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 9, 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 2.02 - Results of Operations and Financial Condition.

On August 9, 2021, Sesen Bio, Inc. (the "Company") announced its financial results for the quarter ended June 30, 2021. 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.

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.

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.

[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 9, 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 9, 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 Reports Second Quarter 2021 Financial Results and Significant Global Progress for **Vicineum™**

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

The Company also believes it remains on track for potential approval in Europe and key markets in MENA in 2022

Strengthened balance sheet with $151M in cash and cash equivalents as of June 30, 2021

CAMBRIDGE, Mass., Aug. 9, 2021 – 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, 2021. The Biologics License Application (BLA) for the Company's lead program, Vicineum for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC), 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.

"We are excited about the regulatory progress we are making across our global markets," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "We remain focused on executing a world-class launch in the US if Vicineum is approved, and we also continue to support our partners outside of the United States, as part of our commitment to deliver a therapy we believe can improve patient outcomes globally while reducing overall healthcare costs for patients."

US and Outside of the US (OUS) Regulatory Update

US:

- On July 13, 2021, Sesen Bio participated in a productive Late-Cycle Meeting with the FDA regarding the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. In the meeting, the FDA confirmed that there is no Advisory Committee meeting planned at this time, and that no post-marketing requirements, including a confirmatory trial, have been identified at this time. Also in the meeting, the Company and the FDA discussed remaining questions related to manufacturing facility inspections, product quality information requests and additional information related to chemistry, manufacturing and controls (CMC), and a timeline to submit additional supporting information was agreed upon. 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.

Europe:

- In Europe, the Company believes it remains on track for potential approval of **Vysyneum™** in 2022. The Company has received the Day 80 and Day 120 questions from the European Medicines Agency (EMA) and is responding to inquiries and providing supporting information as part of the official review process.

China:

- On July 20**, 2021, Sesen Bio and Qilu Pharmaceutical, the Company's partner in Greater** China, announced that the first patient had been enrolled in China in the clinical trial to assess the efficacy and safety of Vicineum in patients with BCG-unresponsive NMIBC. The trial, which plans to enroll approximately 53 patients with carcinoma in situ (CIS), is being run at the sole cost of Qilu Pharmaceutical. If the trial is successful, Qilu Pharmaceutical anticipates submission of the product market application for Vicineum in China in 2022, with potential approval expected in 2023.

Middle East and North Africa (MENA):

- The Company continues to work closely with its partner in MENA, Hikma Pharmaceuticals, to submit marketing authorization applications for Vicineum in 2021 in seven key markets in the region: Kingdom of Saudi Arabia, Jordan, Morocco, Egypt, Lebanon, Kuwait and Algeria. These markets represent a significant opportunity, with some of the most advanced healthcare systems and largest economies in the MENA region. The Company believes it is on track for potential market approvals to begin in the region in 2022.

Business Development Update

- On June 1, 2021, the Company entered into a global supply agreement with Qilu Pharmaceutical to become part of the manufacturing network for global commercial supply of Vicineum drug substance and drug product. This was an expansion of the initial commercial manufacturing and supply framework agreement entered into by Sesen Bio and Qilu Pharmaceutical in December 2020, and sets specific terms such as capacity, forecasts, pricing and product delivery. Along with existing world-class supply partners, Sesen Bio expects the global supply agreement with Qilu Pharmaceutical will enable the Company to meet anticipated significant global demand for Vicineum.

- On August 5, 2021, Sesen Bio announced it had entered into a licensing agreement with Eczacibasi Pharmaceuticals Marketing (EIP) for the registration and commercialization of Vicineum in Turkey. Under the terms of the licensing agreement, Sesen Bio will receive an upfront payment of $1.5 million, is eligible to receive additional regulatory and commercial milestone payments and is also entitled to receive a 30% royalty on net sales in Turkey. EIP was granted an exclusive license to register and commercialize Vicineum for the treatment of BCG-unresponsive NMIBC in Turkey, where bladder cancer is the sixth most commonly diagnosed cancer and 11th most common cause of death. This agreement represents the third OUS partnership that Sesen Bio has entered to date.

Commercial Planning Update

- Sesen Bio completed its commercial build phase in preparation for the anticipated launch of Vicineum, if approved, in the US, and has advanced to the implementation phase that will commence promptly, if approved, and will focus **on executing the Company's** commercial strategy for Vicineum. The Company has completed the hiring of ~25 talented internal employees to support the Company cross-functionally, as well as the hiring of 35 sales representatives as part of the contract sales organization who will target approximately 2,000 high-prescribers of BCG to drive awareness, trial and adoption of Vicineum for the treatment of patients with BCG-unresponsive NMIBC.

In addition to building its sales force, as part of the Sesen Bio national speaker programs, the Company has identified and commenced training of 14 key opinion leader (KOL) speakers to educate their peers on Vicineum for the treatment of BCG-unresponsive NMIBC, if approved. Upon product availability, the Company will utilize a two-pronged market access and reimbursement strategy to ensure maximum coverage for Vicineum.

Promotional efforts will begin immediately upon the anticipated approval of Vicineum in the US, and the Company expects Vicineum product to be available to physicians and patients in the fourth quarter of 2021.

- Results of market research conducted by the Company show that when given the choice between the product profile of Vicineum, based on Phase III clinical trial data[1], and the product profile of Keytruda®, physicians will choose Vicineum over 80% of the time. This data highlights urologists' preferences that the Company believes spans clinical, emotional and economic reasons to prescribe Vicineum. If approved by the FDA, the Company believes Vicineum could be a best-in-class treatment option for patients, and a critical step in Sesen Bio realizing its mission to save and improve the lives of patients with cancer.

[1]The Phase III clinical data are based on the data submitted in the BLA on December 18, 2020 and are currently under review by the FDA. Final efficacy and safety data are pending.

Second Quarter 2021 Financial Results

- Cash Position: Cash, cash equivalents and restricted cash were $151.1 million as of June 30, 2021, compared to $55.4 million as of December 31, 2020.
- R&D Expenses: Research and development expenses for the second quarter of 2021 were $7.2 million compared to $4.6 million for the same period in 2020. The increase of $2.7 million was due to increased costs associated with technology transfer and manufacturing ($1.0 million), professional services in support of regulatory activity ($0.7 million), employee-related compensation ($0.7 million), and other increases ($0.3 million).
- G&A Expenses: General and administrative expenses for the second quarter of 2021 were $6.8 million compared to $3.3 million for the same period in 2020. The increase of $3.5 million was due primarily to increases in sales and marketing expense for Vicineum pre-commercial launch planning ($1.6 million), employee-related compensation driven by increased headcount as part of the commercial build ($1.3 million), and other increases for commercial launch preparation ($0.6 million).
- Net Loss: Net loss was $25.4 million, or $0.15 per share, for the second quarter of 2021, compared to net loss of $26.3 million, or $0.24 per share, for the second quarter of 2020. The change was attributable to license revenue recognized ($2.2 million), offset by higher operating expenses ($1.3 million).

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 "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "potential," "target," "strategy," "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, the target PDUFA date of August 18, 2021, successful resolution of topics discussed at the Late-Cycle Meeting (including those related to manufacturing facility inspections, product quality information requests and additional information related to CMC), no advisory committee meeting on the BLA being planned at this time, and no post-marketing requirements being identified at this time, the Company's expectations about its ability to execute a world-class launch of Vicineum in the US, if approved by the FDA, and its plans to support its OUS partners, the Company's beliefs about Vicineum's ability to be a best-in-class treatment for patients with BCG-unresponsive NMIBC, if approved, and to improve patient outcomes while reducing overall

healthcare costs, the timing of approval of the Company's Marketing Authorization Application (MAA) for Vysyneum for the treatment of BCG-unresponsive NMIBC with the EMA if at all, the timing and results of any clinical trial for Vicineum in China, the timing for submission and potential approval of the product market application for Vicineum for the treatment of BCG-unresponsive NMIBC to the National Medical Products Administration (NMPA) in China if at all, the timing for submissions and any product market approvals of Vicineum for the treatment of BCG-unresponsive NMIBC in key markets in MENA, the ability of the Company's supply partners to enable the Company to meet global demand for Vicineum, the timing and receipt by the Company of any milestone payments or royalties from its OUS partner in Turkey, the Company's ability to implement its commercial strategy for Vicineum, if approved for the treatment of BCG-unresponsive NMIBC, in the US, the Company's plans to pursue certain strategies to increase market access and reimbursement to maximize coverage of Vicineum for the treatment of BCG-unresponsive NMIBC, the Company's expectations regarding the timing for commercial availability of Vicineum for the treatment of BCG-unresponsive NMIBC in the US, the Company's expectations based on its market research findings regarding preference for the profile of Vicineum over the profile of Keytruda, 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 risk that the EMA may not approve the MAA for Vysyneum within the anticipated timing, or at all, the risk that the NMPA may not approve the product market application for Vicineum 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, if approved in the US, the risk that the Company may not be successful in commercializing Vicineum for the treatment of BCG-unresponsive NMIBC, if and when it is approved in the US, the risk that Vicineum may not gain market acceptance among physicians, patients, third-party payors or the medical community, the risk that Vicineum may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, 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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SESEN BIO, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)
(Unaudited)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 151,036	$ 52,389
Accounts receivable	2,303	-
Prepaid expenses and other current assets	21,760	7,478
Restricted cash	-	3,000
Total current assets	175,099	62,867
Non-current assets:		
Restricted cash	20	20
Property and equipment, net	109	123
Intangible assets	46,400	46,400
Goodwill	13,064	13,064
Long term prepaid expenses	6,150	-
Other assets	205	349
Total non-current assets	65,948	$ 59,956
Total Assets	$ 241,047	$ 122,823
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	$ 1,228	$ 3,102
Accrued expenses	5,301	3,973
Deferred revenue	1,500	1,500
Contingent consideration	10,300	8,985
Other current liabilities	498	489
Total current liabilities	18,827	18,049
Non-current liabilities:		
Contingent consideration, net of current portion	160,300	99,855
Deferred tax liability	12,528	12,528
Deferred revenue, net of current portion	-	1,500
Other non-current liabilities	43	118
Total non-current liabilities	172,871	114,001
Total liabilities	191,698	132,050
Stockholders' Equity (Deficit):		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized at June 30, 2021 and December 31, 2020; no shares issued and outstanding at June 30, 2021 and December 31, 2020	-	-
Common stock, $0.001 par value per share; 400,000,000 and 200,000,000 shares authorized at June 30, 2021 and December 31, 2020, respectively; 188,460,951 and 140,449,647 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	188	140
Additional paid-in capital	446,036	306,554
Accumulated deficit	(396,875)	(315,921)
Total Stockholders' Equity (Deficit)	49,349	(9,227)
Total Liabilities and Stockholders' Equity	$ 241,047	$ 122,823

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

	Three Months ended June 30,		Six Months ended June 30,	
	2021	2020	2021	2020
License and related revenue	$ 2,234	$ -	$ 6,544	$ -
Operating expenses:				
Research and development	$ 7,228	$ 4,562	$ 13,306	$ 13,429
General and administrative	$ 6,805	$ 3,318	$ 12,098	$ 6,766
Change in fair value of contingent consideration	$ 13,600	$ 18,480	$ 61,760	$ (35,220)
Total operating expenses	27,633	$ 26,360	$ 87,164	(15,025)
(Loss) Income from Operations	(25,399)	$ (26,360)	$ (80,620)	15,025
Other (expense) income , net	$ (43)	$ 16	$ (46)	$ 195
Net (Loss) Income and Comprehensive (Loss) Income Before Taxes	$ (25,442)	$ (26,344)	$ (80,666)	$ 15,220
Provision for income taxes	$ -	$ -	$ (288)	$ -
Net (Loss) Income and Comprehensive (Loss) Income After Taxes	$ (25,442)	$ (26,344)	$ (80,954)	$ 15,220
Net (loss) income attributable to common stockholders - basic	$ (25,442)	$ (26,491)	$ (80,954)	$ 14,751
Net (loss) income attributable to common stockholders - diluted	$ (25,442)	$ (26,491)	$ (80,954)	$ 12,600
Net (loss) income per common share - basic	$ (0.15)	$ (0.24)	$ (0.49)	$ 0.13
Weighted-average common shares outstanding - basic	175,393	112,569	166,264	111,189
Net (loss) income per common share - diluted	$ (0.15)	$ (0.24)	$ (0.49)	$ 0.11
Weighted-average common shares outstanding - diluted	175,393	112,569	166,264	111,203