
**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 1, 2020

SESEN BIO, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36296
(Commission
File Number)

26-2025616
(I.R.S. Employer
Identification No.)

245 First Street, Suite 1800
Cambridge, MA
(Address of principal executive offices)

02142
(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 1, 2020, Sesen Bio, Inc. (the “Company”) issued a press release announcing that the Company has entered into an exclusive licensing agreement with Hikma Pharmaceuticals LLC for the registration and commercialization of Vicineum™, the Company’s lead product candidate for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (“NMIBC”), for NMIBC and other types of cancer in the Middle East and North Africa region.

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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated December 1, 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 1, 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 Partnership with Hikma Pharmaceuticals for the Commercialization of Vicineum™ in the Middle East and North Africa

CAMBRIDGE, Mass., December 1, 2020 – Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, and Hikma Pharmaceuticals, a multi-national pharmaceutical company and leading licensing partner in the Middle East and North Africa (“MENA”) region specializing in the development and commercialization of a broad range of high-quality medicines, today announced that the companies have entered into an exclusive licensing agreement for the registration and commercialization of Vicineum for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (“NMIBC”) and other types of cancer in MENA. Vicineum, a locally administered fusion protein, is Sesen Bio’s lead product candidate currently in the follow-up stage of a Phase 3 registration trial for the treatment of high-risk, BCG-unresponsive NMIBC. In December 2019, the Company initiated the BLA submission for Vicineum to the FDA under Rolling Review.

“Sesen is committed to saving and improving the lives of patients, and Hikma is an ideal partner to deliver Vicineum to patients with NMIBC in the MENA region,” said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. “As we continue to work toward regulatory approval in the US and Europe, we also continue to execute partnerships outside of the US as part of our mission to deliver this important medicine to patients around the world. Hikma has strong expertise in commercializing innovative products in the MENA region and a successful track record of serving patients worldwide. This partnership represents a further step in realizing the significant global opportunity for Vicineum.”

“At Hikma, we believe that partnerships with innovative pharma companies are a key contributor to the success of our business. We are very pleased to enter into an exclusive partnership with Sesen given their expertise in NMIBC and the strong clinical profile of Vicineum,” said Mazen Darwazah, Hikma’s Executive Vice Chairman and President of MENA. “As a company whose mission is to put better health within reach every day, we regard being the partner of choice to Sesen in MENA as a key collaboration that augments Hikma’s biotechnology and oncology portfolio to deliver on our strategy of bringing innovative products to patients in the region. Vicineum - our first innovative fusion protein - is a highly differentiated product candidate and is positioned to make a meaningful impact on the lives of bladder cancer patients.”

Under the terms of the agreement, Sesen Bio granted Hikma an exclusive license to register and commercialize Vicineum in all 19 MENA markets in an arrangement anticipated to deliver equal value share to both parties. Financial terms of the agreement are confidential and include an upfront payment to Sesen Bio, sales related milestone payments, and royalties on net sales in the region for the term of the agreement. Sesen Bio 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 and MENA.

Al-Tamimi and Hogan Lovells acted as a legal advisors to Sesen Bio for this transaction.

About Vicineum™

Vicineum, a locally administered fusion protein, is Sesen Bio's lead product candidate currently in the follow-up stage of a Phase 3 registration trial for the treatment of high-risk, BCG-unresponsive NMIBC. In December 2019, the Company initiated the BLA submission for Vicineum to the FDA under Rolling Review. 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 no 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.

About Hikma Pharmaceuticals

(LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated BBB-/stable S&P, BBB-/stable Fitch and Ba1/stable Moody's)

Hikma helps put better health within reach every day for millions of people in more than 50 countries around the world. For more than 40 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are a global company with a local presence across the United States (US), the Middle East and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines. Together, our 8,600 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: www.hikma.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: our ability to successfully develop our product candidates and complete our planned clinical programs, expectations regarding the safety and efficacy of Vicineum, expectations regarding possible milestone and royalty payments under the license agreement with Hikma, expectations regarding Hikma's ability to register and commercialize Vicineum in MENA, expectations regarding potential partnerships to develop and commercialize Vicineum outside of the US, 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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