone payments and the previously paid upfront payment, the Company is entitled to receive royalties on net sales of potential future products containing EBI-031 or any other potential IL-6 antagonist antibody technology owned by Sesen Bio.

The milestone payment from Roche will further strengthen the Company's balance sheet as it works toward an additional clinical trial for Vicineum™ for the treatment of BCG-unresponsive non-muscle invasive bladder cancer ("NMIBC"), followed by a potential resubmission of a Biologics License Application ("BLA").

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS:

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, statements regarding any future payments to the Company pursuant to the Roche License Agreement including any future milestone payments and royalty payments, the Company's expectation that the payment from Roche will further strengthen the Company's balance sheet, the Company's expectation that with the payment from Roche the Company's cash and cash equivalents will be sufficient to fund its current operating plan into 2024 and the Company's plans to conduct an additional clinical trial for Vicineum for the treatment of BCG-unresponsive NMIBC prior to potential resubmission of a BLA for Vicineum, which are based on the Company's current expectations and inherently involve significant risks and uncertainties. The Company's actual results could differ materially from those indicated by such forward-looking statements as a result of various important factors, including the occurrence of any event, change or other circumstances that could give rise to the termination of the Roche License Agreement, the uncertainties inherent in the initiation and conduct of clinical trials, availability and timing of data from clinical trials, whether results of early clinical trials or preclinical studies will be indicative of the results of future trials, the adequacy of any clinical models, uncertainties associated with regulatory review of clinical trials and applications for marketing approvals, the risk that the Company may not resume its plans to pursue regulatory approval for Vicineum, the risk that clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC, including the additional clinical trial required for potential resubmission of the BLA, may fail to demonstrate safety and efficacy to the satisfaction of the FDA, 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 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, limit the commercial profile of its labeling, if approved, or result in significant negative consequences following any marketing approval, 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: January 6, 2022

Sesen Bio, Inc.

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