UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

_____, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. SESEN BIO, INC., THOMAS R. CANNELL, and MONICA FORBES, Defendants.	Case No. **CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

Plaintiff _____ ("Plaintiff"), individually and on behalf of all others similarly situated, by and through his attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, among other things, his counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Sesen Bio, Inc. ("Sesen Bio" or the "Company") with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Sesen Bio; and (c) review of other publicly available information concerning Sesen Bio.

NATURE OF THE ACTION AND OVERVIEW

1. This is a class action on behalf of persons and entities that purchased or otherwise acquired Sesen Bio securities between December 21, 2020 and August 17, 2021, inclusive (the "Class Period"). Plaintiff pursues claims against the Defendants under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Sesen Bio is a late-stage clinical company that purports to advance targeted fusion protein ("TFP") therapeutics for cancer treatments. Its most advanced product candidate is Vicineum (VB4-845), a locally administered TFP developed as a treatment of bacillus Calmette-Guérin ("BCG")-unresponsive non-muscle invasive bladder cancer ("NMIBC"). Sensen Bio reported preliminary efficacy data from its ongoing Phase 3 clinical trial for Vicineum, the VISTA trial, in August 2019.

3. On December 21, 2020, the Company announced that it had submitted its Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") for Vicineum for the treatment of BCG-unresponsive NIMBC.

4. On August 13, 2021, Sesen Bio announced that the FDA declined to approve its BLA for Vicineum in its current form. The FDA provided certain "recommendations specific to additional clinical/statistical data and analyses in addition to Chemistry, Manufacturing and Controls (CMC) issues pertaining to a recent pre-approval inspection and product quality."

5. On this news, the Company's share price fell $2.80, or 57%, to close at $2.11 per share on August 13, 2021, on unusually heavy trading volume.

6. Then, on August 16, 2021, Sesen Bio further revealed that "it appears that [the Company] will 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." As a result, the Company expected that it could not resubmit its BLA until 2023.

7. On this news, the Company's share price fell $0.89, or 42%, to close at $1.22 per share on August 16, 2021, on unusually heavy trading volume.

8. Then, on August 18, 2021, before the market opened, *STAT* published an article entitled "Sesen Bio trial of cancer drug marked by misconduct and worrisome side effects, documents show." Citing "hundreds of pages of internal documents" and "three people familiar with the matter, the article detailed that the clinical trial for Vicineum was "marked by thousands of violations of study rules, damning investigator conduct, and worrying signs of toxicity the company did not publicly disclose."

9. On this news, the Company's share price fell $0.20, or 13%, to close at $1.31 per share on August 18, 2021, on unusually heavy trading volume.

10. Throughout the Class Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that Sesen

Bio's clinical trial for Vicineum had more than 2,000 violations of trial protocol, including 215 classified as "major"; (2) that three of Sesen Bio's clinical investigators were found guilty of "serious noncompliance," including "back-dating data"; (3) that Sesen Bio had submitted the tainted data in connection with the BLA for Vicineum; (4) that Sesen Bio's clinical trials showed that Vicineum leaked out into the body, leading to side effects including liver failure and liver toxicity, and increasing the risks for fatal, drug-induced liver injury; (5) that, as a result of the foregoing, the Company's BLA for Vicineum was not likely to be approved; (6) that, as a result of the foregoing, there was a reasonable likelihood that Sesen Bio would be required to conduct additional trials to support the efficacy and safety of Vicineum; and (7) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

11. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

12. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

14. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts

charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District.

15. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

PARTIES

16. Plaintiff _____, as set forth in the accompanying certification, incorporated by reference herein, purchased Sesen Bio securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

17. Defendant Sesen Bio is incorporated under the laws of Delaware with its principal executive offices located in Cambridge, Massachusetts. Sesen Bio's common stock trades on the NASDAQ under the symbol "SESN."

18. Defendant Thomas R. Cannell ("Cannell") was the Chief Executive Officer ("CEO") of Sesen Bio at all relevant times.

19. Defendant Monica Forbes ("Forbes") was the Chief Financial Officer ("CFO") of Sesen Bio at all relevant times.

20. Defendants Cannell and Forbes (collectively the "Individual Defendants"), because of their positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, i.e., the market. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and

opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

21. Sesen Bio is a late-stage clinical company that purports to advance targeted fusion protein ("TFP") therapeutics for cancer treatments. Its most advanced product candidate is Vicineum (VB4-845), a locally administered TFP developed as a treatment of bacillus Calmette-Guérin ("BCG")-unresponsive non-muscle invasive bladder cancer ("NMIBC"). Sensen Bio reported preliminary efficacy data from its ongoing Phase 3 clinical trial for Vicineum, the VISTA trial, in August 2019.

Materially False and Misleading Statements Issued During the Class Period

22. The Class Period begins on December 21, 2020. On that day, Sesen Bio announced that it had submitted a "completed Biologics License Application" to the FDA for Vicineum. In a press release, the Company stated, in relevant part:

> Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today announced submission of the completed Biologics License Application (BLA) to the FDA for Vicineum for the treatment of high-risk, BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) on December 18, 2020.
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> Within 60 days after receipt of the completed application, the FDA will issue a decision to the Company on the acceptance of the filing, and whether the BLA has received Priority Review (six-month target PDUFA date) under its existing Fast Track designation.

> The BLA is supported by the pivotal Phase 3 VISTA trial, which the Company believes demonstrates a strong benefit-risk profile. The BLA also includes positive chemistry, manufacturing and controls (CMC) data that the Company believes validates the analytical comparability between clinical and commercial supply.
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> "There remains a significant unmet need for high-risk NMIBC, and we believe the differentiated clinical profile of Vicineum will provide a best-in-class option for physicians and their patients," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "Our strong non-clinical and clinical data, in addition to our positive comparability data, give us confidence in the regulatory path forward. I would like to thank the entire Sesen Bio team and our regulatory and manufacturing partners for their tireless dedication in helping us to complete the BLA submission. We look forward to continuing our regulatory progress by submitting a Marketing Authorization Application in Europe, which we anticipate in early 2021."

23. On February 1, 2021, Sesen Bio announced that it had a "productive Application Orientation Meeting" with the FDA regarding the BLA for Vicineum. In a press release, the Company stated, in relevant part:

> Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today reported that on January 29, 2021 the Company participated in a productive Application Orientation Meeting with the FDA regarding its Biologic License Application (BLA) for Vicineum, for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC).
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> After the Company submitted its BLA to the FDA in December 2020, Sesen Bio was invited to participate in an Application Orientation Meeting, which is available in certain Center for Drug Evaluation and Research (CDER) review divisions, at the review team's discretion, for priority applications where early action is expected and/or desired. The objectives of an Application Orientation Meeting include familiarizing the FDA with application datasets, discussing scientific aspects including clinical risk-benefit, and establishing early communication between applicants and the FDA.
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> "We are very pleased with the outcome of Friday's 90-minute meeting with the FDA," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "We continue to believe Vicineum has a favorable risk-benefit profile which positions it to be best-in-class, and we are encouraged by the high level of time and engagement the FDA has demonstrated toward our review. We look forward to continuing to work with the FDA to expeditiously bring Vicineum to the market."

24. On February 16, 2021, Sesen Bio announced that the FDA had accepted the Company's BLA for Vicineum and granted priority review. In a press release, the Company stated:

> Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, announced today that the U.S. Food and Drug Administration (FDA) accepted for filing the Company's Biologics License Application (BLA) for Vicineum for the treatment of high-risk, BCG-unresponsive non-muscle invasive bladder cancer (NMIBC), and granted the application Priority Review. In addition, the FDA stated that it is not currently planning to hold an advisory committee meeting to discuss the BLA for Vicineum.
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> * * *
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> With Priority Review, the anticipated target Prescription Drug User Fee Act (PDUFA) date for a decision on the BLA is August 18, 2021.
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> "***We have been meeting with the FDA regularly for the past two years on the application for Vicineum***," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "We understand the FDA's position and guidance very clearly and have found the review process to be collaborative and engaging. With these critical FDA decisions, we have reached an inflection point for the Company. In addition to a clear regulatory path forward, we have continued to strengthen our balance sheet in preparation for the potential launch of a product we believe represents a significant advancement over available therapies. We remain focused on the patient and our mission to save and improve lives and expect to continue to make progress around the world in the coming months."

25. On March 15, 2021, Sesen Bio announced its fourth quarter and full year 2020 financial results as well as "significant regulatory and commercial readiness progress" for Vicineum. In a press release, the Company stated:

> We continue to make tremendous progress on our regulatory path with potential US approval later this year," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "Our talented and growing team is laser-focused on bringing a best-in-class treatment to the market that has the potential to improve patient outcomes while reducing healthcare costs. With a strong balance sheet and clear regulatory path forward in both the US and Europe, we are positioned to fully realize the potentially significant global opportunity for Vicineum. We expect 2021 to be a transformative year for Sesen Bio and the patients we serve."

US and European Regulatory Update

US:

- **On February 12, 2021, Sesen Bio received notice from the FDA that the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC was accepted for filing as of February 16th and granted Priority Review.** The FDA set an accelerated 6-month target Prescription Drug User Fee Act (PDUFA) date of August 18, 2021 for a decision on the BLA. The FDA also stated that they are not currently planning to hold an advisory committee meeting to discuss the BLA for Vicineum.

* * *

Commercial Update

- **In October 2020, Sesen Bio entered into an exclusive agreement with Cardinal Health for third-party logistics (3PL) and specialty pharmacy distribution services for Vicineum for the treatment of BCG-unresponsive NMIBC in the US.** As part of the agreement, Cardinal Health will provide comprehensive end-to-end 3PL, order-to-cash management and specialty pharmaceutical distribution services to Sesen Bio in support of commercialization in the US. In addition to Fujifilm and Baxter, the Cardinal Health relationship completes the selection of major supply chain partners in support of the commercial distribution of Vicineum, if approved. The Company believes that the supply chain will be ready to support the potential commercial launch of Vicineum with product supply available in Urology clinics by the fourth quarter of 2021.

26. Also on March 15, 2021, Sesen Bio filed its annual report on Form 10-K for the period ended December 31, 2020 (the "2020 10-K"), affirming the previously reported financial results. Regarding the safety and efficacy of Vicineum, the 2020 10-K purported to warn:

> ***If clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC fail to demonstrate safety and efficacy to the satisfaction of the FDA or other foreign regulatory authorities or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be delayed or unable to complete, the development and commercialization of Vicineum for the treatment of BCG-unresponsive NMIBC.***
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> Before obtaining marketing approval from regulatory authorities for the sale of Vicineum for the treatment of BCG-unresponsive NMIBC, we must complete pre-clinical development and conduct extensive clinical trials to demonstrate the safety and efficacy of Vicineum in humans. Clinical testing is expensive, difficult

to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of pre-clinical studies and early clinical trials may not be predictive of the success of later clinical trials, and preliminary results of a clinical trial do not necessarily predict final results. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates.

27. The 2020 10-K further stated that Vicineum "***may*** cause undesirable side effects" that could, among other things, prevent regulatory approval. Specifically, the 2020 10-K stated:

> ***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, limit the commercial profile of its labeling, if approved, or result in significant negative consequences following any marketing approval.***
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> Undesirable side effects or serious adverse events caused by Vicineum for the treatment of BCG-unresponsive NMIBC could cause us or regulatory authorities to interrupt, delay or halt respective clinical trials and could result in a restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities.
>
> There were no Grade 4 or Grade 5 serious adverse events that were considered by the clinical investigators to be related to Vicineum during the Phase 1 and Phase 2 clinical trials of Vicineum for the treatment of NMIBC BCG failures. There was one Grade 5 serious adverse event, or death, which was determined by the clinical investigator to be unrelated to Vicineum. The most common reported treatment-related adverse events were an abnormally frequent passage of small amounts of urine, blood in the urine and painful urination, the majority of which were considered to be mild or moderate in severity. No patients discontinued treatment due to a Vicineum-related adverse event during the Phase 1 and Phase 2 clinical trials.
>
> As of the May 29, 2019 data cutoff date, in patients across all cohorts (n=133) of our Phase 3 VISTA Trial of Vicineum for the treatment of BCG-unresponsive NMIBC, 88% experienced at least one adverse event, with 95% of adverse events being Grade 1 or 2. The most commonly reported treatment-related adverse events were dysuria (14%), hematuria (13%) and urinary tract infection (12%) - all of which are consistent with the profile of bladder cancer patients and the use of catheterization for treatment delivery. ***These adverse events were determined by the clinical investigators to be manageable and reversible, and only four patients (3%) discontinued treatment due to an adverse event. Serious adverse events, regardless of treatment attribution, were reported in 14% of patients.***

> ***There were four treatment-related serious adverse events reported in three patients including acute kidney injury (Grade 3), pyrexia (Grade 2), cholestatic hepatitis (Grade 4) and renal failure (Grade 5).*** There were no age-related increases in adverse events observed in the VISTA Trial.
>
> In addition, side effects and serious adverse events or further safety or toxicity issues that we may experience in our clinical trials or in post-marketing experience could lead to the FDA's or other comparable foreign regulatory authority's imposition of a REMS or other post-marketing obligations, which could hinder us from generating revenues or achieving profitability. ***Results of our clinical trials could reveal an unacceptably high severity and prevalence of side effects or serious adverse events. As a result, our clinical trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development or deny approval of Vicineum for the treatment of BCG-unresponsive NMIBC.*** The related drug-side effects or serious adverse events in our clinical trials could affect clinical trial patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims.

28. The 2020 10-K also contained certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") signed by Defendants Cannell and Forbes attesting to, among other things, the disclosure of all material facts.

29. On May 4, 2021, Sesen Bio issued a press release entitled "Sesen Bio Announces Commercial Launch Readiness Progress as the Company Approaches the Potential Approval and Launch of Vicineum,"

> Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today announced the expansion of its leadership team with the appointment of experienced commercial industry leader, Lisa LaMond, as Vice President, Sales and Corporate Systems. The Company also announced its engagement of leading contract sales organization (CSO), Syneos Health, for field sales support and execution in the US for Vicineum.

30. On May 10, 2021, Sesen Bio announced its first quarter 2021 financial results and a commercial launch readiness update for Vicineum in a press release, stating in relevant part:

> **US:**
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> - **In February 2021, Sesen Bio received notice from the FDA that the BLA for Vicineum was accepted for filing.** Along with the acceptance,

the Company was granted Priority Review with a target PDUFA date of August 18, 2021 for a decision on the BLA. The FDA also stated that an advisory committee meeting was not currently planned to discuss the BLA.

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Commercial Update

- **The Company continues to build its commercial organization with key leadership appointments and a partnership with a leading contract sales organization (CSO), Syneos Health, as it prepares for the anticipated commercial launch of Vicineum in the US in 3Q 2021.** Sesen Bio has begun to hire key commercial roles and has entered into a partnership with Syneos Health who will provide speed and logistical support in the hiring and deployment of the sales force. The sales force will include 35 sales representatives across four regions to target approximately 2,000 high prescribers of BCG.

31. Also on May 10, 2021, Sesen Bio filed its quarterly report on Form 10-Q for the period ended March 31, 2021, affirming the previously reported financial results. The report incorporated by reference the risk factors included in the 2020 10-K and contained SOX certifications signed by Defendants Cannell and Forbes attesting to, among other things, the disclosure of all material facts.

32. On July 14, 2021, Sesen Bio announced that it had a "productive Late-Cycle Meeting" with the FDA. In a press release, the Company stated, in relevant part:

> 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 July 13, 2021, the Company participated in a productive Late-Cycle Meeting with the U.S. Food and Drug Administration (FDA) regarding the Company's Biologics License Application (BLA) for Vicineum for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) currently under Priority Review with a target Prescription Drug User Fee Act (PDUFA) date of August 18, 2021.
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> The Late-Cycle Meeting is held late in the BLA review process between members of the FDA review team and the applicant to discuss the status of the review. The purpose of the meeting is to share information, discuss any substantive review items identified to date and to discuss the objectives for the remainder of the

review. The meeting does not address the final regulatory decision for the application.

"We are very pleased with the outcome of the Late-Cycle Meeting and continue to feel encouraged by the level of engagement from the FDA in our ongoing discussions regarding the BLA for Vicineum," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "We understand the FDA's position on the remaining review items and anticipate a successful resolution of these matters prior to the target PDUFA date. We remain focused on the patient and bringing a differentiated product to market that has the potential to improve patient outcomes while reducing overall healthcare costs."

Key Review Updates Include:

- The Company and the FDA discussed remaining questions related to manufacturing facilities inspection, product quality information requests and additional information related to chemistry, manufacturing and controls (CMC), and agreed upon a timeline for supporting information to be submitted.

- No Discipline Review letters have been issued to date.

- The FDA confirmed that there is no Advisory Committee meeting planned at this time.

- No issues related to risk management have been identified to date.

- No post-marketing requirements, including a confirmatory trial, have been identified as necessary at this time.

- The Company and the FDA discussed clinical trial and manufacturing post-marketing commitments required at this time.

- The FDA's review of the BLA is ongoing and the Company believes the BLA remains on track for an anticipated regulatory decision by August 18, 2021, the target PDUFA date.

33. On July 26, 2021, Sesen Bio announced "significant commercial progress" as it "approache[d] the potential approval and launch of Vicineum." In a press release, the Company stated, in relevant part:

"We are thrilled to have this experienced commercial team on board at Sesen Bio to build capabilities as we approach the potential commercial launch of Vicineum in the US market," said Patricia Drake, chief commercial officer of Sesen Bio. "They have made incredible progress across the core functions of sales, marketing

> and market access. We also believe our network of Urology and Uro-oncology KOL speakers will play an integral role in allowing us to educate their peers about Vicineum, which we believe will be a new tool in their practices to serve a large unmet medical need in NMIBC."
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> The Company has completed the hiring of ~25 talented internal employees to support the Company cross-functionally, as well as the hiring of 34 of 35 sales representatives as part of the contract sales organization, which will be deployed across four customer-centric regions and will target approximately 2,000 high-prescribers of BCG to drive awareness, trial and adoption of Vicineum for the treatment of BCG-unresponsive NMIBC. If approved, promotional efforts will begin immediately, and the Company expects Vicineum product to be commercially available to physicians and patients in the fourth quarter of 2021.

34. On August 2, 2021, Sesen Bio announced that it had hired Amy Ponpipom as Vice President, Assistant General Counsel in anticipation of the approval of Vicineum. In a press release entitled "Sesen Bio Strengthens Leadership Team as the Company Approaches the Potential Approval and Launch of Vicineum," the Company stated, in relevant part:

> Sesen Bio (Nasdaq:SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today announced the expansion of its leadership team in support of the Company's transformation into a commercial-stage company with the hiring of Amy Ponpipom as Vice President, Assistant General Counsel. The Company's Biologics License Application (BLA) for Vicineum for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC), the Company's lead program, 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.
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> "I am delighted to have Amy join the team here at Sesen Bio," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "Her strong industry experience and deep expertise in commercialization activities will be invaluable as we continue to work toward our PDUFA date and the potential launch of Vicineum in the US. I am confident that Amy's knowledge and skills will enable us to execute a world-class launch in order to fulfill our mission to save and improve the lives of patients."

35. On August 9, 2021, Sesen Bio announced its second quarter 2021 financial results and "significant global progress" for Vicineum in a press release, stating in relevant part:

> **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.

36. Also on August 9, 2021, Sesen Bio filed its quarterly report on Form 10-Q for the period ended June 30, 2021, affirming the previously reported financial results. The report incorporated by reference the risk factors included in the 2020 10-K and contained SOX certifications signed by Defendants Cannell and Forbes attesting to, among other things, the disclosure of all material facts.

37. On August 11, 2021, Sesen Bio announced that it had hired John Knighton as Vice President and Chief Compliance Officer in anticipation of the approval of Vicineum. In a press release entitled "Sesen Bio Strengthens Executive Leadership Team as the Company Approaches the Potential Approval and Commercial Launch of Vicineum," the Company stated:

> Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today announced the expansion of its executive leadership team in support of the Company's continued transformation into a commercial-stage company with the hiring of John Knighton as Vice President and Chief Compliance Officer, effective August 16, 2021. The Company's Biologics License Application (BLA) for Vicineum for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC), the Company's lead program, 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.
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> "At Sesen Bio, ***we believe a strong culture of compliance is a source of competitive advantage, because a thorough understanding of laws and regulatory guidance allows us to fully explore innovative commercial models and strategies***," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "This enables us to do the right thing while maximizing launch uptake

> of Vicineum. As we near our PDUFA date, I am confident that John's extensive experience in establishing compliance programs and enabling the implementation of innovative commercial model elements will further position us to execute a world-class launch."

38. The above statements identified in ¶¶ 22-37 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that Sesen Bio's clinical trial for Vicineum had more than 2,000 violations of trial protocol, including 215 classified as "major"; (2) that three of Sesen Bio's clinical investigators were found guilty of "serious noncompliance," including "back-dating data"; (3) that Sesen Bio had submitted the tainted data in connection with the BLA for Vicineum; (4) that Sesen Bio's clinical trials showed that Vicineum leaked out into the body, leading to side effects including liver failure and liver toxicity, and increasing the risks for fatal, drug-induced liver injury; (5) that, as a result of the foregoing, the Company's BLA for Vicineum was not likely to be approved; (6) that, as a result of the foregoing, there was a reasonable likelihood that Sesen Bio would be required to conduct additional trials to support the efficacy and safety of Vicineum; and (7) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

The Truth Begins to Emerge

39. On August 13, 2021, Sesen Bio announced that the FDA declined to approve its BLA for Vicineum in its current form. The FDA provided certain "recommendations specific to additional clinical/statistical data and analyses in addition to Chemistry, Manufacturing and Controls (CMC) issues pertaining to a recent pre-approval inspection and product quality." In a press release the Company stated:

> Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today

> announced that it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its Biologics License Application (BLA) for Vicineum™ (oportuzumab monatox-qqrs) for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC).
>
> The FDA has determined that it cannot approve the BLA for Vicineum in its present form and has provided recommendations specific to additional clinical/statistical data and analyses in addition to Chemistry, Manufacturing and Controls (CMC) issues pertaining to a recent pre-approval inspection and product quality.
>
> "We are deeply disappointed by this unexpected result, and it is an unfortunate day for patients suffering from BCG-unresponsive NMIBC," said Dr. Thomas Cannell, president, and chief executive officer of Sesen Bio. "We remain dedicated to our mission to save and improve the lives of patients by bringing new treatment options to patients, and we intend to work closely with the FDA to understand next steps."
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> The Company plans to request a Type A meeting as soon as possible with the FDA to discuss the next steps that are needed before the application may be approved.

40. On this news, the Company's share price fell $2.80, or 57%, to close at $2.11 per share on August 13, 2021, on unusually heavy trading volume.

41. On August 16, 2021, Sesen Bio held a conference call to discuss the CRL with analysts and investors. During the call, Defendant Cannell revealed that "it appears that [Sesen Bio] will 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." The Company would request a Type A meeting with the FDA to discuss the study design, including the primary endpoints and the sample size, to provide sufficient information to assess the benefit-risk profile of Vicineum. As a result, the Company expected that it could not resubmit its BLA until 2023.

42. On this news, the Company's share price fell $0.89, or 42%, to close at $1.22 per share on August 16, 2021, on unusually heavy trading volume.

43. The above statements identified in ¶¶ 39, 41 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business,

operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that Sesen Bio's clinical trial for Vicineum had more than 2,000 violations of trial protocol, including 215 classified as "major"; (2) that three of Sesen Bio's clinical investigators were found guilty of "serious noncompliance," including "back-dating data"; (3) that Sesen Bio had submitted the tainted data in connection with the BLA for Vicineum; (4) that Sesen Bio's clinical trials showed that Vicineum leaked out into the body, leading to side effects including liver failure and liver toxicity, and increasing the risks for fatal, drug-induced liver injury; and (5) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

The Truth Fully Emerges

44. On August 18, 2021, before the market opened, *STAT* published an article entitled "Sesen Bio trial of cancer drug marked by misconduct and worrisome side effects, documents show." Citing "hundreds of pages of internal documents" and "three people familiar with the matter, the article detailed that the clinical trial for Vicineum was "marked by thousands of violations of study rules, damning investigator conduct, and worrying signs of toxicity the company did not publicly disclose." The article summarized:

> Sesen Bio, a small biotech company that developed the bladder cancer drug, spent all of this year telling investors that its treatment was on its way to approval. After the FDA rejected it, CEO Thomas Cannell, fielding analyst questions on a Monday morning conference call, deemed it "a very surprising turn of events."
>
> But Sesen's ***internal documents — which include safety reports, raw data, and communications between employees — suggest a seismic difference between the company's public statements and the realities of the drug's development.*** They also lift the curtain on revelations that might have played a role in the decision of regulators at the FDA, which, consistent with its practice in the case of rejected drugs, did not comment on its decision.
>
> According to the documents, Sesen's drug, called Vicineum, has led to dangerous elevations in liver enzymes that are associated with organ failure and death, which the Cambridge, Mass., company did not mention in its filings with the Securities

> and Exchange Commission. ***The bladder cancer study, which enrolled about 130 patients, had more than 2,000 violations of trial protocol, including 215 classified as "major," according to company documents.*** The study's independent monitors reported three investigators to the FDA for particularly egregious violations, calling them issues of "serious noncompliance" that "placed subjects at risk of harm," according to the documents.
>
> * * *
>
> In a statement to STAT provided a day before the rejection, Sesen did not deny the protocol violations, the investigator misconduct, or the omission of a drug-related death in its 2018 presentation. The company said Vicineum was not associated with life-threatening elevations in liver enzymes, a claim that contradicts multiple internal documents.
>
> "We are confident that we have fully disclosed all relevant data to the FDA," Sesen said. "We stand by the safety and efficacy data of Vicineum," the company said, and as to the accuracy of its public statements, "we stand by the integrity of our disclosures and affirm they are based on the best information we have at the time."

45. The *STAT* article further stated that Vicenum had led to "worrisome side effects," including "a serious risk for fatal, drug-induced liver injury."

> Because that toxin, produced by the bacterium Pseudomonas aeruginosa, can be deadly if it reaches the liver, Vicineum has to be administered directly to the site of the cancer.
>
> But data from Sesen's clinical trials suggested Vicineum was leaking out into the body, leading to worrisome side effects, according to internal company documents. In clinical trials testing Vicineum against head and neck cancer, one patient died of liver failure, according to the documents, and another matched the criteria for a clinical rule of thumb called Hy's Law, meaning a patient is at serious risk for fatal, drug-induced liver injury. That risk is particularly serious in the eyes of the FDA, and it's the most common reason drugs are pulled from the market over safety, according to an agency guidance.
>
> A similar pattern emerged in Sesen's Phase 3 bladder cancer study, called VISTA. One patient met the criteria for Hy's Law, suggesting Vicineum led to serious liver toxicity, according to the documents. Another patient was diagnosed with life-threatening, drug-induced liver failure, confirmed by biopsy, according to the documents.
>
> In its statement, Sesen said the company " thoroughly reviewed" data from VISTA and "confirmed there were no cases of Hy's Law based on the clinical criteria as stipulated by FDA guidance." In the head and neck cancer study, "the

> data showed some elevated liver enzymes that have not been determined to be cases of Hy's Law," Sesen said. Both claims are contradicted by company documents, including a clinical report concluding one patient "met the criteria for Hy's Law" and internal communications about a second patient in which one employee wrote "I agree this is a Hy's Law case."

46. The *STAT* article also revealed that the trials purportedly supporting the BLA were "plagued by serious investigator misconduct that threatened the integrity of the data."

> VISTA was also plagued by serious investigator misconduct that threatened the integrity of the data, according to documents. In 2017 and 2018, Copernicus, a firm Sesen hired to monitor its trial, found three doctors in the study were guilty of "serious noncompliance," "continued noncompliance," and actions that "placed subjects at risk of harm," according to reports sent to the FDA.
>
> Separately, one investigator had his clinic closed in 2017 after his hospital's disciplinary committee concluded he had engaged in "disgraceful, dishonorable, or unprofessional" behavior. A second investigator was found to be back-dating data, according to internal Sesen documents, casting serious doubt on any information gathered from his clinic. In each case, the company was advised that "the data from these affected centers cannot be used in any data analysis" submitted to the FDA, according to the documents. Despite that, Sesen included results from both sites in its application for Vicineum's approval, according to the documents.
>
> In its statement, Sesen did not deny any instances of investigator misconduct in VISTA and did not dispute that it submitted tainted data to the FDA. "We are confident that we have fully disclosed all relevant data to the FDA," the company said, adding that "great care was taken every step of the way to ensure patient safety."

47. On this news, the Company's share price fell $0.20, or 13%, to close at $1.31 per share on August 18, 2021, on unusually heavy trading volume.

CLASS ACTION ALLEGATIONS

48. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that purchased or otherwise acquired Sesen Bio securities between December 21, 2020 and August 17, 2021, inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their

immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

49. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Sesen Bio's shares actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class. Millions of Sesen Bio shares were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Sesen Bio or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

50. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

51. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

52. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Sesen Bio; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

53. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

UNDISCLOSED ADVERSE FACTS

54. The market for Sesen Bio's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and/or misleading statements, and/or failures to disclose, Sesen Bio's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired Sesen Bio's securities relying upon the integrity of the market price of the Company's securities and market information relating to Sesen Bio, and have been damaged thereby.

55. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Sesen Bio's securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or misleading because they failed to disclose material adverse information and/or misrepresented the truth about Sesen Bio's business, operations, and prospects as alleged herein.

56. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Sesen Bio's financial well-being and prospects. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed.

LOSS CAUSATION

57. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

58. During the Class Period, Plaintiff and the Class purchased Sesen Bio's securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

SCIENTER ALLEGATIONS

59. As alleged herein, Defendants acted with scienter since Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or

disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding Sesen Bio, their control over, and/or receipt and/or modification of Sesen Bio's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Sesen Bio, participated in the fraudulent scheme alleged herein.

APPLICABILITY OF PRESUMPTION OF RELIANCE
(FRAUD-ON-THE-MARKET DOCTRINE)

60. The market for Sesen Bio's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Sesen Bio's securities traded at artificially inflated prices during the Class Period. On August 12, 2021, the Company's share price closed at a Class Period high of $4.91 per share. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Sesen Bio's securities and market information relating to Sesen Bio, and have been damaged thereby.

61. During the Class Period, the artificial inflation of Sesen Bio's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Sesen Bio's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Sesen Bio and its business, operations, and prospects, thus causing the price of the Company's securities to be

artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company shares. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

62. At all relevant times, the market for Sesen Bio's securities was an efficient market for the following reasons, among others:

(a) Sesen Bio shares met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Sesen Bio filed periodic public reports with the SEC and/or the NASDAQ;

(c) Sesen Bio regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) Sesen Bio was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

63. As a result of the foregoing, the market for Sesen Bio's securities promptly digested current information regarding Sesen Bio from all publicly available sources and reflected such information in Sesen Bio's share price. Under these circumstances, all purchasers

of Sesen Bio's securities during the Class Period suffered similar injury through their purchase of Sesen Bio's securities at artificially inflated prices and a presumption of reliance applies.

64. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

NO SAFE HARBOR

65. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or

misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Sesen Bio who knew that the statement was false when made.

FIRST CLAIM

Violation of Section 10(b) of The Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

66. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

67. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Sesen Bio's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each defendant, took the actions set forth herein.

68. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Sesen Bio's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

69. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Sesen Bio's financial well-being and prospects, as specified herein.

70. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Sesen Bio's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Sesen Bio and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

71. Each of the Individual Defendants' primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

72. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Sesen Bio's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

73. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Sesen Bio's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired Sesen Bio's securities during the Class Period at artificially high prices and were damaged thereby.

74. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff

and the other members of the Class and the marketplace known the truth regarding the problems that Sesen Bio was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Sesen Bio securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

75. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

76. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

SECOND CLAIM

Violation of Section 20(a) of The Exchange Act Against the Individual Defendants

77. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

78. Individual Defendants acted as controlling persons of Sesen Bio within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other

statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

79. In particular, Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

80. As set forth above, Sesen Bio and Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their position as controlling persons, Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: _____, 2021

By: _____

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