# 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 5, 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**<br>**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 5, 2021, Sesen Bio, Inc. (the "Company") issued a press release announcing that the Company has entered into an exclusive licensing agreement with Eczacibasi Pharmaceuticals for the registration and commercialization of Vicineum™ for the treatment of BCG-unresponsive non-muscle invasive bladder cancer ("NMIBC") in Turkey and Northern Cypress.

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

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.

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. 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 NMIBC

**Item 9.01 - Financial Statements and Exhibits**.

(d) Exhibits.

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release dated August 5, 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 5, 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 Partnership with Eczacibasi Pharmaceuticals Marketing (EIP) **for the Commercialization of Vicineum™ in Turkey**

Sesen Bio to receive $1.5 million upfront and is eligible for additional regulatory and commercial milestone payments

Sesen Bio is entitled to receive a 30% royalty on net sales in Turkey

CAMBRIDGE, Mass., Aug. 5, 2021 – Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, and Eczacibasi Pharmaceuticals Marketing (EIP), part of the Eczacibasi Group and one of Turkey's pioneering pharmaceutical companies with a focus on innovative, branded products, today announced that the companies have entered into a licensing agreement for the registration and commercialization of Vicineum for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC)[1]. The Company's Biologics License Application (BLA) for the Company's lead program, Vicineum, is currently under Priority Review with the US Food and Drug Administration (FDA) for the treatment of BCG-unresponsive NMIBC in the US with a target Prescription Drug User Fee Act (PDUFA) date of August 18, 2021.

"EIP is a partner of choice in Turkey and has a proven track record and experience in marketing innovative, life-saving medicines with an expertise in oncology and urology," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "This partnership with EIP marks a further step in realizing our mission to save and improve the lives of patients, and in achieving the significant global opportunity projected for Vicineum."

"International partnerships are a central component of EIP's growth strategy and Sesen Bio is an ideal partner given their mission and expertise in NMIBC," said Muge Satir, General Manager of EIP. "Vicineum is a potential first-in-class treatment with a differentiated clinical profile which we believe can make a significant impact on patients with NMIBC. We look forward to working with Sesen Bio closely to expeditiously bring Vicineum to patients in Turkey."

In Turkey, bladder cancer is the sixth most commonly diagnosed cancer with about 36,000 cases, and it ranks 11$^{th}$ in cause of death with approximately 4,000 deaths per year. Approximately 75% of these patients are diagnosed with NMIBC, of which many will initially be treated with BCG. If BCG fails, there are no second line treatment options for patients except radical cystectomy, total surgical removal of the bladder. Additionally, over 99% of the population in Turkey is fully insured with access to medications and healthcare services. If approved in Turkey, Vicineum will be the first product approved for patients with BCG-unresponsive NMIBC in over 20 years with a high level of access to physicians and their patients anticipated.

Under the terms of the licensing agreement, Sesen granted EIP an exclusive license to register and commercialize Vicineum in Turkey for the treatment of BCG-unresponsive NMIBC. Sesen Bio will receive an upfront payment of $1.5 million and is eligible to receive additional regulatory and commercial milestone payments. Upon commercialization in Turkey, Sesen Bio is also entitled to receive a 30% royalty on net sales in Turkey. Sesen retains full development

and commercialization rights for Vicineum for the treatment of NMIBC in the US and the rest of the world excluding Greater China, the Middle East and North Africa (MENA) and Turkey.

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

Hogan Lovells and Paksoy acted as legal advisors to Sesen Bio for this transaction.

[1]The geography under the licensing agreement includes Turkey and Northern Cyprus.

**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 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 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 US 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 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.

About Eczacibasi Pharmaceuticals Marketing (EIP)

Eczacibasi Pharmaceuticals Marketing is part of the Eczacibasi Group, a prominent Turkish business group established in 1942 that is active in healthcare, building products, consumer products and natural resources. Eczacibasi Pharmaceuticals Marketing has a successful track record of partnerships with leading pharmaceutical companies and thrives on making the R&D expertise of its partners accessible to patients in Turkey through high value pharmaceutical products that best serve their needs. The company is dedicated to increasing the quality of life of patients in Turkey by providing them high-quality innovative solutions with a patient-centric mindset.
https://www.eczacibasiilac.com.tr/en

## 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," "may," "project," "target," "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 size of the global opportunity for Vicineum for the treatment of BCG-unresponsive NMIBC and the Company's ability to achieve such opportunity, the potential for Vicineum to be a first-in-class treatment and impact patients with NMIBC, the ability of the Company and EIP to bring Vicineum to patients in Turkey, the possibility that Vicineum, if approved, will be the first product approved for patients with BCG-unresponsive NMIBC in over 20 years, the timing and amounts of any payments or royalties due to the Company under its licensing agreement with EIP, 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 the FDA may not approve the BLA for Vicineum within the anticipated timing, or at all, the Company and EIP may not successfully obtain regulatory approval for Vicineum in Turkey, Vicineum may not gain market acceptance for the treatment of BCG-unresponsive NMIBC in Turkey, market opportunity for Vicineum in Turkey may be more limited than anticipated, competitors may develop or commercialize products before, or more successfully than, the Company and EIP, 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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