UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

_____, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. HUMANIGEN, INC., CAMERON DURRANT, TIMOTHY MORRIS, and DALE CHAPPELL, Defendants	Case No. CLASS ACTION COMPLAINT JURY TRIAL DEMANDED

Plaintiff _____ ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by

Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Humanigen, Inc. ("Humanigen" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Humanigen securities between May 16, 2020 and July 12, 2022, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Humanigen is a clinical-stage biopharmaceutical company that focuses on preventing and treating an immune hyper-response called "cytokine storm", a physiological reaction in which the immune system causes an uncontrolled and excessive release of pro-inflammatory signaling molecules called cytokines, the sudden release of which in large quantities can cause multisystem organ failure and death. The Company's lead product candidate is its proprietary antibody lenzilumab,

which is under development as a treatment for, among other things, cytokine storm associated with COVID-19.

3. Among other trials, Humanigen is investigating lenzilumab for the treatment of hospitalized COVID-19 patients in the ACTIV-5/BET-B study, which is part of a directed public-private partnership with the National Institutes of Health ("NIH").

4. In May 2021, Humanigen submitted an application to the U.S. Food and Drug Administration ("FDA") requesting Emergency Use Authorization ("EUA") for lenzilumab for the treatment of patients hospitalized with COVID-19 (the "lenzilumab EUA").

5. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) lenzilumab created patient risks that outweighed its benefits insofar as the drug prevented inflammation but also interfered with the positive effects of GM-CSF on patient lungs, *i.e.*, alveoli; (ii) linzilumab was the only GM-CSF treatment in active clinical trials; (iii) lenzilumab was less effective in treating hospitalized COVID-19 patients than Defendants had represented; (iv) as a result, the FDA was unlikely to approve the lenzilumab EUA and the ACTIV-5/BET-B study was unlikely to meet its primary endpoint; (v) accordingly, lenzilumab's clinical

and commercial prospects were overstated; and (vi) as a result, the Company's public statements were materially false and misleading at all relevant times.

6. On September 9, 2021, Humanigen issued a press release announcing that the FDA had rejected the lenzilumab EUA, advising investors that, "[i]n its letter, [the] FDA stated that it was unable to conclude that the known and potential benefits of lenzilumab outweigh the known and potential risks of its use as a treatment for COVID-19."

7. On this news, Humanigen's stock price fell $7.14 per share, or 47.25%, to close at $7.97 per share on September 9, 2021.

8. On December 28, 2021, one of Humanigen's competitors, Kiniksa Pharmaceuticals, Ltd., announced unsuccessful results from its Phase 3 trial of mavrilimumab in COVID-19-related acute respiratory syndrome, which, similar to lenzilumab, was a GM-CSF therapeutic intended to treat COVID-19 patients. Defendants had previously told investors that lenzilumab was the only drug of its kind in this regard.

9. Then, on July 13, 2022, Humanigen disclosed that lenzilumab had failed to show statistical significance on the primary endpoint of the ACTIV-5/BET- B study.

10. On this news, Humanigen's stock price fell $2.38 per share, or 79.6%, to close at $0.61 per share on July 13, 2022.

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 and pursuant to 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.

14. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Humanigen is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' actions took place within this Judicial District.

15. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

16. Plaintiff, as set forth in the attached Certification, acquired Humanigen securities at artificially inflated prices during the Class Period and was damaged upon

the revelation of the alleged corrective disclosures.

17. Defendant Humanigen is a Delaware corporation with principal executive offices located at 830 Morris Turnpike, 4th Floor, Short Hills, New Jersey 07078. Humanigen's common stock trades on the Nasdaq Stock Market ("NASDAQ") under the trading symbol "HGEN". Prior to trading on the NASDAQ, Humanigen's common stock traded on the OTCQB Venture Market ("OTCBQ") operated by OTC Market's Group, Inc. under the symbol "HGEND". At all relevant times, Humanigen's common stock traded in an efficient market.

18. Defendant Cameron Durrant ("Durrant") has served as Humanigen's Chairman and Chief Executive Officer at all relevant times.

19. Defendant Timothy Morris ("Morris") has served as Humanigen's Chief Operating Officer and Chief Financial Officer at all relevant times.

20. Defendant Dale Chappell ("Chappell") has served as Humanigen's Chief Scientific Officer at all relevant times.

21. Defendants Durrant, Morris, and Chappell are sometimes referred to herein as the "Individual Defendants."

22. The Individual Defendants possessed the power and authority to control the contents of Humanigen's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Humanigen's SEC filings 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 to cause them to be corrected. Because of their positions with Humanigen, and their access to material information available to them but not to the public, 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 being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

23. Humanigen and the Individual Defendants are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

Background

24. Humanigen is a clinical-stage biopharmaceutical company that focuses on preventing and treating an immune hyper-response called "cytokine storm", a physiological reaction in which the immune system causes an uncontrolled and excessive release of pro-inflammatory signaling molecules called cytokines, the sudden release of which in large quantities can cause multisystem organ failure and death. The Company's lead product candidate is its proprietary antibody lenzilumab, which is under development as a treatment for, among other things, cytokine storm associated with COVID-19.

25. Among other trials, Humanigen is investigating lenzilumab for the treatment of hospitalized COVID-19 patients in the ACTIV-5/BET-B study, which is part of a directed public-private partnership with the NIH.

Materially False and Misleading Statements Issued During the Class Period

26. On May 15, 2020, after market hours, Humanigen filed its quarterly report on Form 10-Q for the period ended March 31, 2020. Defendant Durrant signed the report. In pertinent part, Humanigen stated as follows in the quarterly report:

> The Company's lead product candidate is lenzilumab, a proprietary Humaneered® monoclonal antibody (a biologic) that has been demonstrated to neutralize a naturally occurring inflammatory factor (GM-CSF). GM-CSF is a cytokine which acts directly on myeloid cells to cause expansion, activation, and to initiate and promote the production of other chemokines, including MCP-1, MIP-1a, and IP-10, and cytokines, including TNFa, IL-6 and IL-1 as part of the body's immune response. GM-CSF is thought of as a communication conduit between the innate and adaptive immune systems. Once initiated, the inflammatory cascade in certain cases may quickly evolve into a self-perpetuating "storm" as the production of chemokines increases expansion and trafficking of myeloid cells. This, in turn, leads to abnormally high levels of inflammatory cytokines, endothelial activation, vascular permeability, disseminated intravascular coagulation, and neurologic inflammation. This "cytokine storm" is frequently referred to as cytokine release syndrome, or CRS. The neutralization of GM-CSF has been shown to prevent and potentially treat cytokine storm through a decrease in levels of IL-6, MCP-1, MIP1a, IP-10, VEGF, TNFα and other factors and reduce levels of inflammatory myeloid cells. Reduction of these factors demonstrates that GM-CSF is a critical upstream and early regulator of many inflammatory cytokines known to be important in the pathophysiology of CRS (Sterner RM et al. Blood 2019. 133(7): 697–709).
>
> During 2019 and throughout the early portion of the first quarter of 2020, the Company continued to pursue its anti-GM-CSF programs to prevent

> or reduce the serious and potentially life-threatening side effects associated with chimeric antigen receptor T-cell ("CAR-T") therapy and to prevent or treat graft-versus-host disease ("GvHD") in patients undergoing allogeneic hematopoietic stem cell transplantation ("HSCT"). In collaboration with Kite Pharmaceuticals, Inc., a Gilead company ("Kite or the "Kite Collaboration"), the Company seeks to study the effect of lenzilumab on the safety of Yescarta®, axicabtagene ciloleucel ("Yescarta"), Kite's FDA-approved CAR-T therapy. A clinical trial is underway to measure the effect of lenzilumab in reducing CRS and neurotoxicity (NT), with a secondary endpoint of increased efficacy of Yescarta.

27. On August 5, 2020, after market hours, Humanigen filed a prospectus relating to the registration and/or resale of 82,563,584 shares of its common stock to be listed on the NASDAQ. At the time, the last reported sale price of Humanigen's common stock on the OTCQB was $4.95/share. In pertinent part, Humanigen's prospectus stated as follows:

> We believe that, as an upstream regulator of cytokine storm, GM-CSF neutralization with lenzilumab may offer advantages over other immunomodulator strategies that either target other downstream cytokines such as IL-1, IL-6, CCR5 or MIP-1 alpha or are broadly immunosuppressive and target cytokine signaling pathways non-selectively through JAK inhibition. In addition, lenzilumab is the only immunomodulator that was in an active clinical trial in another indication to prevent cytokine storm prior to embarking upon the Phase III COVID-19 trial and is currently the only agent in an active Phase III trial targeting GM-CSF.
>
> . . .
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> As an upstream regulator of cytokine storm, GM-CSF neutralization with lenzilumab may offer advantages over other immunomodulator strategies that either target other downstream cytokines such as IL-1, IL-6, CCR5 or MIP-1 alpha or are broadly immunosuppressive and target cytokine signaling pathways non-selectively through JAK inhibition. In

> addition, lenzilumab is the only immunomodulator that was in an active clinical trial to prevent cytokine storm prior to COVID-19 and is currently the only agent in an active Phase III trial targeting GM-CSF.

28. On May 28, 2021, Humanigen issued a press release during pre-market hours announcing that the Company had submitted the lenzilumab EUA to the FDA. The press release stated that "[t]his EUA application follows positive results from the LIVE-AIR Phase 3 clinical trial evaluating the ability of lenzilumab to improve the likelihood of survival without ventilation (SWOV) in newly hospitalized COVID-19 patients."

29. With respect to lenzilumab's purported effectiveness in treating hospitalized COVID-19 patients, the same press release stated, in relevant part:

> Lenzilumab achieved the primary endpoint with a 54% relative improvement in the likelihood of SWOV compared to placebo. Lenzilumab also improved the relative likelihood of SWOV by 92% in subjects who received both corticosteroids and remdesivir and resulted in a 3-fold improvement in the likelihood of SWOV in patients with a CRP<150 mg/L and less than 85 years of age. In these patients, a 2.2-fold improvement in the likelihood of survival was observed with lenzilumab.

30. On July 30, 2021, Humanigen issued a press release announcing that the NIH had advanced the ACTIV-5/BET-B study to a Phase 2/3 study. The press release quoted Defendant Durrant, who stated, in relevant part: "We believe ACTIV- 5/BET-B, along with LIVE-AIR, will provide the sufficient size and statistical power typically required for a [Biologics License Application ('BLA')] to be submitted to FDA."

31. On August 12, 2021, Humanigen issued a press release announcing its second quarter 2021 financial results, stating, *inter alia*, that since submitting the lenzilumab EUA to the FDA, "the company has responded to several requests from the [FDA] regarding the application" and that "the company anticipates that ACTIV-5/BET-B may serve as a second confirmatory study required for submission to FDA as part of a [BLA] that the company would submit if the ACTIV-5/BET-B data further validate the benefits of lenzilumab in COVID-19 patients."

32. The same press release quoted Defendant Durrant, who stated "[w]e remain firm in our belief the results of our LIVE-AIR Phase 3 study warrant lenzilumab being granted [EUA]" and that "[t]he achievement of the primary endpoint for the overall patient population, and the recent supplemental subset analysis which showed significant response to treatment by Black and African-American patients in the study, support our view of the potential benefit lenzilumab could bring to patient care if authorization were to be granted[.]"

33. Also on August 12, 2021, Humanigen filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operational results for the quarter ended June 30, 2021 (the "2Q21 10-Q"). The 2Q21 10-Q stated that "[l]enzilumab is a monoclonal antibody that has been demonstrated to neutralize GM-CSF, a cytokine that the Company believes is of critical importance in the hyperinflammatory cascade, sometimes referred to as cytokine release syndrome

('CRS') or cytokine storm, associated with COVID-19," and that "[t]he Company believes the results from its Phase 3 study in COVID-19, its Phase 1b study in CAR-T, and four other clinical trials support the mechanism of action of lenzilumab."

34. With respect to lenzilumab's purported efficacy in treating hospitalized COVID-19 patients, the 2Q21 10-Q stated, in relevant part:

> On May 5, 2021, data from a Phase 3, multi-center, double-blind, placebo-controlled potential registrational trial of lenzilumab as a potential therapeutic for hospitalized, hypoxic patients with COVID-19 pneumonia was published on MedRxiv, a non-peer reviewed journal. We refer to this study as the "LIVE-AIR" study. Data from LIVE-AIR support the previously reported primary endpoint that demonstrated lenzilumab improved the likelihood of survival without ventilation ("SWOV"), sometimes referred to as "ventilator-free survival", by 54% in the modified intent-to-treat ("mITT") population . . . . SWOV also improved on a relative basis by 92% in subjects who received both corticosteroids and remdesivir . . .; by 3.04-fold in subjects with baseline C-reactive protein ("CRP") levels <150 mg/L and age <85 years Survival was improved by 2.22-fold in subjects with baseline CRP<150 mg/L and age <85 years . . . . Subjects with baseline CRP<150 mg/L and age <85 years demonstrated an improvement in survival and appeared to derive the greatest benefit from lenzilumab. An additional analysis of minority groups that are at greater risk of poor outcomes with COVID-19 demonstrated a nearly 9-fold relative improvement in SWOV in Black and African-American Subjects with CRP < 150 mg/L at baseline[.]

35. Appended as exhibits to the 2Q21 10-Q were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), wherein the Individual Defendants (excluding Chappell) certified that the 2Q21 10-Q "fully complies with the requirements of Section 13(a) or 15(d) of the [Exchange Act] and that information contained in [the 2Q21 10-Q] fairly presents in all material respects the financial

condition and results of operations of Humanigen[.]"

36. The statements referenced in ¶¶26-35 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) lenzilumab created patient risks that outweighed its benefits insofar as the drug prevented inflammation but also interfered with the positive effects of GM-CSF on patient lungs, *i.e.*, alveoli; (ii) lenzilumab was not the only immunomodulator in an active clinical trial and was not the only agent in an active Phase III trial targeting GM-CSF in light of the fact that mavrilimumab was being evaluated for treatment in rheumatoid arthritis and in an active Phase 2/3 clinical trial targeting GM-CSF sponsored by Kiniksa Pharmaceuticals, Ltd.; (iii) lenzilumab was less effective in treating hospitalized COVID-19 patients than Defendants had represented; (iv) as a result, the FDA was unlikely to approve the lenzilumab EUA and the ACTIV-5/BET-B study was unlikely to meet its primary endpoint; (v) accordingly, lenzilumab's clinical and commercial prospects were overstated; and (vi) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Begins to Emerge

37. On September 9, 2021, during pre-market hours, Humanigen issued a

press release (the "September 2021 Press Release") announcing that the FDA had rejected the lenzilumab EUA, stating, in relevant part:

> [T]he U.S. FDA has declined its request for emergency use authorization of lenzilumab to treat newly hospitalized COVID-19 patients. In its letter, FDA stated that it was unable to conclude that the known and potential benefits of lenzilumab outweigh the known and potential risks of its use as a treatment for COVID-19.

38. On this news, Humanigen's stock price fell $7.14 per share, or 47.25%, to close at $7.97 per share on September 9, 2021. Despite this decline in the Company's stock price, Humanigen securities continued trading at artificially inflated prices throughout the remainder of the Class Period because of Defendants' continued misstatements and omissions regarding lenzilumab's clinical and commercial prospects.

39. For example, the September 2021 Press Release stated that "NIH's ACTIV-5/BET-B study is expected to provide further data that may support a new EUA request" and that "Humanigen remains committed to completing regulatory processes underway seeking Marketing Authorization for lenzilumab to treat hospitalized COVID-19 patients in the U.K. and other territories[.]"

40. The September 2021 Press Release also quoted Defendant Durrant, who likewise assured investors that "[w]e remain committed to bringing lenzilumab to patients hospitalized with COVID-19" and that "[w]e believe the ongoing ACTIV-5/BET-B trial, which has been advanced to enroll up to 500 patients, may provide

additional safety and efficacy data sufficient to support our efforts to obtain an EUA to treat hospitalized COVID-19 patients."

41. On November 12, 2021, Humanigen issued a press release announcing its third quarter 2021 financial results and providing a corporate update. The press release quoted Defendant Durrant, who stated, in relevant part: "We are continuing our efforts to get lenzilumab to hospitalized COVID-19 patients. The recent selection of lenzilumab by the European Commission as one of the 10 most promising treatments for COVID-19, validates our view that lenzilumab offers meaningful clinical potential."

42. Also on November 12, 2021, Humanigen filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operational results for the quarter ended September 30, 2021 (the "3Q21 10-Q"). The 3Q21 10-Q contained substantively the same statements as referenced in ¶¶33-34, *supra*, regarding lenzilumab's purported mechanism of action and efficacy.

43. With respect to lenzilumab's remaining clinical and commercial prospects, the 3Q21 10-Q stated, among other things, that following the FDA's rejection of the lenzilumab EUA, Humanigen had "requested and . . . been granted a Type B meeting with FDA"; that "[i]ncluded in the briefing materials for the meeting request were day 60 data as well as detailed CRP analysis from the LIVE- AIR study"; that "[w]e intend to submit a [BLA] to FDA for lenzilumab in the treatment of

hospitalized COVID-19 patients"; and that "we plan to include the results of the expanded ACTIV-5/BET-B study as a basis for a BLA-confirmatory study for lenzilumab and believe data from ACTIV-5/BET-B, along with LIVE- AIR, should provide the sufficient size and statistical power typically required for a BLA to be submitted to FDA."

44. Appended as exhibits to the 3Q21 10-Q were substantively the same SOX certifications as referenced in ¶35, *supra*, signed by the Individual Defendants (excluding Chappell).

The Truth Continues to Emerge

45. On December 28, 2021, Kiniksa Pharmaceuticals, Ltd. announced results from its Phase 3 trial of mavrilimumab in COVID-19-related acute respiratory syndrome. Similar to lenzilumab, mavrilimumab was an investigational fully human monoclonal antibody that targeted granulocyte macrophage colony stimulating factor receptor alpha, or GM-CSFRα. According to Kiniksa Pharmaceuticals' press release, "the Phase 3 portion of the Phase 2/3 trial of mavrilimumab in COVID-19-related acute respiratory syndrome (ARDS) did not meet the primary efficacy endpoint."

46. Contrary to Defendants' earlier statements, lenzilumab was not the "only immunomodulator that was in an active clinical trial in another indication to prevent cytokine storm prior to embarking upon the Phase III COVID-19 trial" and was not the "only agent in an active Phase III trial targeting GM-CSF." Thus, when industry

participants and market analysts learned that Kiniksa Pharmaceuticals' GM-CSF treatment failed, the public doubted the truthfulness and accuracy of Defendants' statements about lenzilumab's clinical benefits.

47. On January 5, 2022, Humanigen issued a press release announcing that target enrollment in the Phase 2/3 ACTIV-5/BET-B study had been achieved. The press release quoted Defendant Durrant, who stated, in relevant part:

> Completion of target enrollment in ACTIV-5/BET-B is a significant milestone in the development of lenzilumab . . . . We have alignment with the FDA that, if the trial is successful, we can include the results from ACTIV-5/BET-B in an amended [EUA] submission for lenzilumab for hospitalized patients with COVID-19. We look forward to sharing the topline results from ACTIV-5, when available, and submitting an amended EUA.

48. On March 1, 2022, Humanigen filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operational results for the quarter and year ended December 31, 2021 (the "2021 10-K"). The 2021 10-K continued to represent that "[l]enzilumab is a monoclonal antibody that has been demonstrated to neutralize . . . a cytokine that we believe is of critical importance in the hyperinflammatory cascade, sometimes referred to as cytokine release syndrome ('CRS') or cytokine storm, associated with COVID-19[.]"

49. With respect to lenzilumab's remaining clinical and commercial prospects, the 2021 10-K stated, among other things, that "[d]espite . . . regulatory setbacks, we continue to believe in [lenzilumab's] potential therapeutic benefits and

remain committed to bringing lenzilumab to patients hospitalized with COVID-19"; that "[t]he next anticipated step in our development program for lenzilumab in COVID-19 is the release of results from the . . . ACTIV-5/BET-B trial"; that "[i]f confirmatory of the findings of the CRP subgroup from the LIVE-AIR study, we plan to include the results from ACTIV-5/BET-B in an amendment to EUA submission"; and that "[w]e believe that we have built a strong intellectual property position in the area of GM-CSF neutralization through multiple approaches and mechanisms, as they pertain to COVID-19[.]"

50. Appended as exhibits to the 2021 10-K were substantively the same SOX certifications as referenced in ¶35, *supra*, signed by the Individual Defendants (excluding Chappell).

51. On May 5, 2022, Humanigen issued a press release announcing the Company's first quarter 2022 financial results. The press release quoted Defendant Durrant, who stated, in relevant part:

> A key highlight of the first quarter was the completion of enrollment in the ACTIV-5/BET-B study. We also held a productive Type B pre-EUA meeting with FDA where we gained alignment on the data and statistical analysis plan to be included as part of the amendment to our EUA for [lenzilumab] in COVID-19 patients. In concert with the NIH, we anticipate top-line data in the primary analysis population to be reported in the second quarter, with an amendment to our EUA submission planned to follow[.]

52. Also on May 5, 2022, Humanigen filed a quarterly report on Form 10- Q with the SEC, reporting the Company's financial and operational results for the

quarter ended March 31, 2022 (the "1Q22 10-Q"). The 1Q222 10-Q continued to represent that "[l]enzilumab is a monoclonal antibody that has been demonstrated to neutralize . . . a cytokine that we believe is of critical importance in the hyperinflammatory cascade, sometimes referred to as cytokine release syndrome ('CRS') or cytokine storm, associated with COVID-19[.]"

53. With respect to lenzilumab's remaining clinical and commercial prospects, the 1Q22 10-Q stated, among other things, that "[t]he next anticipated step in the Company's development program for lenzilumab in COVID-19 is the release of results from the . . . ACTIV-5/BET-B trial," and that "[i]f confirmatory of the findings of the CRP subgroup from the Company's LIVE-AIR study, the Company plans to include the results from ACTIV-5/BET-B in an amendment to its [EUA] submission to the [FDA.]"

54. Appended as exhibits to the 1Q22 10-Q were substantively the same SOX certifications as referenced in ¶35, *supra*, signed by the Individual Defendants (excluding Chappell).

55. On June 21, 2022, Humanigen presented at Lytham Partners' Summer Investor Conference in San Francisco, California. Defendant Dale Chappell presented on behalf of Humanigen. In response to analyst questions, Chappell stated in pertinent part as follows:

> Joe Diaz Lytham Partners – Managing Partner With regards to that trial, what gives you confidence in the potential for a positive outcome from

it?

Dale Chappell Humanigen, Inc. – Chief Scientific Officer So we've already announced and have now published a Phase 3 study. That was a company-sponsored Phase 3 study that involved 520 hospitalized COVID-19 patients. We published that data. That was a positive study; we hit our primary endpoint with statistical significance, and that data is now published in Lancet Respiratory Medicine.

So if you look at the outcome of that study, lenz showed the ability to reduce hospitalized patients -- their progression to invasive mechanical ventilation and death, and that reduction was a relative reduction of about 33%. We went on and looked at the data even further to try to identify whether there were patients who were deriving even more benefit.

And using an inflammatory marker, which almost every hospitalized patient gets -- that inflammatory marker is called C-reactive protein. We'll call it CRP as we go along in this fireside chat. But when we look at patients who have a CRP below a certain threshold, and that threshold is 150, we see an even greater benefit to patients treated with lenzilumab. And that translates to a 62% relative risk reduction of needing invasive mechanical ventilation or dying in the first month after treatment.

And if we look at how that compares to other therapies -- on the slide here, you can see remdesivir, dexamethasone, tocilizumab, and baricitinib. Now that data all comes from a meta analysis. So that basically incorporates all the randomized trials that have been conducted to date, looking at those drugs' ability to reduce the need for invasive mechanical ventilation or death.

And then on the right, you can see what we have in the LIVE-AIR study, and that's what we refer to as our Phase 3 study. We call it LIVE-AIR. And the overall population -- there was a 33% reduction, and of course, a 62% reduction.

In our, what we're calling, our target population -- the reason we call it the target population because now that's the group that the NIH is studying. So the NIH looked at this data. They thought that the 62% reduction in the CRP subgroup was compelling, and they decided to advance the NIH study, which is called ACTIV-5 or BET-B to a Phase

2/3 confirmatory study.

> Now sometimes, when you look at subgroups, they make up a small fraction of the study, and they're always subject to sampling bias. In this case, our CRP subgroup makes up 78% of the patient population. So this is the large majority of the study population. And again, this is an overall positive study.
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> So this is not some sort of data hacking where you go back and try to figure out where the drug worked because it didn't work in the overall population. This is really trying to maximize the benefit for patients and for payers and the health care system. So this gives us confidence in the upcoming data readout and why we're excited about that study readout.

56. The statements referenced in ¶¶47-55 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) lenzilumab was less effective in treating hospitalized COVID-19 patients than Defendants had represented; (ii) as a result, the ACTIV-5/BET-B study was unlikely to meet its primary endpoint; (iii) accordingly, lenzilumab's clinical and commercial prospects were overstated; (iv) Defendants knew that they had overstated lenzilumab's clinical and commercial prospects in light of mavrilimumab's failed clinical trial; and (v) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Fully Emerges

57. On July 12, 2022, during after-market hours, Humanigen disclosed that

lenzilumab had failed to show statistical significance on the primary endpoint of the ACTIV-5/BET-B study, stating, in relevant part:

> Humanigen . . . has been informed of preliminary topline results from the National Institute of Allergy and Infectious Diseases' (NIAID) ACTIV-5/BET-B trial evaluating lenzilumab plus remdesivir versus placebo plus remdesivir in hospitalized COVID-19 patients. The trial did not achieve statistical significance on the primary endpoint The data also showed a non-significant trend toward a reduction in mortality in the overall patient population[.]

58. On this news, Humanigen's stock price fell $2.38 per share, or 79.6%, to close at $0.61 per share on July 13, 2022.

59. 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.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

60. 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 those who purchased or otherwise acquired Humanigen securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, 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.

61. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Humanigen securities were actively traded on the OTCQB and/or NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Humanigen 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.

62. 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.

63. 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. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

64. 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 misrepresented material facts about the business, operations and management of Humanigen;

c. whether the Individual Defendants caused Humanigen to issue false and misleading financial statements during the Class Period;

d. whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

e. whether the prices of Humanigen securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

f. whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

65. 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 make 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.

66. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

b. the omissions and misrepresentations were material;

c. Humanigen securities are traded in an efficient market;

d. the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;

e. the Company traded on the OTCQB and/or NASDAQ and was covered by multiple analysts;

f. the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

g. Plaintiff and members of the Class purchased, acquired and/or sold Humanigen securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

67. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

68. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

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

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

70. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated

thereunder by the SEC.

71. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Humanigen securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Humanigen securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

72. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Humanigen

securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Humanigen's finances and business prospects.

73. By virtue of their positions at Humanigen, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

74. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Humanigen, the Individual Defendants had knowledge of the details of Humanigen's internal affairs.

75. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content

of the statements of Humanigen. As officers and/or directors of a publicly- held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Humanigen's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Humanigen securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Humanigen's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Humanigen securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

76. During the Class Period, Humanigen securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Humanigen securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated

prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Humanigen securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Humanigen securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

77. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

78. 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, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

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

79. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

80. During the Class Period, the Individual Defendants participated in the operation and management of Humanigen, and conducted and participated, directly

and indirectly, in the conduct of Humanigen's business affairs. Because of their senior positions, they knew the adverse non-public information about Humanigen's misstatement of income and expenses and false financial statements.

81. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Humanigen's financial condition and results of operations, and to correct promptly any public statements issued by Humanigen which had become materially false or misleading.

82. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Humanigen disseminated in the marketplace during the Class Period concerning Humanigen's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Humanigen to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Humanigen within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Humanigen securities.

83. Each of the Individual Defendants, therefore, acted as a controlling person of Humanigen. By reason of their senior management positions and/or being

directors of Humanigen, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Humanigen to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Humanigen and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

84. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Humanigen.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just

and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.