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 18, 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 18, 2020, Sesen Bio, Inc. (the "Company") issued a press release announcing favorable results for the cost-effectiveness of Vicineum™, the Company's lead product candidate, based on an independent report issued by the Institute for Clinical and Economic Review ("ICER") on December 17, 2020.

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 18, 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 18, 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 Announces Positive Cost-Effectiveness Profile for Vicineum™ Based on the Final Evidence Report Issued by the Institute for Clinical and Economic Review (ICER)

The majority of the ICER Council (8 yes votes; 3 no votes) judged Vicineum as superior to best supportive care

ICER report estimates that treatment with Vicineum results in a decrease in cumulative health care costs compared to usual care of approximately $101,000 by year five

CAMBRIDGE, Mass., December 18, 2020 – Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today announced favorable results for the cost-effectiveness of Vicineum based on an independent analysis issued by ICER in its final report published on December 17, 2020.

ICER is the leading Health Technology Assessment body in the United States, and is an independent non-profit, research organization that conducts assessments to examine the clinical and economic value of health care innovations such as prescription medications.

The final report used publicly available clinical data from the Company's Phase 3 VISTA trial, and focused on adults with BCG-unresponsive, high-risk non-muscle invasive bladder cancer (NMIBC), including those with Carcinoma in situ, as well as those with high-risk Papillary (Ta/T1) disease.

The ICER report states that for many patients with NMIBC that is unresponsive to BCG, there are limited treatment options that are bladder preserving. As a potential treatment option for patients with NMIBC, the report describes Vicineum as demonstrating Complete Response and Recurrence-Free Survival rates that appear to be greater than would be expected, based on historical data, with few serious adverse events and low discontinuation rates.

The majority of the ICER Council (8 yes votes; 3 no votes) judged that the evidence was adequate to demonstrate that the net health benefit of Vicineum is superior to that of best supportive care.

The report estimates that treatment with Vicineum results in an additional per-patient cost of approximately $123,000 in year one — with net savings in the following years, leading to a decline in cumulative health care costs, compared to usual care, of approximately $101,000 by year five.

"We are very pleased with the final ICER report and found the entire process to be transparent, evidence-based and professional," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "The findings in the ICER report give us confidence in the value and cost-effectiveness of Vicineum. It is our goal to bring Vicineum to market to improve patient outcomes while reducing health care costs. The ICER report is very encouraging in that regard, and we look forward to working physicians, patients and payers to make that goal a reality."

The full report, including relevant disclaimers and assumptions, can be accessed at the following link: https://icer.org/wp-content/uploads/2020/08/ICER_Bladder_Cancer_Final_Report_121720.pdf

The Company is on track to complete and submit its Biologics License Application for Vicineum to the FDA by next week.

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 a Phase 3 registration trial for the treatment of high-risk, BCG-unresponsive non-muscle invasive bladder cancer (NMIBC). In December 2019, the Company initiated the BLA submission for Vicineum to the FDA under Rolling Review. 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 the completion of the Company's BLA submission for Vicineum, expectations regarding the potential cost savings of Vicineum, expectations regarding the safety and efficacy of Vicineum, 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:

Erin Clark, Vice President, Corporate Strategy & Investor Relations
ir@sesenbio.com