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): December 21, 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 December 21, 2020, Sesen Bio, Inc. (the "Company") issued a press release announcing the December 18, 2020 submission of the completed Biologics License Application to the United States Food and Drug Administration for Vicineum™, the Company's lead product candidate, for the treatment of high-risk, BCG-unresponsive non-muscle invasive bladder cancer.

A copy of the press release is attached as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01 - Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated December 21, 2020

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: December 21, 2020

Sesen Bio, Inc.

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

Sesen Bio Submits Completed Biologics License Application to the FDA for Vicineum™ and has Requested Priority Review

BLA supported by strong Phase 3 VISTA trial data and positive analytical comparability data

Priority Review requested with potential approval in mid-2021

Estimated peak revenue of $1B-$3B globally, $400M-$900M projected in the US

CAMBRIDGE, Mass., December 21, 2020 – Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today announced submission of the completed Biologics License Application ("BLA") to the FDA for Vicineum for the treatment of high-risk, BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) on December 18, 2020.

Within 60 days after receipt of the completed application, the FDA will issue a decision to the Company on the acceptance of the filing, and whether the BLA has received Priority Review (six-month target PDUFA date) under its existing Fast Track designation.

The BLA is supported by the pivotal Phase 3 VISTA trial, which the Company believes demonstrates a strong benefit-risk profile. The BLA also includes positive chemistry, manufacturing and controls (CMC) data that the Company believes validates the analytical comparability between clinical and commercial supply.

"There remains a significant unmet need for high-risk NMIBC, and we believe the differentiated clinical profile of Vicineum will provide a best-in-class option for physicians and their patients," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "Our strong non-clinical and clinical data, in addition to our positive comparability data, give us confidence in the regulatory path forward. I would like to thank the entire Sesen Bio team and our regulatory and manufacturing partners for their tireless dedication in helping us to complete the BLA submission. We look forward to continuing our regulatory progress by submitting a Marketing Authorization Application in Europe, which we anticipate in early 2021."

Bladder cancer is the sixth most commonly diagnosed cancer in the US, in which approximately 80% of patients are diagnosed with NMIBC. For patients who do not respond to BCG, the recommended option for treatment is radical cystectomy (the complete removal of the bladder) or Keytruda. Results of market research conducted by the Company show that when given the choice between Vicineum and Keytruda®, doctors will choose Vicineum over 80% of the time. If approved by the FDA, Vicineum could be a best-in-class treatment option for patients, and a critical step in Sesen Bio realizing its mission to save and improve the lives of patients.

About Vicineum™

Vicineum, a locally administered fusion protein, is Sesen Bio's lead product candidate being developed for the treatment of high-risk non-muscle invasive bladder cancer (NMIBC). Vicineum is comprised of a recombinant fusion protein that targets epithelial cell adhesion

molecule (EpCAM) antigens on the surface of tumor cells to deliver a potent protein payload, Pseudomonas Exotoxin A. Vicineum is constructed with a stable, genetically engineered peptide tether to ensure the payload remains attached until it is internalized by the cancer cell, which is believed to decrease the risk of toxicity to healthy tissues, thereby improving its safety. In prior clinical trials conducted by Sesen Bio, EpCAM has been shown to be overexpressed in NMIBC cells with minimal to no EpCAM expression observed on normal bladder cells. Sesen Bio is currently conducting the Phase 3 VISTA trial, designed to support the registration of Vicineum for the treatment of high-risk NMIBC in patients who have previously received a minimum of two courses of bacillus Calmette-Guérin (BCG) and whose disease is now BCG-unresponsive. Additionally, Sesen Bio believes that cancer cell-killing properties of Vicineum promote an anti-tumor immune response that may potentially combine well with immuno-oncology drugs, such as checkpoint inhibitors. The activity of Vicineum in BCG-unresponsive NMIBC is also being explored at the US National Cancer Institute in combination with AstraZeneca's immune checkpoint inhibitor durvalumab.

About Non-Muscle Invasive Bladder Cancer

Bladder cancer is the sixth most commonly diagnosed cancer in the United States, and approximately 80 percent of patients have non-muscle invasive bladder cancer (NMIBC). In NMIBC, cancer cells are in the lining of the bladder or have grown into the lumen of the bladder but have not spread into muscle or other tissue. NMIBC primarily affects men and is associated with carcinogen exposure. Initial treatment includes surgical resection; however, there is a high rate of recurrence and more than 60 percent of all patients diagnosed with NMIBC will receive bacillus Calmette-Guérin (BCG) immunotherapy. While BCG is effective in many patients, challenges with tolerability have been observed and many patients will experience recurrence of disease. If BCG is not effective or a patient can longer receive BCG, the recommended option for treatment is radical cystectomy, the complete removal of the bladder.

About Sesen Bio

Sesen Bio, Inc. is a late-stage clinical company advancing targeted fusion protein therapeutics for the treatment of patients with cancer. The Company's lead program, Vicineum™, also known as VB4-845, 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 (NMIBC). In December 2020, the Company submitted the completed BLA submission for Vicineum to the FDA. Sesen Bio retains worldwide rights to Vicineum except for Greater China and the Middle East and North Africa regions, for which the Company has partnered with Qilu Pharmaceutical and Hikma Pharmaceuticals, respectively, for commercialization. Vicineum is a locally administered targeted fusion protein composed of an anti-EpCAM antibody fragment tethered to a truncated form of Pseudomonas Exotoxin A for the treatment of high-risk NMIBC. For more information, please visit the company's website at www.sesenbio.com.

COVID-19 Pandemic Potential Impact

Sesen Bio continues to monitor the rapidly evolving environment regarding the potential impact of the COVID-19 pandemic on our Company. The Company has not yet experienced any disruptions to our operations as a result of COVID-19, however, we are not able to quantify or predict with certainty the overall scope of potential impacts to our business, including, but not

limited to, our ability to raise capital and, if approved, commercialize Vicineum. Sesen Bio remains committed to the health and safety of patients, caregivers and employees.

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and complete its planned clinical programs, expectations regarding potential approval of the Company's BLA for Vicineum in mid-2021, expectations regarding the potential market size for Vicineum, the Company's expectations to submit its MAA for Vicineum in early 2021, expectations regarding the potential for Vicineum to receive priority review, the Company's belief with respect to analytical comparability between clinical and commercial supply, and other factors discussed in the "Risk Factors" section of the Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other reports filed with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

Contact:

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