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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**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 7, 2020**

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

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**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.)

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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:

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- 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 7, 2020, Sesen Bio, Inc. (the “Company”) issued a press release announcing that the Company entered into a global commercial manufacturing and supply framework agreement on Friday, December 4, 2020 with Qilu Pharmaceutical Co., Ltd. to be a contract manufacturer for the Company for the global commercial supply of Vicineum™, the Company’s lead product candidate.

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	<a href="#">Press Release dated December 7, 2020</a>

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**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 7, 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 Commercial Manufacturing and Global Supply Partnership with Qilu Pharmaceutical

Technology transfer to Qilu anticipated to be completed in mid-2021

Sesen Bio to receive \$2M milestone payment upon completion of technology transfer

Extensive biomanufacturing expertise and capacity positions Qilu Pharmaceutical to support anticipated significant global demand for Vicineum™

CAMBRIDGE, Mass., December 7, 2020 – Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today announced that on Friday, December 4, 2020 the Company entered into a commercial manufacturing and supply framework agreement (the “CMO Agreement”) with the Company’s partner in China, Qilu Pharmaceutical Co., Ltd. (“Qilu”).

Under the CMO Agreement, Qilu will be part of the contract manufacturing network for global commercial supply of Vicineum. The Company’s lead program, Vicineum, is currently in the follow-up stage of a Phase 3 registration trial in the United States (“US”) for the treatment of high-risk, BCG-unresponsive non-muscle invasive bladder cancer (“NMIBC”). The Company is on track to complete the BLA for Vicineum and submit to the FDA later this month.

In July 2020, the Company and Qilu entered into an agreement which grants Qilu an exclusive license to develop, manufacture and commercialize Vicineum in China.

“NMIBC is a disease area that has chronically suffered from manufacturing and CMC issues with significant impacts on patient care,” said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. “Given this, we have taken a thoughtful approach to our supply chain and partnerships in order to meet the significant anticipated global demand for Vicineum. Qilu has a large and experienced manufacturing team and currently supplies products for commercial sale around the world. The CMO Agreement represents an exciting expansion of our strong partnership with Qilu and will help Sesen Bio to reliably meet the projected global demand, while also creating an opportunity to reduce the cost of goods.”

The Company believes that the technology transfer to Qilu for manufacturing of Vicineum is on track to be completed in mid-2021. Upon completion of the technology transfer, Sesen Bio is entitled to receive a \$2M milestone payment.

In addition to Fujifilm and Baxter, the CMO partnership with Qilu expands the Company’s network of world-class partners committed to providing reliable supply of Vicineum around the world.

### About Vicineum™

Vicineum, a locally administered fusion protein, is Sesen Bio’s lead product candidate being developed for the treatment of high-risk non-muscle invasive bladder cancer (NMIBC).

Vicineum is comprised of a recombinant fusion protein that targets epithelial cell adhesion

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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 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](http://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 "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 Company's ability to successfully develop its product candidates and complete its planned clinical programs, expectations regarding the completion of the tech transfer to Qilu, expectations that the Company will complete its BLA submission for Vicineum in December 2020, expectations regarding the timing and amounts of any payments due under the Company's license agreement with Qilu, expectations regarding the significant global demand for Vicineum, and other factors discussed

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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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