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 10, 2020

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 2.02 - Results of Operations and Financial Condition.

On August 10, 2020, Sesen Bio, Inc. (the "Company") announced its financial results for the quarter ended June 30, 2020. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information provided under this Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 - Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press Release dated August 10, 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: August 10, 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 Reports Second Quarter 2020 Financial Results and Business Update

On-track to complete BLA submission in the US in the fourth quarter of 2020

Entered into a license agreement with Qilu Pharmaceutical for the development and *commercialization of Vicineum™ in Greater China with* $12M upfront payment

Manufacturing of PPQ campaign drug substance batches has been completed

CAMBRIDGE, Mass., August 10, 2020 – Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today reported operating results for the second quarter ended June 30, 2020. The Company also provided an update on recent business development activities and the progress of manufacturing activities related to the PPQ campaign. The Company's lead program, Vicineum, also known as VB4-845, is currently in the follow-up stage of 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.

"We are extremely pleased with the progress at Sesen Bio over the past quarter," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "We signed our first licensing agreement for Vicineum outside the US with Qilu Pharmaceutical, which is a strong sign of confidence in our mission to bring this innovative therapy to more patients in need. We expect to sign additional partnerships over the next six months. Equally important, we have now completed the manufacturing of the PPQ campaign drug substance batches at Fujifilm, an important milestone in our path to completion of the BLA submission. We are currently in an exciting phase at Sesen Bio and we remain as driven as ever to bring Vicineum to market to save and improve the lives of patients with cancer."

US and European Regulatory Update

US:

- On June 17, 2020, Sesen received conditional acceptance of the proprietary brand name Vicineum for the Company's product candidate, oportuzumab monatox. The Company believes Vicineum is a name with strong marketing potential that is also consistent with the FDA's goal of preventing medication errors and potential harm to the public by ensuring that only appropriate proprietary names are approved for use. Final approval of the Vicineum brand name is conditional on FDA approval of the Company's product candidate. The conditional acceptance of Vicineum is an important milestone in commercial readiness in the US. The Company remains on track to complete the BLA submission in the fourth quarter of 2020 and anticipates potential approval in mid-2021.

Europe:

- Sesen Bio concluded a five-month scientific opinion process in Europe and received positive Scientific Advice for both clinical and CMC. Importantly, the Committee for

Medical Products for Human Use ("CHMP") agreed that the nonclinical and clinical pharmacology studies, and safety database are all sufficient to support a Marketing Authorization Application ("MAA") submission for Vicineum and no additional clinical trials were requested. Additionally, the CHMP agreed that the CMC comparability plan provides a strong analytical package, and no additional clinical trials to establish comparability are deemed necessary at this time. Based on the guidance received, the Company expects to submit the MAA for Vicineum to the EMA in early 2021 with potential approval anticipated in early 2022.

- On July 3, 2020, the Company received a product-specific pediatric waiver from the EMA for Vicineum. As part of the regulatory process for the registration of new medicines with the EMA, pharmaceutical companies are required to provide a Pediatric Investigation Plan ("PIP") that outlines the clinical development strategy for studying the investigational product in the pediatric population. In some instances, a waiver from required pediatric studies for certain conditions may be granted by the EMA when development of a medicine for use in children is not feasible or appropriate. The PIP waiver from the EMA applies to Vicineum across all subsets of the pediatric population for the treatment of urothelial carcinoma. The receipt of the waiver will allow the Company to submit a MAA for Vicineum to the EMA without the requirement to conduct clinical studies in a pediatric population either pre-approval or post-approval.

Business Development Update

On July 30, 2020, Sesen Bio and Qilu Pharmaceutical signed a license agreement for the commercialization of Vicineum in Greater China. Under the terms of the agreement, Sesen granted Qilu Pharmaceutical a license to manufacture, develop and commercialize Vicineum for the treatment of NMIBC and other types of cancer in China, Hong Kong, Macau and Taiwan ("Greater China"). Key terms of the deal include:

- Financial terms include significant sources of non-dilutive capital
  - Upfront payment of $12M in cash
  - Eligibility to receive up to $23M in regulatory and tech transfer milestones in addition to sales royalties for at least 12 years
- Qilu will be the Marketing Authorization Holder and will have the exclusive rights to develop, manufacture and commercialize Vicineum in Greater China
  - Qilu will be responsible for all expenses related to these activities
  - Sesen retains full development and commercialization rights in the US and the rest of world excluding Greater China
- Terms of the agreement include tech transfer, creating an opportunity for future CMO partnership to meet significant global demand forecasts

Manufacturing Update

Sesen Bio completed the manufacturing of the PPQ campaign drug substance batches at Fuji on schedule. Release testing is underway, and upon completion, the drug substance will be shipped to Baxter to finish the PPQ campaign for drug product, which is anticipated to be completed in September 2020. Comparability data from the PPQ campaign for drug substance and drug product are the last material deliverables before submitting the BLA in the fourth quarter of 2020.

Second Quarter 2020 Financial Results

- Cash Position: Cash and cash equivalents were $37.7 million as of June 30, 2020, compared to $48.1 million as of December 31, 2019.
- R&D Expenses: Research and development expenses for the second quarter of 2020 were $4.6 million compared to $7.9 million for the same period in 2019. The second quarter decrease was due primarily to timing of costs related to the ongoing technology transfer process and commercial manufacturing, in addition to lower employee compensation and lower clinical expenses related to the Phase 3 VISTA trial for Vicineum.
- G&A Expenses: General and administrative expenses for the second quarter of 2020 were $3.3 million compared to $2.6 million for the same period in 2019. The second quarter increase was due primarily to increases in employee compensation, and legal and insurance costs, offset by slightly lower audit and professional fees.
- Net Income (Loss): Net loss was $26.3 million, or $0.24 per basic and diluted share, for the three months ended June 30, 2020, compared to a net loss of $54.3 million, or $0.67 per basic and diluted share, for the same period in 2019. The change was primarily the result of the non-cash change in fair value of contingent consideration due to significantly higher discount rates associated with market conditions related to the COVID-19 pandemic.

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 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 the VISTA Clinical Trial

The VISTA trial is an open-label, multicenter, single-arm Phase 3 clinical trial evaluating the efficacy and tolerability of Vicineum™ as a monotherapy in patients with high-risk, bacillus Calmette-Guérin (BCG) unresponsive non-muscle invasive bladder cancer (NMIBC). The primary endpoints of the trial are the complete response rate and the duration of response in patients with carcinoma in situ with or without papillary disease. Patients in the trial received

locally administered Vicineum twice a week for six weeks, followed by once-weekly treatment for another six weeks, then treatment every other week for up to two years. To learn more about the Phase 3 VISTA trial, please visit www.clinicaltrials.gov and search the identifier NCT02449239.

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.

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: our ability to successfully develop our product candidates and complete our planned clinical programs, expectations regarding the impact of the COVID-19 pandemic, expectations regarding the timing or amounts of any payments by Qilu Pharmaceutical, expectations regarding additional partnerships for the commercialization of Vicineum outside of the US, expectations regarding the timing of completion of our BLA submission for Vicineum, expectations regarding the timing of potential approval of our BLA submission by the FDA, expectations regarding the timing of the submission of our MAA for Vicineum to the EMA, expectations regarding the timing of potential approval of our MAA submission by the EMA, expectations regarding the need for any additional clinical trials, expectations regarding the potential successful launch of Vicineum, if approved, our ability to obtain marketing approvals for our product candidates, 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:
Erin Clark, Vice President, Corporate Strategy & Investor Relations
ir@sesenbio.com

SESEN BIO, INC.
CONDENSED CONSOLIDATED STATEMENTS OF INCOME (OPERATIONS) AND COMPREHENSIVE INCOME (LOSS)
(In thousands, except per share data)
(Unaudited)

	Three Months ended June 30,		Six Months ended June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 4,562	$ 7,944	$ 13,429	$ 12,630
General and administrative	3,318	2,617	6,766	5,672
Change in change in fair value of contingent consideration	18,480	44,000	(35,220)	43,000
Total operating expenses	26,360	54,561	(15,025)	61,302
Income (Loss) from Operations	(26,360)	(54,561)	15,025	(61,302)
Other income (expense):				
Other income, net	16	226	195	487
Net Income (Loss) and Comprehensive Income (Loss)	$ (26,344)	$ (54,335)	$ 15,220	$ (60,815)
Net income (loss) per common share - basic	$ (0.24)	$ (0.67)	$ 0.13	$ (0.77)
Weighted-average common shares outstanding - basic	112,569	80,739	111,189	79,107
Net income (loss) per common share - diluted	$ (0.24)	$ (0.67)	$ 0.11	$ (0.77)
Weighted-average common shares outstanding - diluted	112,569	80,739	111,203	79,107

SESEN BIO, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)
(Unaudited)

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 37,741	$ 48,121
Prepaid expense and other current assets	3,727	6,326
Total current assets	41,468	54,447
Restricted cash	20	20
Property and equipment, net	185	238
Intangibles	46,400	46,400
Goodwill	13,064	13,064
Other assets	76	196
Total Assets	$ 101,213	$ 114,365
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 1,274	$ 1,902
Accrued expenses	4,866	6,169
Other current liabilities	373	446
Total current liabilities	6,513	8,517
Contingent consideration	84,800	120,020
Deferred tax liability	12,528	12,528
Total Liabilities	103,841	141,065
Commitments and contingencies		
Stockholders' Deficit:		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized at June 30, 2020 and December 31, 2019; no shares issued and outstanding at June 30, 2020 and December 31, 2019		
Common stock, $0.001 par value per share; 200,000,000 shares authorized at June 30, 2020 and December 31, 2019; 116,627,653 and 106,801,409 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	116	107
Additional paid-in capital	275,560	266,717
Accumulated deficit	(278,304)	(293,524)
Total Stockholders' Deficit	(2,628)	(26,700)
Total Liabilities and Stockholders' Deficit	$ 101,213	$ 114,365