UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE SESEN BIO, INC. DERIVATIVE LITIGATION	Lead Case No.: 1:21-cv-11538

VERIFIED CONSOLIDATED SHAREHOLDER DERIVATIVE COMPLAINT

INTRODUCTION

Plaintiffs Joshua Myers and Peter D'Arcy ("Plaintiffs"), by Plaintiffs' undersigned attorneys, derivatively and on behalf of Nominal Defendant Sesen Bio, Inc. ("Sesen" or the "Company"), file this Verified Consolidated Shareholder Derivative Complaint against Defendants Thomas R. Cannell ("Cannell"), Monica Forbes ("Forbes"), Carrie L. Bourdow ("Bourdow"), Jay S. Duker ("Duker"), Jane V. Henderson ("Henderson"), Peter K. Honig ("Honig"), Michael Jewett ("Jewett"), and Jason A. Keyes ("Keyes") (collectively, the "Individual Defendants" and with Sesen, "Defendants") for breaches of their fiduciary duties as directors and/or officers of Sesen, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, violations of Section 14(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), and for contribution under Sections 10(b) and 21D of the Exchange Act. As for Plaintiffs' complaint against the Individual Defendants, Plaintiffs allege the following based upon personal knowledge as to Plaintiffs and Plaintiffs' own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiffs' attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Sesen, legal filings, news reports, securities analysts' reports and advisories about the Company, and

information readily obtainable on the Internet. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a shareholder derivative action that seeks to remedy wrongdoing committed by Sesen's directors and officers from December 21, 2020 through August 17, 2021 (the "Relevant Period").

2. Sesen, a Delaware corporation based in Cambridge, Massachusetts, is a late-stage clinical company advancing targeted fusion protein ("TFP") therapeutics for the treatment of patients with cancer. The Company's most advanced product candidate, Vicineum, is a locally-administered targeted fusion protein designed to treat bacillus Calmette-Guérin ("BCG")-unresponsive, non-muscle invasive bladder cancer ("NMIBC") or a form of squamous cell carcinoma of the head and neck.

3. The Company has an ongoing Phase 3 clinical trial of Vicineum as a monotherapy in patients with BCG-unresponsive NMIBC (the "VISTA trial"). The VISTA trial completed enrollment in April 2018 with a total of 133 patients. Vicineum has also been tested in clinical trials for treatment against head and neck cancer.

4. Vicineum is dispensed with a catheter in the bladder directly and contains especially toxic substances designed to kill the cells it interacts with. The Company maintains that Vicineum selectively interacts with cancer cells existing in the bladder only before it ultimately leaves the body two hours after its administration via urination.

5. On December 18, 2020, the Company submitted its completed Biologics License Application ("BLA") for Vicineum (the "Vicineum BLA") for the treatment of BCG-unresponsive NMIBC to the United States Food and Drug Administration ("FDA"). In submitting the Vicineum BLA to the FDA, the Company included results from the sites where investigator misconduct had

occurred (the "Submission Misconduct").

6. Beginning December 21, 2020 and throughout the Relevant Period, the Individual Defendants made, or caused the Company to make, materially false and misleading statements concerning Sesen's business, operations, and prospects. Specifically, during the Relevant Period, the Company issued press releases and filed documents with the SEC which touted Vicineum's safety profile, efficacy, and trial results and the ostensible progress it had made towards swift regulatory approval in the United States, Europe, and worldwide, including FDA approval of the Vicineum BLA, and in preparing to commercialize Vicineum.

7. During this time, the Individual Defendants failed to disclose that clinical trials of Vicineum were plagued by thousands of protocol violations, damning investigator misconduct, and worrying signs of toxicity. Indeed, during the Company's Vicineum trials, several instances of investigator misconduct occurred. In the first, the "investigator had his clinic closed in 2017 after his hospital's disciplinary committee concluded he had engaged in '***disgraceful, dishonorable, or unprofessional***' behavior." (Emphasis added.) In the second, the "***investigator was found to be back-dating data***, according to internal Sesen documents, casting serious doubt on any information gathered from his clinic." (Emphasis added.)

8. The Company failed to disclose the Submission Misconduct, and that, as a result of the foregoing, Vicineum was subject to material risks that threatened regulatory approval both in the United States and in Europe.

9. In March 2021, a few months after announcing the Company's BLA to the FDA, Sesen announced that it submitted a marketing authorization application ("MAA") to the European Medicines Agency ("EMA") seeking regulatory approval for Vicineum in Europe.

10. Given the sad financial state at the Company and given that Vicineum was Sesen's

sole product candidate, it was imperative that Defendants obtained regulatory approval—or at least achieved the appearance thereof, in order to appeal to investors about the Company's standing and prospects. However, during the time the aforementioned statements were made, regulators—the EMA in particular—had communicated serious concerns with Vicineum and Sesen's clinical trials to Defendants.

11. The Individual Defendants' misrepresentations had the effect of misleading the investing public and artificially inflating the Company's stock during the Relevant Period. In fact, the Company's stock price sky-rocketed during the Relevant Period, enabling Defendants to raise $175 million in capital from unsuspecting investors in an "at the market" offering during the first three quarters of 2021 (the "Offering").

12. The truth began to emerge on August 13, 2021, when the Company announced that the FDA had declined to approve the Vicineum BLA. Specifically, the FDA specified "recommendations specific to additional clinical/statistical data and analysis in addition to Chemistry, Manufacturing and Controls (CMC) issues pertaining to a recent pre-approval inspection and product quality."

13. On this news, the Company's share price fell $2.80 per share, or 57%, from its closing price of $4.91 per share on August 12, 2021, to close at $2.11 per share on August 13, 2021.

14. The Company held a conference call on the morning of August 16, 2021, in which Defendant Cannell disclosed that Sesen would "need to do a clinical trial to provide the additional efficacy and safety data necessary for the FDA to assess the benefit-risk profile, which is the basis for approval." He further disclosed that the Company did not expect to resubmit the BLA until 2023.

15. On this news, the Company's share price fell $0.89 per share, or 42%, from its closing price of $2.11 per share on August 13, 2021, to close at $1.22 per share on August 16, 2021.

16. On August 18, 2021, the health-oriented news website statnews.com ("*STAT*") published an article entitled "Sesen Bio trial of cancer drug marked by misconduct and worrisome side effects, documents show" (the "Article"). The Article stated that Vicineum's clinical trial "was marked by thousands of violations of study rules, damning investigator misconduct, and worrying signs of toxicity the company did not publicly disclose, according to hundreds of pages of internal documents obtained by *STAT* and confirmed by three people familiar with the matter."

17. Following the Article's release, the Company's share price fell $0.20 per share, or 13%, from its closing price of $1.51 per share on August 17, 2021, to close at $1.31 per share on August 18, 2021.

18. Shortly thereafter, on August 20, 2021, the Company announced that it withdrew its MAA to the EMA. On October 20, 2021, the EMA published a "Withdrawal assessment report" noting, among other things, that the drug was "not approvable since 'major objections' have been identified [.]" *See* Exhibit A hereto.

19. During the Relevant Period, the Individual Defendants breached their fiduciary duties by personally making and/or causing the Company to make to the investing public a series of materially false and misleading statements regarding the Company's business, operations, and prospects. Specifically, the Individual Defendants willfully or recklessly made and/or caused the Company to make false and misleading statements that failed to disclose, *inter alia*, that: (1) clinical trials of Vicineum revealed that the drug leaked from the administration site out into the body, impacting healthy cells as opposed to only cancerous cells, and caused worrisome side

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