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): July 20, 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 5.02 - Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On July 20, 2021, the board of directors (the "Board") of Sesen Bio, Inc. (the "Company"), following the recommendation of the Nominating and Corporate Governance Committee of the Board, elected Peter K Honig, M.D. and Michael A.S. Jewett, M.D. to the Board, effective immediately, to fill vacancies on the Board created as a result of the Board increasing the size of the Board from five (5) members to seven (7) members.

Peter K Honig, M.D. was designated as a Class II member of the Board to serve until the 2022 annual meeting of the stockholders of the Company and thereafter until his successor has been duly elected and qualified, or until his earlier death, resignation or removal. Dr. Honig has been appointed to the Audit Committee of the Board.

Michael Jewett, M.D. was designated as a Class III member of the Board to serve until the 2023 annual meeting of the stockholders of the Company and thereafter until his successor has been duly elected and qualified, or until his earlier death, resignation or removal. Dr. Jewett has been appointed as a member of the Nominating and Corporate Governance Committee of the Board

There are no arrangements or understandings between either Dr. Honig or Dr. Jewett and any other person pursuant to which Dr. Honig or Dr. Jewett was elected as a director. There are no transactions in which either Dr. Honig or Dr. Jewett has an interest requiring disclosure under Item 404(a) of Regulation S-K of the Securities Act of 1933, as amended. Dr. Honig and Dr. Jewett will be compensated in the same manner as the Company's other non-employee directors.

Currently, the Company's non-employee directors are compensated for their services on the Board as follows:

Compensation	
Annual Board Cash Retainer	$40,000
Additional Retainer for Non-Executive Chair of the Board	$30,000
Additional Retainers for Committee Chairs	
• Audit	$15,000
• Compensation	$10,000
• Nominating and Corporate Governance	$8,000
Additional Retainers for Committee Members	
• Audit	$7,500
• Compensation	$5,000
• Nominating and Corporate Governance	$4,000
Annual Equity Award (non-employee directors)	92,500 shares of common stock
Initial Equity Award (non-employee directors)	185,000 shares of common stock

The stock options granted to the Company's non-employee directors will have an exercise price equal to the fair market value of the Company's common stock on the date of grant and will expire ten years after the date of grant. The initial stock options granted to Company's non-employee directors will, subject to the director's continued service on the Board, vest monthly in equal amounts over a three-year period following the grant date. The annual stock options granted to Company's non-employee directors will, subject to the director's continued service on the Board, vest monthly in equal amounts over a one-year period following the grant date. Each annual cash fee will be payable in arrears in four equal quarterly installments on the last day of each quarter, provided that the amount of each payment will be prorated for any portion of a quarter that a director is not serving on the Board. Each member of the Board will also be entitled to reimbursement for reasonable travel and other expenses incurred in connection with attending meetings of the Board and any committee on which he or she serves.

Accordingly, each of Dr. Honig and Dr. Jewett received upon their elections to the Board an option to purchase 185,000 shares of the Company's common stock at an exercise price of $3.86 per share.

In connection with their appointments, each of Dr. Honig and Dr. Jewett will enter into the Company's standard form of Indemnification Agreement, a copy of which was filed as Exhibit 10.9 to the Annual Report on Form 10-K

(File No. 001-36296) filed with the SEC on March 16, 2020. Pursuant to the terms of this agreement, the Company may be required, among other things, to indemnify Dr. Honig and Dr. Jewett for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by each of them in any action or proceeding arising out of each of their services as one of the Company's directors.

On July 21, 2021, the Company issued a press release announcing the appointments of Dr. Honig and Dr. Jewett to the Board. A copy of the press release is attached as Exhibit 99.1 to this report and incorporated herein by reference.

In the US, 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 non-muscle invasive bladder cancer

Item 9.01 - Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated July 21, 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: July 21, 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 New Appointments to its Board of Directors

Peter K Honig, MD, MPH and Michael A.S. Jewett, MD, FRCSC, FACS have joined the Sesen *Bio Board of Directors as the Company nears potential US approval of Vicineum™ in August* 2021

CAMBRIDGE, Mass., Jul. 21, 2021 – Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today announced the appointments of Dr. Peter K Honig, MPH, former Senior Vice President and Head of Global Regulatory Affairs and Group Head of Development China and Japan at Pfizer, and Dr. Michael A.S. Jewett, FRCSC, FACS, a practicing Oncologist and global Key Opinion Leader (KOL) to the Sesen Bio Board of Directors. The Company's Biologics License Application (BLA) for the Company's lead program, Vicineum, is currently under Priority Review with the Food and Drug Administration (FDA) for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) in the US with a target Prescription Drug User Fee Act (PDUFA) date of August 18, 2021.

"I am pleased to welcome Dr. Peter Honig and Dr. Michael Jewett to our Board of Directors," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "We have reached a transformational time for the Company as we approach the potential approval and launch of Vicineum in the US. We are very fortunate to add the deep global regulatory experience of Dr. Honig and the extensive clinical expertise of Dr. Jewett to further strengthen our Board. Their wealth of experience will be invaluable as we continue to make progress in bringing a potential best-in-class treatment to markets globally."

Peter K Honig, MD, MPH is an experienced leader in the strategic and tactical aspects of medicine and vaccine development with expertise in clinical pharmacology, clinical programs, setting clinical trial design, compliance, medical product safety, and medical product regulation. Dr. Honig recently retired from Pfizer as Senior Vice President and Head of Global Regulatory Affairs and Group Head of Development China and Japan. Dr. Honig led Pfizer's commitment to patient safety by working across the organization to ensure regulatory effectiveness, quality control and compliance throughout all stages of product development and post-approval. Prior to joining Pfizer, he held senior leadership positions at AstraZeneca and Merck Research Laboratories and with the FDA, including a role as the first Director of the Office of Drug Safety in the FDA's Center for Drug Evaluation and Research (CDER).

In addition to his industry and FDA experience, Dr. Honig has been the PhRMA representative to the International Conference on Harmonisation (ICH) Steering Committee from 2002 to 2021, is a past President of the American Society for Clinical Pharmacology and Therapeutics (ASCPT) and is currently an associate editor of their flagship journal. Dr. Honig received medical and public health degrees from Columbia University in New York.

"I am honored to join the Sesen Bio Board of Directors," said Dr. Honig. "Sesen Bio has made tremendous progress in key markets with the upcoming potential product approvals in the US in

August and in Europe in 2022 with a promising pipeline to fuel future growth. I look forward to working with the Board and management team in contributing to Sesen Bio's future success."

Michael A.S. Jewett, MD, FRCSC, FACS is a prominent Oncologist who is internationally recognized for his life-saving innovations in surgical oncology, his advocacy of patient-centered clinical care, and his contributions to research in the field of bladder cancer. Dr. Jewett is currently a professor in the Departments of Surgical Oncology and Surgery (Urology) at the Princess Margaret Cancer Centre, University Health Network and the University of Toronto. A graduate of Queen's University, Faculty of Medicine, Kingston, Ontario, Canada, where BCG for bladder cancer was first prescribed, Dr. Jewett completed his Urology training at the University of Toronto, Canada and Memorial Sloane-Kettering Cancer Center in New York. Dr. Jewett has played a leading role in national and international consensus statements, including as a committee chair for the International Consultation on Bladder Tumors in 2004 Consensus. He has appeared before the FDA as an expert including the presentation that led to the historic approval of BCG for NMIBC. Dr. Jewett has published more than 400 peer-reviewed papers, mostly in Uro-oncology and in technology assessment and medical informatics. Dr. Jewett was a member of the inaugural Medical Advisory Board of the Bladder Cancer Advocacy Network (BCAN). He is an Honorary Member of the American Urological Association (AUA) and the European Association of Urology (EAU) and has been a visiting professor in more than 40 institutions and associations. In December 2020, Dr. Jewett was appointed to the Order of Canada based on his achievements listed above, among others.

"It is a pleasure to join the Sesen Bio Board of Directors at such an exciting time in the Company's evolution," said Dr. Jewett. "I have been watching the progress of Vicineum carefully for more than 10 years and I am delighted with the progress. I believe Vicineum has the potential to transform the way Urologists treat patients with BCG-unresponsive NMIBC with promising expansion potential into earlier treatment intervention and possible combination regimens with checkpoint inhibitors. I look forward to working with the talented leadership team as they continue to execute on their mission of saving and improving the lives of patients with cancer."

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

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 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 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. Sesen Bio retains worldwide rights to Vicineum with the exception of Greater China and the Middle East and North Africa (MENA), for which the Company has partnered with Qilu Pharmaceutical and Hikma Pharmaceuticals, 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 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," "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 timing of the potential commercial launch of Vicineum in the US, the Company's beliefs regarding the potential for Vicineum to be a best-in-class treatment for the BCG-unresponsive NMIBC, the timing of potential approval of Vysyneum™ for the treatment of BCG-unresponsive NMIBC in Europe, the ability of Vicineum to transform treatment of patients with BCG-unresponsive NMIBC, the potential expansion of Vicineum into earlier treatment intervention and possible combination regimens with checkpoint inhibitors, the ability of

Vicineum to save and improve the lives of patients with cancer, 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 clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC may fail to demonstrate safety and efficacy to the satisfaction of the FDA, the European Medicines Agency or other foreign regulatory authorities or not otherwise produce favorable results, the risk that Vicineum for the treatment of BCG-unresponsive NMIBC may cause undesirable side effects, serious adverse events or have other properties that could delay or halt clinical trials, delay or prevent its regulatory approval by the FDA, the European Medicines Agency or other foreign regulatory authorities, limit the commercial profile of its labeling, if approved, or result in significant negative consequences following any marketing approval, 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:
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