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): August 11, 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 August 11, 2021, Sesen Bio, Inc. (the "Company") issued a press release announcing the appointment of John Knighton as Vice President and Chief Compliance Officer. A copy of the press release is attached as Exhibit 99.1 to this report and is incorporated herein by reference.

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

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 BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. 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, 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 non-muscle invasive bladder cancer ("NMIBC")

Item 9.01 - Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated August 11, 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: August 11, 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 Strengthens Executive Leadership Team as the Company Approaches the Potential Approval and Commercial Launch of Vicineum™

John Knighton to join Sesen Bio as Vice President and Chief Compliance Officer

The Company believes it remains on track for an FDA decision on its BLA for Vicineum by August 18, 2021

CAMBRIDGE, Mass., Aug. 11, 2021 – Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today announced the expansion of its executive leadership team in support of the Company's continued transformation into a commercial-stage company with the hiring of John Knighton as Vice President and Chief Compliance Officer, effective August 16, 2021. The Company's Biologics License Application (BLA) for Vicineum for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC), the Company's lead program, is currently under Priority Review with the US Food and Drug Administration (FDA) with a target Prescription Drug User Fee Act (PDUFA) date of August 18, 2021.

"At Sesen Bio, we believe a strong culture of compliance is a source of competitive advantage, because a thorough understanding of laws and regulatory guidance allows us to fully explore innovative commercial models and strategies," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "This enables us to do the right thing while maximizing launch uptake of Vicineum. As we near our PDUFA date, I am confident that John's extensive experience in establishing compliance programs and enabling the implementation of innovative commercial model elements will further position us to execute a world-class launch."

Mr. Knighton brings over 20 years of legal and compliance experience in the life sciences industry, serving in multiple executive roles at innovative pharmaceutical and medical device companies transitioning from clinical-stage to commercialization. In these roles, he has designed and implemented multiple compliance programs and conducted business development diligence, audit and investigation projects related to the complex circumstances facing global life sciences companies. Mr. Knighton joins Sesen Bio from TherapeuticsMD, where he served as Chief Compliance Officer and supported the launch of three products between 2018 and 2020. Prior to this, he served as Head of Global Compliance at Orexigen Therapeutics, where he played a key role in the launch of an innovative telemedicine and home delivery channel, and as Chief Compliance Officer at MicroPort Orthopedics, among other roles of increasing responsibility where he provided compliance support across functions. Earlier in his career, Mr. Knighton served as a Consultant on the Life Science Compliance team at Ernst and Young, LLP. He received his Juris Doctor degree from Emory University School of Law and his Bachelor of Science in Accounting from Villanova University. He is a member of the Georgia State Bar.

In connection with the hiring of Mr. Knighton, Sesen Bio intends to grant a non-statutory stock option. Under such grant, up to 400,000 shares of Sesen Bio common stock are purchasable upon

vesting of the stock option within the ten-year term. The stock option vests over a four-year period, with one quarter of the underlying shares vesting on the first anniversary of the date of grant, and an additional 6.25% of the underlying shares vesting at the end of each successive three-month period following the one-year anniversary of the date of grant, subject to Mr. Knighton's continued service with Sesen Bio.

The non-statutory stock option will be granted on August 16, 2021, at an exercise price equal to the closing price per share of Sesen Bio's common stock on The Nasdaq Global Market on the date of grant. The stock option will be granted outside of the Company's 2014 Stock Incentive Plan and will be granted as a material inducement to employment in accordance with Nasdaq Listing Rule 5635(c)(4).

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 the Company's BLA file 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 the Company's BLA file 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, the Middle East and North Africa (MENA) and Turkey, for which the Company has partnered with Qilu Pharmaceutical, Hikma Pharmaceuticals and Eczacibasi Pharmaceuticals

Marketing (EIP), 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 the 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 "believe," "may," "target," "potential," "position," "will," "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 Company's expectations to execute a world-class commercial launch of Vicineum for the treatment of BCG-unresponsive NMIBC if approved in the US, the expectation that Mr. Knighton will join the Company, 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 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 Mr. Knighton may not join the Company within the anticipated timing, or at all, the risk that the Company may not be able to establish sales, marketing and distribution capabilities for Vicineum for the treatment of BCG-unresponsive NMIBC, the risk that the Company may not be successful in commercializing Vicineum if approved in the US, the risk that Vicineum may not gain market acceptance for the treatment of BCG-unresponsive NMIBC in the US, 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.

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