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 26, 2021

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 26, 2021, Sesen Bio, Inc. (the "Company") issued a press release announcing the Company's commercial progress as the Company approaches potential FDA approval and the commercial launch of Vicineum™ for the treatment of BCG-unresponsive non-muscle invasive bladder cancer ("NMIBC") in the United States.

The Company believes it remains on track for an FDA decision on its Biologics License Application for Vicineum[1] by the target PDUFA date of August 18, 2021.

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

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS:

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, the Company's beliefs regarding the timing for the U.S. Food and Drug Administration's decision on the Company's Biologics License Application for Vicineum for the treatment of BCG-unresponsive NMIBC and the Company's commercial progress for the launch of Vicineum, if approved, in the US. 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, including the risk that the FDA may not approve the BLA for Vicineum on or before the target PDUFA date, or at all, the risk that the Company may not be successful in commercializing Vicineum for the treatment of BCG-unresponsive NMIBC in the US, if and when the Company's BLA is approved by the FDA, among other risks and uncertainties. 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.

[1] For the treatment of BCG-unresponsive NMIBC

Item 9.01 - Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated July 26, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 26, 2021

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 Significant Commercial Progress as the Company Approaches the Potential Approval and Launch of Vicineum™ in the US

Hiring of the US sales force is 97% complete and sales training has commenced

14 Key Opinion Leader (KOL) speakers have been identified and speaker training has commenced

Two-pronged market access and reimbursement strategy has commenced

CAMBRIDGE, Mass., Jul. 26, 2021 – **Sesen Bio** (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today announced that it has completed its commercial build phase in preparation for the anticipated launch of Vicineum, if approved, in the US, and has advanced to the implementation phase that will focus on executing the Company's commercial strategy for Vicineum. The Biologics License Application (BLA) for Vicineum, the Company's lead program, is currently under Priority Review with the Food and Drug Administration (FDA) for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) in the US, with a target Prescription Drug User Fee Act (PDUFA) date of August 18, 2021.

"We are thrilled to have this experienced commercial team on board at Sesen Bio to build capabilities as we approach the potential commercial launch of Vicineum in the US market," said Patricia Drake, chief commercial officer of Sesen Bio. "They have made incredible progress across the core functions of sales, marketing and market access. We also believe our network of Urology and Uro-oncology KOL speakers will play an integral role in allowing us to educate their peers about Vicineum, which we believe will be a new tool in their practices to serve a large unmet medical need in NMIBC."

The Company has completed the hiring of ~25 talented internal employees to support the Company cross-functionally, as well as the hiring of 34 of 35 sales representatives as part of the contract sales organization, which will be deployed across four customer-centric regions and will target approximately 2,000 high-prescribers of BCG to drive awareness, trial and adoption of Vicineum for the treatment of BCG-unresponsive NMIBC. If approved, promotional efforts will begin immediately, and the Company expects Vicineum product to be commercially available to physicians and patients in the fourth quarter of 2021.

In addition to building its sales force, as part of Sesen Bio's national speaker programs, the Company has identified and commenced training of 14 KOL speakers to engage physicians and educate them on Vicineum for the treatment of BCG-unresponsive NMIBC.

Upon product availability, the Company will utilize a two-pronged market access strategy to ensure maximum coverage for Vicineum. The Company anticipates strong product reimbursement achieved through the deployment of a focused team of National Account Executives (NAEs) who will call on key commercial and Medicare payers. The Company will also provide support to eligible patients with a reimbursement services and support center, which

will help with benefit investigation, prior authorizations, a co-pay assistance program, and any other support resources they may require along their journey.

The Company believes it remains on track for an FDA decision on its BLA for Vicineum by the target PDUFA date August 18, 2021.

About Vicineum™
Vicineum, a locally administered fusion protein, is Sesen Bio's lead product candidate being developed for the treatment of BCG-unresponsive 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 to the antibody binding fragment until it is internalized by the cancer cell. This fusion protein design 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 in the follow-up stage of a Phase 3 registration trial in the US for the treatment of BCG-unresponsive NMIBC. In February 2021, the FDA accepted for filing the Company's BLA for Vicineum for the treatment of BCG-unresponsive NMIBC and granted the application Priority Review with a target PDUFA date of August 18, 2021. 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. For this reason, 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 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 oportuzumab monatox, is currently in the follow-up stage of a Phase 3 registration trial for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC). In February 2021, the FDA accepted for filing the Company's BLA for Vicineum for the treatment of BCG-unresponsive NMIBC and granted the application Priority Review with a target PDUFA date of August 18, 2021. Sesen Bio retains worldwide rights to Vicineum with the exception of Greater China and the Middle East and North Africa (MENA), 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, which is being developed for the treatment of BCG-unresponsive 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 "expect," "anticipate," "believe," "may," "target," "strategy," "potential," "will," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. For example, statements regarding the timing for the FDA's decision on the Company's BLA for Vicineum for the treatment of BCG-unresponsive NMIBC based on the FDA granting the BLA Priority Review and the target PDUFA date of August 18, 2021, the timing of the potential commercial launch of Vicineum in the US, the Company's beliefs regarding the ability of Vicineum to serve unmet medical needs in NMIBC, the Company's expectations regarding the size, scope and ability to execute its commercial strategy and promotion of Vicineum, if approved, in the US market, the Company's expectations regarding the timing for availability of Vicineum, if approved, in the US, the Company's ability to ensure maximum coverage of Vicineum and its expectations regarding reimbursement of Vicineum, and the impact of COVID-19 on the Company, including its ability to raise capital, and, if approved, its ability to commercialize Vicineum for the treatment of BCG-unresponsive NMIBC. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the risk that clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC may fail to demonstrate safety and efficacy to the satisfaction of the FDA or not otherwise produce favorable results, the risk that the FDA may not approve the BLA for Vicineum within the anticipated timing, or at all, the risk that the Company may not be able to establish sales, marketing and distribution capabilities, the risk that the Company may not be successful in commercializing Vicineum for the treatment of BCG-unresponsive NMIBC, if and when it is approved, the risk that Vicineum may not gain market acceptance among physicians, patients, third-party payors or the medical community, the risk that Vicineum may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, 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, 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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