

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK**

Individually and on Behalf of All Others Similarly Situated,  Plaintiff,  v.  PEPGEN INC., JAMES MCARTHUR, and NOEL DONNELLY,  Defendants.	<b>Case No.</b>  <b><u>CLASS ACTION COMPLAINT</u></b>  <b><u>JURY TRIAL DEMANDED</u></b>
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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 PepGen Inc. (“PepGen” 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 PepGen securities between March 7, 2024 and March 3, 2025, 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. PepGen is a clinical-stage biotechnology company that focuses on the development of oligonucleotide therapeutics for use in the treatment of severe neuromuscular and neurologic diseases. The Company's lead product candidate was PGN-EDO51, a proprietary enhanced delivery oligonucleotide ("EDO") peptide for the treatment of Duchenne muscular dystrophy ("DMD"), a genetic disorder characterized by progressive muscle degeneration and weakness.

3. DMD is caused by the mutation of the dystrophin gene, resulting in, *inter alia*, a limited production of the dystrophin protein, which in turn leads to DMD's clinical features. According to PepGen, "PGN-EDO51 [wa]s designed to skip exon 51 of the dystrophin transcript, an established therapeutic target for approximately 13% of DMD patients, thereby . . . enabling the production of a truncated, yet functional dystrophin protein."

4. PepGen had been evaluating PGN-EDO51 as a treatment for DMD in two Phase 2 clinical trials—the CONNECT1-EDO51 ("CONNECT1") and CONNECT2-EDO51 ("CONNECT2") studies.

5. At all relevant times, Defendants touted PGN-EDO51's clinical, regulatory, and commercial prospects, including, *inter alia*, PGN-EDO51's ability to produce the dystrophin protein and the design, prospects, and results of the CONNECT1 and CONNECT2 studies.

6. 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) PGN-EDO51 was less effective and safe than Defendants had led investors to believe; (ii) the CONNECT2 study was

dangerous or otherwise deficient for purposes of U.S. Food and Drug Administration (“FDA”) approval; (iii) as a result of all the foregoing, PepGen was likely to halt the CONNECT2 study, and PGN-EDO51’s clinical, regulatory, and commercial prospects were overstated; and (iv) as a result, Defendants’ public statements were materially false and misleading at all relevant times.

7. On July 30, 2024, PepGen issued a press release announcing purported “positive clinical data from the first dose cohort (5 mg/kg) of PGN-EDO51” in its ongoing CONNECT1 study. Among other results, the Company reported that “PGN-EDO51 achieved a mean absolute dystrophin level of 0.61% of normal and a 0.26% change from baseline after 4 doses, measured at week 13 by Western blot analysis.” However, as subsequently noted by a Stifel analyst, “the magnitude of dystrophin increase was below what [PepGen] anticipated, which is disappointing[.]” Likewise, a Leerink Partners analyst noted that the low dose missed PepGen’s expectations of 1% or greater dystrophin expression.

8. On this news, PepGen’s stock price fell \$5.55 per share, or 32.69%, to close at \$11.43 per share on July 31, 2024.

9. On December 16, 2024, PepGen issued a press release announcing that it had received a clinical hold notice from the FDA regarding an Investigational New Drug (“IND”) application “to initiate the [CONNECT2] clinical trial in patients with [DMD]” in the U.S. Notably, the FDA’s issuance of a clinical hold notice for the IND application indicated that the FDA had concerns regarding risks posed to patients in the CONNECT2 study and/or there were other deficiencies associated with the study.<sup>1</sup>

10. On this news, PepGen’s stock price fell \$0.17 per share, or 3.63%, to close at \$4.51 per share on December 16, 2024.

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<sup>1</sup> See *IND Application Procedures: Clinical Hold*, FDA, <https://www.fda.gov/drugs/investigational-new-drug-ind-application/ind-application-procedures-clinical-hold> (last visited June 6, 2025).

11. On January 29, 2025, PepGen issued a press release providing updates regarding safety concerns observed in the CONNECT1 study and the FDA's concerns regarding the CONNECT2 study. With respect to the CONNECT1 study, the press release stated, *inter alia*, that “[d]osing of one of the[] . . . participants [in the 10 mg/kg cohort] was paused due to a reduction of his estimated glomerular filtration rate[.]” In addition, PepGen “ha[d] received communication from Health Canada . . . request[ing] additional information from the Company to address Health Canada’s safety concerns before any further dose escalation or enrollment of any additional participants at the current dose levels.” With respect to the CONNECT2 study, the same press release stated, in relevant part, that “[t]he Company is working with the FDA to address its questions regarding supportive data for the dosing levels planned for the patient population.”

12. Following these disclosures, PepGen’s stock price fell \$0.40 per share, or 21.74%, to close at \$1.44 per share on January 30, 2025.

13. On March 4, 2025, PepGen issued a press release “announc[ing] its voluntary decision to temporarily pause the [CONNECT2] study . . . until the Company can review results from the 10 mg/kg cohort in the ongoing [CONNECT1] study.”

14. On this news, PepGen’s stock price fell \$0.53 per share, or 18.86%, to close at \$2.28 per share on March 4, 2025.

15. Then, on May 28, 2025, PepGen issued a press release announcing that “PGN-EDO51 did not achieve target dystrophin levels” in the CONNECT1 study and had chosen to discontinue development of its DMD programs.

16. 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**

17. 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).

18. 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.

19. Venue is proper in this District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Per PepGen's most recent quarterly report on Form 10-Q, as of May 1, 2025, there were 32,720,943 shares of the Company's common stock outstanding. PepGen's common stock trades in the U.S. on the Nasdaq Global Select Market ("NASDAQ"). Accordingly, there are presumably hundreds, if not thousands, of investors in PepGen's securities located in the U.S., some of whom undoubtedly reside in this District.

20. 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**

21. Plaintiff, as set forth in the attached Certification, acquired PepGen securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

22. Defendant PepGen is a Delaware corporation with principal executive offices located at 321 Harrison Avenue, 8th Floor, Boston, Massachusetts 02118. The Company's common stock trades in an efficient market on the NASDAQ under the ticker symbol "PEPG."

23. Defendant James McArthur (“McArthur”) has served as PepGen’s Chief Executive Officer at all relevant times.

24. Defendant Noel Donnelly (“Donnelly”) has served as PepGen’s Chief Financial Officer at all relevant times.

25. Defendants McArthur and Donnelly are collectively referred to herein as the “Individual Defendants.”

26. The Individual Defendants possessed the power and authority to control the contents of PepGen’s SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of PepGen’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 PepGen, 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.

27. PepGen and the Individual Defendants are collectively referred to herein as “Defendants.”

## **SUBSTANTIVE ALLEGATIONS**

### **Background**

28. PepGen is a clinical-stage biotechnology company that focuses on the development of oligonucleotide therapeutics for use in the treatment of severe neuromuscular and neurologic diseases. The Company’s lead product candidate was PGN-EDO51, a proprietary EDO peptide

for the treatment of DMD, a genetic disorder characterized by progressive muscle degeneration and weakness.

29. DMD is caused by the mutation of the dystrophin gene, resulting in, *inter alia*, a limited production of the dystrophin protein, which in turn leads to DMD's clinical features. According to PepGen, "PGN-EDO51 [wa]s designed to skip exon 51 of the dystrophin transcript, an established therapeutic target for approximately 13% of DMD patients, thereby . . . enabling the production of a truncated, yet functional dystrophin protein."

30. PepGen had been evaluating PGN-EDO51 as a treatment for DMD in two Phase 2 clinical trials—the CONNECT1 and CONNECT2 studies. The CONNECT1 study is an open-label, multiple ascending dose ("MAD") clinical trial evaluating PGN-EDO51 in approximately ten male patients at least eight years of age with DMD amenable to an exon 51-skipping approach. The CONNECT2 study is a randomized, double-blind, placebo-controlled, MAD clinical trial evaluating PGN-EDO51 in approximately twenty male patients at least six years of age with DMD amenable to an exon 51-skipping approach.

31. At all relevant times, Defendants touted PGN-EDO51's clinical, regulatory, and commercial prospects, including, *inter alia*, PGN-EDO51's ability to produce the dystrophin protein and the design, prospects, and results of the CONNECT1 and CONNECT2 studies.

**Materially False and Misleading Statements Issued During the Class Period**

32. The Class Period begins on March 7, 2024. On March 6, 2024, during after-market hours, PepGen hosted a conference call with investors and analysts to discuss the Company's financial and operating results for the fourth quarter and year ended December 31, 2023 (the

“4Q/FY23 Conference Call”). In his opening remarks during the 4Q/FY23 Conference Call, Defendant McArthur touted PGN-EDO51’s efficacy, stating, in relevant part<sup>2</sup>:

We anticipate reporting preliminary data for the CONNECT1 5 mg per kg cohort in mid-2024, including safety, exon skipping and dystrophin production. Based upon externally available data and using our own clinical and nonclinical work for internal modeling assumptions, ***PepGen expects treatment with EDO51 in DMD patients to produce high levels of dystrophin protein.***

At the 5 mg per kg dose level, ***we expect to see greater than 1% of normal levels of dystrophin protein above background levels in the CONNECT1-EDO51 trial*** as measured by Western Blot analysis following four repeat doses of EDO51 in DMD patients. For our 10 mg per kg dose cohort, if EDO51 were to achieve dystrophin levels of greater than 7%, this would be the highest level of dystrophin production achieved by a DMD exon-skipping therapy to date.

***Our modeling projections for this dose level suggests the possibility that we could potentially achieve greater than 9% of normal levels of dystrophin protein.***

33. During the question-and-answer (“Q&A”) portion of the 4Q/FY23 Conference Call, in response to an analyst’s question regarding “what’s the expectation that the magnitude of [exon 51] skipping can increase over time[,]” Defendant McArthur stated, in relevant part:

***[W]e do anticipate seeing better than 7% and very likely above 9% dystrophin production*** based on the level of exon skipping and the modeling work that we’ve done, based on the extrapolation we’ve done from prior work of other companies where we compare our single-dose exon skipping in humans to their single-dose exon skipping in humans.

And then lastly, based on the very extensive nonhuman primate modeling work we’ve done looking at both single and multiple doses. So as such, ***we do expect to see very robust levels of exon skipping following four doses. And this will be reflective of what we’re able to achieve, we believe, long term.***

34. Also during the Q&A portion of the 4Q/FY23 Conference Call, in response to an analyst’s question regarding Defendant McArthur’s thoughts on what previous data indicated “about your program concerning the platform and the EDO51[,]” Defendant McArthur stated following regarding PGN-EDO51’s efficacy and safety:

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<sup>2</sup> All emphases hereinafter are added unless otherwise indicated.

So we have done a cross-trial comparison of the ability of EDO51 to mediate exon 51 skipping in humans following a single dose. And there, we were able to observe ***six fold higher levels of exon 51 skipping*** compared to a single dose of the 5051 molecule at 20 mgs per kg. 20 mg per kg 5051 ***was relatively well tolerated at 10 mg per kg***, ED051, demonstrated following the single dose in humans ***only grade 1 reversible transient adverse events. So very, very well tolerated drug.***

We anticipate, as we extrapolate forward that ***we could be producing six fold higher levels of exon skipping and potentially dystrophin*** than what was observed in both the three month Momentum A and the six month Momentum B clinical studies with 5051. ***This is what supports our contention that we have the potential to produce greater than 9% dystrophin levels in patients following four doses.***

And so ***we remain very confident, both based on the extrapolation in the cross-trial comparison to that clinical data, the work that we've done in animal modeling and nonhuman primates and the overall modeling work that has incorporated both mouse, nonhuman primate and human data with EDO051 that indeed, we'll be able to see better than 9% dystrophin in patients.***

If we could even achieve 7% dystrophin production with an exon skipping approach, ***this will be the highest level of dystrophin produced by any exon-skipping drug and projected to be produced by any exon-skipping drug.*** And so we would be -- feel that to be a huge success but ***we believe based on all the work we've done, we have the potential to be greater than to produce later than 9% dystrophin in patients.***

35. Also on March 6, 2024, during after-market hours, PepGen filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2023 (the "2023 10-K"). The 2023 10-K touted PGN-EDO51's efficacy, stating, in relevant part, that "[i]n the Phase 1 clinical trial in HVs [healthy volunteers], treatment with PGN-EDO51 resulted in the highest levels of mean exon skipping in humans following a single dose compared to publicly available data for a single dose of other DMD exon 51-skipping approaches that are approved or in clinical development."

36. With respect to the CONNECT2 study, including its design, the 2023 10-K stated, in relevant part:

The CONNECT2 will enroll approximately 20 ambulatory and non-ambulatory boys and young men living with DMD amenable to exon 51-skipping, who are at

least six years of age. Participants will receive seven doses of either PGN-EDO51 or placebo at approximately four-week intervals for 24 weeks. The starting dose will escalate from 5 mg/kg to 10 mg/kg, and potentially higher (if needed); the same dose levels are being evaluated in the CONNECT1 trial. Dose escalation will be determined based on data review by the DSMB [Data Safety and Monitoring Board]. We will conduct muscle biopsies at baseline and at week 25. We will assess safety, tolerability, exon skipping, dystrophin production and functional outcome measures in this study.

***We believe that this clinical development plan may enable us to pursue an accelerated approval pathway for PGN-EDO51 with the FDA . . . . If we receive positive results from our Phase 2 trials for PGN-EDO51 that show an acceptable emerging safety profile; a clinically meaningful increase in dystrophin levels, a surrogate endpoint in the biceps of DMD patients; and robust exon skipping levels in the same tissue; we intend to pursue discussions with the FDA for a potential accelerated approval pathway.***

37. Appended as exhibits to the 2023 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 (“SOX”), wherein the Individual Defendants certified, in relevant part, that the 2023 10-K “does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report[.]”

38. On May 14, 2024, PepGen issued a press release announcing its financial and operating results for the first quarter of 2024. With respect to the CONNECT2 study, including its design, that press release stated, in relevant part:

CONNECT2 is a Phase 2, randomized, double-blind, placebo-controlled MAD clinical trial, evaluating PGN-EDO51 in approximately 20 male patients at least 6 years of age with DMD amenable to an exon 51-skipping approach. PepGen plans to extend this study to the United States and other countries, subject to regulatory authorizations. ***The CONNECT2 clinical trial, together with the data from CONNECT1, is designed to potentially support a future accelerated approval pathway***, subject to regulatory authority feedback.

39. Also on May 14, 2024, PepGen filed a quarterly report on Form 10-Q with the SEC, reporting the Company’s financial and operating results for the quarter ended March 31, 2024 (the

“1Q24 10-Q”). With respect to the CONNECT2 study, including its design, the 1Q24 10-Q stated, in relevant part:

The CONNECT2 study will evaluate multiple dose cohorts and trial participants will be administered PGN-EDO51 once every four weeks for six months. We will assess safety, tolerability, exon skipping, dystrophin expression and functional outcomes in this study. *The CONNECT2 study, together with data from the CONNECT1 study, is designed to support a potential accelerated approval pathway for PGN-EDO51*, subject to regulatory authority feedback.

40. Appended as exhibits to the 1Q24 10-Q were substantively the same SOX certifications as referenced in ¶ 37, *supra*, signed by the Individual Defendants.

41. The statements referenced in ¶¶ 32-40 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) PGN-EDO51 was less effective and safe than Defendants had led investors to believe; (ii) the CONNECT2 study was dangerous or otherwise deficient for purposes of FDA approval; (iii) as a result of all the foregoing, PepGen was likely to halt the CONNECT2 study, and PGN-EDO51’s clinical, regulatory, and commercial prospects were overstated; and (iv) as a result, Defendants’ public statements were materially false and misleading at all relevant times.

### **The Truth Begins to Emerge**

42. On July 30, 2024, during after-market hours, PepGen issued a press release announcing purported “positive clinical data from the first dose cohort (5 mg/kg) of PGN-EDO51” in its ongoing CONNECT1 study (the “July 2024 Press Release”). Among other results, PepGen reported that “PGN-EDO51 at 5 mg/kg showed mean absolute dystrophin level of 0.61%, a 0.26% increase from baseline, after three months of dosing[.]” These efficacy results were disappointing and shocked the market.

43. Indeed, the next day, shortly after markets opened, *Bloomberg* published an article entitled “PepGen Shares Sink by Record as Muscle Disease Data Disappoints” (the “*Bloomberg Article*”). The *Bloomberg Article* reported that “PepGen shares plummet[ed] as much as 53%, a record drop, after the drug developer gave disappointing data from a low-dose cohort in an ongoing trial of its experimental therapy for” DMD. The *Bloomberg Article* also quoted a Stifel analyst as stating that the low-dose data “misses the bar” and that “the magnitude of dystrophin increase was below what [PepGen] anticipated, which is disappointing[.]” In addition, the *Bloomberg Article* cited a Leerink Partners analyst as noting that the low dose missed PepGen’s expectations of 1% or greater dystrophin expression.

44. Following these revelations, PepGen’s stock price fell \$5.55 per share, or 32.69%, to close at \$11.43 per share on July 31, 2024. Despite this decline in PepGen’s stock price, the Company’s securities continued trading at artificially inflated prices throughout the remainder of the Class Period because of Defendants’ continued misstatements and omissions regarding PGN-EDO51.

45. For example, the July 2024 Press Release quoted Defendant McArthur as stating, in relevant part:

We are encouraged by the early data from our CONNECT1 clinical trial of PGN-EDO51 in people with DMD. In three months, the starting monthly dose of 5 mg/kg achieved high levels of exon skipping and all patients showed increases in dystrophin. PGN-EDO51 produced meaningfully higher levels of exon skipped transcript at lower doses and in a shorter time period compared to other exon 51 therapies, approved and in development, indicating that our [EDO] technology is delivering higher levels of oligonucleotide to the nuclei . . . . Importantly, PGN-EDO51 has demonstrated a favorable safety profile, supporting our ongoing evaluation of the 10 mg/kg monthly dose cohort in CONNECT1. We intend to leverage the early observations from CONNECT1 to optimize our CONNECT2-EDO51 Phase 2 trial. Based on these initial results, we are optimistic about the possibility that higher levels of dystrophin production will be observed in the 10 mg/kg cohort of CONNECT1.

46. On August 8, 2024, PepGen issued a press release announcing its financial and operating results for the second quarter of 2024 (the “2Q24 Press Release”). The 2Q24 Press Release quoted Defendant McArthur as stating, in relevant part:

In three months, PGN-EDO51 produced higher mean levels of exon skipped transcript at lower doses and in a shorter period than other exon 51 therapies, approved or in development. We believe this indicates our [EDO] technology is delivering greater levels of oligonucleotide to the nuclei. We are also very pleased PGN-EDO51 was well tolerated and that all patients experienced increases in dystrophin production.

47. With respect to the CONNECT2 study, the 2Q24 Press Release stated, in relevant part:

Based on the data from CONNECT1, including PGN-EDO51’s emerging safety profile to date, the Company is working to optimize the design of the multinational CONNECT2 [study] . . . . The Company . . . expects to open the clinical trial in the United States by year-end, subject to regulatory clearance.

48. Also on August 8, 2024, PepGen filed a quarterly report on Form 10-Q with the SEC, reporting the Company’s financial and operating results for the quarter ended June 30, 2024 (the “2Q24 10-Q”). The 2Q24 10-Q stated, *inter alia*, that “[a]s of July 29, 2024, two participants had received a total of four doses at 10 mg/kg in the ongoing CONNECT1 study, and as of such date, ***PGN-EDO51 had been generally well tolerated at this dose level.***”

49. With respect to the CONNECT2 study, including its design, the 2Q24 10-Q stated, in relevant part:

CONNECT2[] is a multinational, randomized, double-blind, placebo-controlled MAD study. The CONNECT2 study will evaluate multiple dose cohorts and trial participants will be administered PGN-EDO51 once every four weeks for six months. We will assess safety, tolerability, exon skipping, dystrophin expression and functional outcomes in this study. ***Based on the data from CONNECT1, including PGN-EDO51’s emerging safety profile to date, we are working to optimize the design of the CONNECT2 trial. The CONNECT2 study, together with data from the CONNECT1 study, is intended to support a potential accelerated approval pathway for PGN-EDO51,*** subject to regulatory authority feedback.

50. Appended as exhibits to the 2Q24 10-Q were substantively the same SOX certifications as referenced in ¶ 37, *supra*, signed by the Individual Defendants.

51. On October 8, 2024, PepGen issued a press release announcing that it would present at the 29th Annual Congress of the World Muscle Society. The press release quoted Defendant McArthur as stating, in relevant part:

Based on the totality of data in both our 5 mg/kg cohort and the ongoing 10 mg/kg cohort in the CONNECT1-EDO51 trial as of October 3, we believe PGN-EDO51 has a favorable emerging safety profile. There have been no serious adverse events, and all treatment-related adverse events have been mild and have resolved. Hypomagnesemia was observed in one patient and resolved with oral supplementation. All participants continue in the study as planned, with no discontinuations, dose interruptions or reductions.

52. On November 7, 2024, PepGen issued a press release announcing its financial and operating results for the third quarter of 2024 (the “3Q24 Press Release”). The 3Q24 Press Release quoted Defendant McArthur as stating, in relevant part:

We leveraged the encouraging 5 mg/kg results from our CONNECT1[] study in DMD reported in July to further optimize the study designs of both [the] CONNECT1 and CONNECT2[ studies]. With these protocol enhancements in place, we expect to report data from the expanded CONNECT1 10 mg/kg cohort before year-end 2025. We remain deeply committed to advancing our programs[.]

53. With further respect to the CONNECT1 study, the 3Q24 Press Release stated, in relevant part:

Following encouraging data from the 5 mg/kg cohort reported in July, the Company continues to advance the CONNECT1 study . . . . The Company has also expanded the 10 mg/kg cohort from 3 to 4 participants. With these adjustments, the Company now expects to report results from the 10 mg/kg cohort by year-end 2025.

54. With respect to the CONNECT2 study, including its design, the 3Q24 Press Release stated, in relevant part:

Based on the data from CONNECT1, including the favorable emerging safety profile of PGN-EDO51, the Company is also working to optimize the design of the

multinational CONNECT2 Phase 2 double-blind, placebo-controlled, MAD, 25-week trial . . . . The Company . . . expects to open the clinical trial in the United States by year-end, subject to regulatory clearance.

55. Also on November 7, 2024, PepGen filed a quarterly report on Form 10-Q with the SEC, reporting the Company’s financial and operating results for the quarter ended September 30, 2024 (the “3Q24 10-Q”). With respect to the CONNECT1 study, the 3Q24 10-Q stated, in relevant part:

As of October 31, 2024, a total of 10 doses had been administered at 10 mg/kg in the ongoing CONNECT1 study. ***Based on the totality of data in both the 5 mg/kg cohort and the ongoing 10 mg/kg cohort in the CONNECT1 trial as of October 31, 2024, we believe PGN-EDO51 has a favorable emerging safety profile.*** There have been no treatment-related serious adverse events, or SAEs, and all treatment-related adverse events have been mild or moderate. There was no sustained elevation in kidney biomarkers. There were also no changes in hepatic function and no cases of hypokalemia, anemia or thrombocytopenia. Asymptomatic hypomagnesemia has been observed in two participants in the 10 mg/kg cohort and treated with oral magnesium supplementation. As of October 31, 2024, all participants continue in the study as planned, with no discontinuations, dose modifications or dose interruptions.

56. With respect to the CONNECT2 study, including its design, and PepGen’s submission of an IND application to the FDA to initiate the same in the U.S., the 3Q24 10-Q stated, in relevant part:

CONNECT2[] is a multinational, randomized, double-blind, placebo-controlled MAD study. The CONNECT2 study will evaluate multiple dose cohorts and trial participants will be administered PGN-EDO51 once every four weeks for six months. We will assess safety, tolerability, exon skipping, dystrophin expression and functional outcomes in this study. ***Based on the data from CONNECT1, including PGN-EDO51’s favorable emerging safety profile to date, we are also working to optimize the design of the CONNECT2 trial. The CONNECT2 study, together with data from the CONNECT1 study, is intended to support a potential accelerated approval pathway for PGN-EDO51,*** subject to regulatory authority feedback.

\* \* \*

We . . . expect to file an investigational new drug, or IND, application and open the clinical trial in the U.S. by year-end, subject to regulatory clearance.

57. Appended as exhibits to the 3Q24 10-Q were substantively the same SOX certifications as referenced in ¶ 37, *supra*, signed by the Individual Defendants.

58. The statements referenced in ¶¶ 45-57 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) PGN-EDO51 was less effective and safe than Defendants had led investors to believe; (ii) the CONNECT2 study was dangerous or otherwise deficient for purposes of FDA approval; (iii) as a result of all the foregoing, PepGen was likely to halt the CONNECT2 study, and PGN-EDO51's clinical, regulatory, and commercial prospects were overstated; and (iv) as a result, Defendants' public statements were materially false and misleading at all relevant times.

### **The Truth Continues to Emerge**

59. On December 16, 2024, during pre-market hours, PepGen issued a press release announcing that it "received a clinical hold notice from the [FDA] regarding its [IND] application to initiate the CONNECT2[] clinical trial in patients with [DMD]." Accordingly, the FDA had concerns regarding risks posed to patients in the CONNECT2 study and/or there were other deficiencies associated with the study.

60. On this news, PepGen's stock price fell \$0.17 per share, or 3.63%, to close at \$4.51 per share on December 16, 2024.

61. On January 29, 2025, during after-market hours, PepGen issued a press release providing updates regarding safety concerns observed in the CONNECT1 study and the FDA's concerns regarding the CONNECT2 (the "January 2025 Press Release"). With respect to the CONNECT1 study, the January 2025 Press Release stated, in relevant part:

Magnesium levels in two of the participants in the 10 mg/kg cohort, who were previously reported as having asymptomatic hypomagnesemia, have returned to baseline levels with administration of ongoing oral magnesium supplementation. ***Dosing of one of these two participants was paused due to a reduction of his estimated glomerular filtration rate (eGFR) . . . .*** The participant's eGFR is improving and the investigator is evaluating for the resumption of dosing as this value normalizes. The Company is continuing to review the event and associated potential confounding factors to better understand its manifestation.

***The Company has received communication from Health Canada . . . request[ing] additional information from the Company to address Health Canada's safety concerns before any further dose escalation or enrollment of any additional participants at the current dose levels.*** The Company is working with Health Canada to address its questions.

62. With respect to the CONNECT2 study, the January 2025 Press Release stated, in relevant part, that “[t]he Company is working with the FDA to address its questions regarding ***supportive data for the dosing levels planned for the patient population.***”

63. Following these disclosures, PepGen's stock price fell \$0.40 per share, or 21.74%, to close at \$1.44 per share on January 30, 2025.

64. Then, on March 4, 2025, during pre-market hours, PepGen issued a press release announcing its decision to temporarily pause the CONNECT2 study pending its review of data from the CONNECT1 study, stating, in relevant part:

PepGen . . . today announced its voluntary decision to temporarily pause the [CONNECT2] study of PGN-EDO51 in patients with [DMD] until the Company can review results from the 10 mg/kg cohort in the ongoing [CONNECT1] study. The first two cohorts of the CONNECT1 study are fully enrolled and data from the 10 mg/kg cohort are expected during the third quarter of 2025. No new safety issues related to PGN-EDO51 have been observed since the Company's last safety update as of January 23, 2025.

65. On this news, PepGen's stock price fell \$0.53 per share, or 18.86%, to close at \$2.28 per share on March 4, 2025.

### **Post-Class Period Developments**

66. On May 28, 2025, PepGen issued a press release announcing that “PGN-EDO51 did not achieve target dystrophin levels” in the CONNECT1 study and had chosen to discontinue development of its DMD programs.

67. 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.

### **Regulation S-K Item 303**

68. Defendants violated Item 303 of SEC Regulation S-K, 17 C.F.R. § 229.303(b)(2)(ii) (“Item 303”), which required PepGen to “[d]escribe any known trends or uncertainties that have had or that are reasonably likely to have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations.” Defendants failed to disclose, *inter alia*, known or emerging negative trends regarding PGN-EDO51’s efficacy and safety, as well as safety or other issues with the CONNECT2 study for purposes of FDA approval. Defendants’ failure to disclose these issues violated Item 303 because these issues represented known trends or uncertainties that were likely to have a material unfavorable impact on the Company’s business and financial results.

### **SCIENTER ALLEGATIONS**

69. During the Class Period, Defendants had both the motive and opportunity to commit fraud. They also had actual knowledge of the misleading nature of the statements they made, or acted in reckless disregard of the true information known to them at the time. In so doing, Defendants participated in a scheme to defraud and committed acts, practices, and participated in

a course of business that operated as a fraud or deceit on purchasers of the Company's securities during the Class Period.

### **PLAINTIFF'S CLASS ACTION ALLEGATIONS**

70. 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 PepGen 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.

71. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, PepGen securities were actively traded on the 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 PepGen 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.

72. 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.

73. 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.

74. 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:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of PepGen;
- whether the Individual Defendants caused PepGen to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of PepGen securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

75. 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.

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

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- PepGen securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold PepGen 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.

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

78. 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)**

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

80. 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.

81. 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 PepGen securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire PepGen 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.

82. 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 PepGen 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 PepGen's finances and business prospects.

83. By virtue of their positions at PepGen, 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.

84. 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 PepGen, the Individual Defendants had knowledge of the details of PepGen's internal affairs.

85. 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 PepGen. 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 PepGen'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 PepGen securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning PepGen's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired PepGen 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.

86. During the Class Period, PepGen 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 PepGen 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 PepGen securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of PepGen securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

87. 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.

88. 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)**

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

90. During the Class Period, the Individual Defendants participated in the operation and management of PepGen, and conducted and participated, directly and indirectly, in the conduct of PepGen's business affairs. Because of their senior positions, they knew the adverse non-public information about PepGen's misstatement of income and expenses and false financial statements.

91. 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 PepGen's financial condition and results of operations, and to correct promptly any public statements issued by PepGen which had become materially false or misleading.

92. 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 PepGen disseminated in the marketplace during the Class Period concerning PepGen's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause PepGen to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of PepGen 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 PepGen securities.

93. Each of the Individual Defendants, therefore, acted as a controlling person of PepGen. By reason of their senior management positions and/or being directors of PepGen, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, PepGen to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of PepGen 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.

94. 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 PepGen.

**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.