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): May 21, 2018

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))

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 May 21, 2018, Sesen Bio, Inc. (the "Company"), issued a press release announcing three-month data from the Company's ongoing Phase 3 VISTA Trial, which is evaluating Vicinium™ for the treatment of patients with high-grade non-muscle invasive bladder cancer who have been previously treated with bacillus Calmette-Guérin. 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 May 21, 2018

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: May 21, 2018

Sesen Bio, Inc.

By: /s/ Richard F. Fitzgerald
Richard F. Fitzgerald
Chief Financial Officer, Secretary and Treasurer

Phase 3 Registration Trial for Non-Muscle Invasive Bladder Cancer Achieves 42% Complete Response Rate at Three Months in Carcinoma in Situ Patients

Sesen Bio (Formally Eleven Biotherapeutics) Reports Positive, Three-Month Data from VISTA Trial of Vicinium™ in High-Grade NMIBC

Data Presented During Plenary Session at American Urological Association Annual Meeting

Company to Host Conference Call Today at 4:05 p.m. ET

CAMBRIDGE, Mass., May 21, 2018 – Sesen Bio, Inc. (NASDAQ: SESN), a late-stage clinical company advancing next-generation antibody-drug conjugate (ADC) therapies for the treatment of cancer, today announced positive, three-month data from its ongoing Phase 3 VISTA Trial of Vicinium™ for the treatment of patients with high-grade non-muscle invasive bladder cancer (NMIBC) who have been previously treated with bacillus Calmette-Guérin (BCG). The efficacy data being reported are based on three-month follow-ups from 111 patients with high-grade NMIBC that is either carcinoma in situ (CIS), which is cancer found on the inner lining of the bladder that has not spread into muscle or other tissue, with or without papillary disease, or from patients with papillary disease without CIS, which is cancer that has grown from the bladder lining out into the bladder, but has not spread into muscle or other tissue.

"High-grade NMIBC is a devastating cancer that typically occurs later in life and for which treatment options are limited. Over the last 30 years, our industry has seen little innovation for the treatment of this prevalent cancer. The current standard-of-care, BCG, works in many patients, but many will also eventually relapse. For those patients who relapse or who don't respond at all, the standard alternative is radical cystectomy. In a cystectomy, the bladder is removed along with surrounding lymph nodes and other organs that contain cancer. I am very encouraged by both the safety and these three-month efficacy data with Vicinium, and I look forward to continuing to work with the Sesen Bio team to help bring forward this potential treatment as a safe and effective option for my patients," said Rian Dickstein, M.D. F.A.C.S., chief of urology, University of Maryland Baltimore Washington Medical Center; medical director of GU oncology, Tate Cancer Center at The University of Maryland Baltimore Washington Medical Center; clinical assistant professor, Department of Surgery, University of Maryland School of Medicine; director, bladder cancer program, Chesapeake Urology; and an investigator in the VISTA Trial.

"The VISTA Trial three-month data are encouraging for our company and the patients with high-grade NMIBC who have been underserved for many years," said Stephen Hurly, president and chief executive officer of Sesen Bio. "We have made tremendous progress over the last several years to get us to where we are today, and I am proud of what our team has accomplished. Our new name is a reflection of the journey we've taken to get to this point and represents our

mission of improving lives. With 12-month data expected by mid-2019, we are continuing to advance Vicinium to assess its full potential in treating this devastating cancer."

VISTA Trial Design and Patient Cohorts

The Phase 3 VISTA Trial completed recruitment in March 2018 with a total of 133 patients with high-grade NMIBC that is either CIS or papillary with or without CIS, who have been previously treated with BCG. The primary endpoint of the trial is the complete response rate in patients with CIS with or without papillary disease.

The clinical trial includes three patient cohorts based on histology and time to recurrence after adequate BCG:

- Cohort 1 (n=87): patients with CIS with or without papillary disease whose cancer recurred within six months of their last course of BCG treatment.
- Cohort 2 (n=6): patients with CIS with or without papillary disease whose cancer recurred after six months, but before 11 months, after their last course of BCG treatment.
- Cohort 3 (n=40): patients with papillary disease without CIS whose cancer recurred within six months of their last course of BCG treatment.

Three-Month Efficacy Results: CIS Patients

In cohort 1, 72 patients were evaluable for three-month data as of the April 20, 2018 data cut-off date. In these patients, treatment with Vicinium demonstrated a complete response rate of 39 percent. In evaluable patients in cohort 2 (n=5), treatment with Vicinium demonstrated a complete response rate of 80 percent. In an analysis assessing pooled CIS patients from cohorts 1 and 2 (n=77), based on final U.S. Food and Drug Administration guidance on treatment of BCG-unresponsive CIS NMIBC patients (defined as patients with recurrent CIS within 12 months of adequate BCG therapy), Vicinium treatment resulted in a complete response rate of 42 percent at three months.

Three-Month Efficacy Results: Papillary Patients

Patients with papillary disease without CIS were enrolled in cohort 3, but are not included in the primary endpoint assessment. At screening, all of these patients underwent mandatory resection of their tumors and upon starting treatment, were deemed to have no visible evidence of disease. As such, in this patient population, rates of disease recurrence and time to disease recurrence are standard criteria to evaluate response. In these evaluable patients (n=34), treatment with Vicinium demonstrated a 68 percent recurrence-free rate at three months.

Preliminary Safety Results

To date, Vicinium has been well-tolerated in the VISTA Trial. In treated patients across cohorts (n=129), 72 percent of all adverse events were Grade 1 or 2. The most commonly reported treatment-emergent adverse events (all grades) were urinary tract infection (29%), dysuria (19%), hematuria (16%), pollakiuria (12%), diarrhea (10%), fatigue (10%), micronutrition urgency (9%), nausea (8%) and increased lipase (8%, all asymptomatic). Of the treatment-related adverse events, four percent were Grade 3 or 4, with no Grade 5 treatment-related adverse events. Four treatment-related serious adverse events were reported, including acute kidney injury or renal failure and cholestatic hepatitis.

"The positive, three-month data from the VISTA Trial support Vicinium's potential to offer a new and completely different treatment option for patients who need it," said Donald L. Lamm, M.D., BCG Oncology, P.C., Phoenix. "In contrast to the many other advances in cancer therapy, treatment for high-grade NMIBC has suffered from little innovation, and Vicinium represents a unique approach with a targeted protein, an entirely new mechanism for treating this disease. I believe this new treatment approach, which has demonstrated a 42 percent, three-month complete response rate in patients who have failed to respond to BCG and good tolerability, gives these patients new hope for beating bladder cancer without life-changing major surgery. High-grade NMIBC patients have a high chance of losing their bladder after having gone through unreliable and often difficult treatments. I believe that Vicinium, a first-in-class, innovative therapy, may change that in the future."

Conference Call Information

To participate in the conference call, please dial (844) 831-3025 (domestic) or (315) 625-6887 (international) and refer to conference ID 4453267. The webcast can be accessed in the Investor Relations section of the company's website at www.sesenbio.com. The replay of the webcast will be available in the investor section of the company's website at www.sesenbio.com for 60 days following the call.

About the VISTA Clinical Trial

The VISTA Trial is an open-label, multicenter, single-arm Phase 3 clinical trial evaluating the efficacy and tolerability of Vicinium™ in patients with high-grade non-muscle invasive bladder cancer (NMIBC) that is carcinoma in situ (CIS), which is cancer found on the inner lining of the bladder that has not spread into muscle or other tissue) and/or papillary, which is cancer that has grown from the bladder lining out into the bladder but has not spread into muscle or other tissue, who have been previously treated with bacillus Calmette-Guérin (BCG). The primary endpoint of the trial is the complete response rate in patients with CIS with or without papillary disease. Patients in the trial receive locally administered Vicinium twice a week for six weeks, followed by once-weekly treatment for another six weeks, then treatment every other week for up to two years. Twelve-month data are anticipated in mid-2019. To learn more about the Phase 3 VISTA Trial, please visit www.clinicaltrials.gov and search the identifier NCT02449239.

About Vicinium™

Vicinium™, also known as VB4-845, is Sesen Bio's lead product candidate and is a next-generation antibody-drug conjugate (ADC), developed using the company's proprietary Targeted Protein Therapeutics platform, for the treatment of high-grade non-muscle invasive bladder cancer (NMIBC). Vicinium 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 (ETA). Vicinium is constructed with a stable, genetically engineered peptide linker 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 Vicinium for the treatment of high-grade NMIBC in patients who have previously received two courses of bacillus Calmette-Guérin (BCG) and whose disease is now BCG-unresponsive. Twelve-month data from the trial are anticipated in mid-2019. Additionally, Sesen Bio believes that Vicinium's cancer cell-killing properties promote an anti-tumor immune response that may potentially combine well with immuno-oncology drugs, such as checkpoint inhibitors. The activity of Vicinium 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 next-generation antibody-drug conjugate therapies for the treatment of cancer based on the company's Targeted Protein Therapeutics platform. The company's lead program, Vicinium™, also known as VB4-845, is currently in a Phase 3 registration trial, the VISTA Trial, for the treatment of high-grade non-muscle invasive bladder cancer. Twelve-month data from the trial are anticipated in mid-2019. Vicinium incorporates a tumor-targeting antibody fragment and a protein cytotoxic payload into a single protein molecule designed to selectively and effectively kill cancer cells while sparing healthy cells. For more information, please visit the company's website at www.sesenbio.com.

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 uncertainties inherent in the initiation and conduct of clinical trials, the possibility that the three-month data of the Phase 3 VISTA Trial are not indicative of final clinical results and final clinical trial results may not be positive with regard to the safety or efficacy of Vicinium, our ability to successfully develop our product candidates and complete our planned clinical programs, our ability to obtain marketing approvals for our product candidates, expectations regarding our ongoing clinical

trials, availability and timing of data from clinical trials, whether interim results from a clinical trial will be predictive of the final results of the trial or results of early clinical studies will be indicative of the results of future studies, the adequacy of any clinical models, expectations regarding regulatory approvals 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.

Contacts:
Monique Allaire, THRUST Strategic Communications
monique@thrustir.com
617-895-9511

Alicia Davis, THRUST Strategic Communications
alicia@thrustir.com