

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA**

Individually and on
Behalf of All Others Similarly Situated,

Plaintiff,

v.

TENAX THERAPEUTICS, INC.,
CHRISTOPHER T. GIORDANO, ELIOT
M. LURIER, LAWRENCE R. HOFFMAN,
THOMAS A. MCGAULEY, and STUART
RICH,

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 Tenax Therapeutics, Inc. (“Tenax” 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 Tenax securities between November 13, 2023 and August 7, 2026, 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. Tenax is a Phase 3, development-stage pharmaceutical company that develops novel cardiopulmonary therapies. Tenax’s prioritized product candidate is levosimendan, which the Company evaluated through, *inter alia*, its Phase 3 LEVEL study of oral levosimendan, or TNX-103, in pulmonary hypertension in heart failure with preserved ejection fraction (“PH-HRpEF”).

3. Before the Class Period, Tenax conducted and completed its Phase 2 HELP study of levosimendan, touting results that showed a “significant improvement” in six-minute walk distance, the primary endpoint for the Phase 3 LEVEL study.

4. At all relevant times, Defendants represented that their approach to developing TNX-103 was “*derisked*”¹ because, *inter alia*, levosimendan was already approved for treatment of conditions other than PHRpEF, Defendants incorporated insights from relevant subject-matter experts, patients in the HELP study showed improvement in

¹ All emphases herein are added unless otherwise indicated.

six minute walk distance, and Defendants modeled the LEVEL study based on assessing which patients in the HELP study responded to levosimendan.

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) TNX-103 was less effective than Defendants had led investors to believe; (ii) accordingly, TNX-103's overall clinical, regulatory, and commercial prospects were overstated; and (iii) as a result, the Company's public statements were materially false and misleading at all relevant times.

6. The truth began to emerge on August 10, 2026, when Tenax issued a press release reporting topline results from its Phase 3 LEVEL clinical trial. This press release stated that TNX-103 "did not meet its primary endpoint of improvement in the 6-minute walk distance versus placebo, or the key secondary endpoint of improvement in Kansas City Cardiomyopathy Questionnaire total symptom score."

7. On this news, Tenax's stock price fell approximately \$12.06 per share, or 89.77%, to close at approximately \$1.38 per share on August 10, 2026.

8. 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

9. 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).

10. 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.

11. 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). Tenax is headquartered in this District, Defendants conduct business in this District, and a significant portion of Defendants' actions took place within this District.

12. 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

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

14. Defendant Tenax is a Delaware corporation with principal executive offices located at 101 Glen Lennox Drive, Suite 300, Chapel Hill, North Carolina 27517. The Company's common stock trades in an efficient market on the Nasdaq Stock Market ("NASDAQ") under the ticker symbol "TENX".

15. Defendant Christopher T. Giordano (“Giordano”) has served as Tenax’s President and Chief Executive Officer at all relevant times.

16. Defendant Eliot M. Lurier (“Lurier”) served as Tenax’s Interim Chief Financial Officer at all relevant times until December 8, 2023.

17. Defendant Lawrence R. Hoffman (“Hoffman”) served as Tenax’s Interim Chief Financial Officer from January 9, 2024 until December 2, 2024.

18. Defendant Thomas A. McGauley (“McGauley”) has served as Tenax’s Chief Financial Officer since December 2, 2024.

19. Defendant Stuart Rich (“Rich”) has served as Tenax’s Chief Medical Officer at all relevant times.

20. Defendants Giordano, Lurier, Hoffman, McGauley, and Rich are collectively referred to herein as the “Individual Defendants.”

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

22. Tenax and the Individual Defendants are collectively referred to herein as “Defendants.”

SUBSTANTIVE ALLEGATIONS

Background

23. Tenax is a Phase 3, development-stage pharmaceutical company that develops novel cardiopulmonary therapies. At all relevant times, Tenax’s prioritized product candidate was levosimendan, which the Company evaluated through, *inter alia*, its Phase 3 LEVEL study of TNX-103 in PH-HRpEF.

24. Before the Class Period, Tenax conducted and completed its Phase 2 HELP study of levosimendan, touting results that showed a “significant improvement” in six-minute walk distance, the primary endpoint for the Phase 3 LEVEL study.

Materially False and Misleading Statements Issued During the Class Period

25. The Class Period begins on November 13, 2023, when Tenax issued a press release announcing that the U.S. Food and Drug Administration (“FDA”) had cleared the Company’s Investigational New Drug (“IND”) Application for TNX-103 for the treatment of PH-HFpEF, and that accordingly, the Company would begin its LEVEL Phase 3 trial. As to the study’s design, Tenax stated that the overall “Phase 3 program for TNX-103 has been designed to exceed the minimal clinically important difference,” stating in relevant part:

The LEVEL study is the first of two planned Phase 3 studies that will evaluate TNX-103 (oral levosimendan) for the treatment of pulmonary hypertension in heart failure with preserved ejection fraction (PH-HFpEF). The LEVEL study will evaluate six-minute walking distance (6MWD) as the primary endpoint, and will enroll a total of 152 patients. *The Phase 3*

program for TNX-103 has been designed to exceed the minimal clinically important difference, and satisfy the U.S. Food and Drug Administration’s request for subject drug exposure of 300 patients for 6 months and 100 patients for 1 year (these are minimum requirements per [International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use] guidelines).

26. That press release also quoted Defendant Rich as stating Defendants expected TNX-103 would prove effective, on the basis that the drug’s activation mechanism boasted “unique properties” that would “provide consistent drug concentration levels, ***supporting improved efficacy***,” and offered as evidence trial results from Tenax’s HELP study, stating in relevant part:

“Based on its unique properties as a K⁺ ATP channel activator, coupled with the proof-of-concept data from the Phase 2 HELP study, TNX-103 has mechanistic potential to address the underlying pathophysiology of PH-HFpEF,” said Stuart Rich, M.D., Chief Medical Officer of Tenax Therapeutics. ***“We expect oral levosimendan will provide consistent drug concentration levels, supporting improved efficacy, as observed in patients who transitioned from weekly IV to oral therapy following the HELP study.”***

27. On February 7, 2024, Tenax issued a press release providing investors with an update on the LEVEL trial, announcing that the Company had enrolled its first patient in the study and quoting Defendant Giordano as stating, in relevant part:

“We are pleased to announce the enrollment of our first patient in the Phase 3 LEVEL study, and delighted we are progressing rapidly from identification to initiation of investigator sites,” said Chris Giordano, President and Chief Executive Officer of Tenax Therapeutics. “The Tenax team and our CRO and other research partners have worked tirelessly to reach this milestone. Our study is generating enthusiasm among North American cardiologists who treat PH-HFpEF. FDA has approved no drugs, to date, for this disease.”

28. Just one day later, on February 8, 2024, Tenax seized upon its positive update concerning the LEVEL trial by announcing the pricing of a public offering of 1.6 million

shares of its common stock and warrants to purchase up to 3.2 million shares of its common stock (the “February 2024 Offering”). Tenax further announced that it expected the February 2024 Offering to generate gross proceeds to the Company of approximately \$9.04 million before deducting placement agent fees and commissions and offering expenses.

29. On February 12, 2024, Tenax announced it had closed the February 2024 Offering, revised to include an aggregate of 421,260 shares of the Company’s common stock, pre-funded warrants to purchase an aggregate of 1,178,740 shares of its common stock, and accompanying warrants to purchase up to an aggregate of 3.2 million shares of its common stock. Tenax stated that the February 2024 Offering yielded gross proceeds to the Company of approximately \$9.0 million, before deducting relevant fees and expenses.

30. On March 28, 2024, Tenax filed with the SEC an annual report on Form 10-K, reporting its financial and operating results for the fiscal year ended December 31, 2023, and issued a press release announcing the same. In that annual report, Tenax told investors that it had elected to “*prioritize*” the LEVEL trial over commencing a Phase 3 trial for another product development candidate, communicating the Company’s confidence in its ability to commercialize TNX-103 with an update concerning the LEVEL trial, stating in relevant part:

Having carefully considered alternatives within the ongoing strategic process announced in September 2022, and having raised capital expected to fund the Company through 2024, the Company has elected to prioritize its LEVEL trial (Phase 3 testing of oral levosimendan), ahead of imatinib. Activity to initiate the LEVEL trial continued in the fourth quarter of 2023, and site qualification, selection, and initiation processes are ongoing, the Company having received U.S. Food and Drug Administration (“FDA”) input into the oral levosimendan protocol and clinical development program in the third quarter of 2023. The Company began initiating sites in the fourth

quarter of 2023, and commenced enrolling patients early in 2024. . . . Given our prioritization of the Phase 3 testing of levosimendan, we have suspended plans to launch an imatinib Phase 3 trial.

31. The related press release quoted Defendant Giordano as stating he believed Tenax’s progress on developing TNX-103 would allow “*millions of patients who suffer from PH-HFpEF [to] finally have a proven medication*”, stating, in relevant part:

“Over the last several weeks, I believe Tenax Therapeutics has made significant progress in advancing TNX-103 so that millions of patients who suffer from PH-HFpEF may finally have a proven medication to treat their disease,” said Chris Giordano, President & Chief Executive Officer of Tenax Therapeutics. “First and foremost, we started enrolling patients in the LEVEL study, and based on the feedback we’re receiving from participating centers and cardiologists, there is strong and growing interest in the TNX-103 program. We also made important progress in further expanding levosimendan’s U.S. intellectual property protections, securing the future commercial value of TNX-103. Finally, we secured global commercial rights for levosimendan for the treatment of PH-HFpEF, giving us additional opportunities to explore partnering collaborations to develop TNX-103 around the world.”

32. On August 12, 2024, Tenax issued a press release announcing it had closed a private placement financing raising gross proceeds of approximately \$100 million (the “August 2024 Placement”). This press release quoted Defendant Giordano connecting the private placement closing to the Company’s newly announced plans to “accelerate” its Phase 3 development program, including the LEVEL trial and its open label extension, stating in relevant part:

“This transformational financing is a significant commitment by top-tier biotech investors who believe in levosimendan’s potential to impact the lives of patients suffering from PH-HFpEF,” said Chris Giordano, President and Chief Executive Officer of Tenax Therapeutics. *“The proceeds position us to accelerate our ongoing Phase 3 development program and shorten the time to NDA submission.* We are now funded through completion of the ongoing Phase 3 LEVEL study, including its open label extension. This

funding should also enable us to initiate all sites and advance enrollment in a second, global Phase 3 study. ***The Tenax team looks forward to completing the Phase 3 studies of oral levosimendan in treatment of PH-HFpEF patients, the only therapy shown to produce favorable hemodynamic changes and improve exercise tolerance in these patients.***

33. On November 13, 2024, Tenax filed with the SEC a quarterly report on Form 10-Q, reporting its financial and operating results for the quarter ended September 30, 2024, and issued a press release announcing the same. That press release quoted Defendant Giordano as touting Defendants' progress on their LEVEL trial, and boasting of the market opportunity that awaited once Defendants secured FDA approval for TNX-103, stating in relevant part:

"The third quarter showcased strong execution across our company," said Chris Giordano, President and Chief Executive Officer of Tenax Therapeutics. "We expanded our pivotal Phase 3 LEVEL study by initiating more investigative sites and we are pleased with the steady pace of patient enrollment. To further drive our progress, we are investing in key talent and operational resources dedicated to advancing the levosimendan Phase 3 program. ***Our goal is to make levosimendan the first approved treatment for the millions of individuals affected with PH-HFpEF, a population in critical need of therapeutic options.***"

34. Also on November 13, 2024, Defendants Giordano and Rich appeared at the Guggenheim Healthcare Innovation Conference on behalf of Tenax. During that appearance, when asked about "the primary endpoint that was selected" and specifically "why it was selected", Defendant Rich stated unequivocally that "***we were told that we would be able to get approval with six-minute walk as a primary endpoint***" and that the secondary endpoints Defendants chose were "***realistic***", stating in relevant part:

[W]e were told that we would be able to get approval with six minute walk as a primary endpoint. Typically in a cardiovascular, they want an outcomes assessment but they consider this pulmonary hypertension, which it is. So

we have a precedent for six-minute walk as the primary endpoint. We were told we had the choice of doing a single trial at P01 or two trials at P05. We chose the latter. ***We've placed as our secondary endpoints things that were realistic, because the trial durations we're doing are short.*** The first trial is 12 weeks, which is the one we're in the middle of at this point in time. Clearly, because of resources we felt that a successful first trial will allow us to raise the money we need for the program to do the second trial.

35. Later during this appearance, when asked “what would constitute success in the LEVEL trial”, Defendant Giordano stated that as to the six-minute walk primary endpoint, ***“opinion[s] suggest that 10 to 15 meters would certainly be beneficial”*** and suggested that TNX-103 would meet its primary endpoint by citing results from the HELP study, stating ***“we got 29 in HELP”***. Defendant Giordano also suggested that TNX-103 would meet its secondary endpoint, the Kansas City Cardiomyopathy Questionnaire assessing how patients feel after their six minute walk, stating in relevant part:

Six-minute walk is the primary endpoint. We are always asked what magnitude of improvement in six-minute walk would be meaningful. It's hard to answer that, because there is no finite number. In group 1 PAH, the average improvement was 30 meters for all of the drugs. But the patients in every trial was different, some were sicker, some were less sick, some -- and so it's hard to make a comparison there. We have no precedent to follow here PH-HFpEF. We are it in terms of we're going to set a parameter. ***So opinion[s] suggest that 10 to 15 meters would certainly be beneficial. Anything more than that would be even better. We got 29 in HELP.*** I will add to that, that it's important that the improvement in six-minute walk be paralleled by the patients admitting they're feeling better. So the [Kansas City Cardiomyopathy Questionnaire] will in fact support that. ***And Seamus, when you have nothing as a treatment and your lifestyle is so limited that just going out for a little trip one day a month is all you can ask for, I think we'll take whatever we can get.***

36. In response to a question asking “how or when you might initiate the second Phase 3 [trial]”, Defendant Giordano stated that Defendants no longer needed to wait for topline results from LEVEL to begin, given additional funding they had secured since

commencing LEVEL and the absence of “something that we need to learn from the first trial in order to start the second”, stating in relevant part:

[A]s Stuart described, our intent had been when designing [LEVEL] to get top line data and on the basis of that raise the funding that we need for the future. As of August, we have funding through the end of 2027, so no longer an issue. What we announced at that time was that we’re now in a position to do everything we can to accelerate the time to NDA. So we haven’t gotten too specific about when we’ll start that trial. ***But we have made it pretty clear that we’re not going to need to wait for top line data anymore.*** As Stuart mentioned, the protocols are very similar. ***So there’s not something that we need to learn from the first trial in order to start the second.***

37. On March 5, 2025, Tenax announced that the FDA had “completed their review” of the Company’s updated Phase 3 development plan for TNX-103, including expanding enrollment and “increasing the statistical power of the [LEVEL] study to over 95%”, and the protocol for Tenax’s second Phase 3 trial of TNX-103, LEVEL-2. This press release quoted Defendant Giordano communicating to investors Defendants’ “expect[ation]” that these two studies would allow Defendants to “satisfy the requirements . . . to file in the U.S. and other geographies”, stating in relevant part:

“We are increasing our investment in the clinical development plan for TNX-103 by expanding the ongoing LEVEL study and accelerating our plans to initiate the second registrational study, LEVEL-2. With the momentum provided from our \$100 million financing in August 2024 and alignment with the FDA, we are now able to execute on our plan to advance these two Phase 3 registrational studies for TNX-103 in parallel. LEVEL is enrolling well: we are confident that, with more than 50 North American sites already activated, we can complete enrollment of this upsized study around year end, while also commencing the global LEVEL-2 study later this year,” said Chris Giordano, President and Chief Executive Officer of Tenax Therapeutics. ***“We expect these two registrational studies will satisfy the requirements, including the safety data expectations, to file in the U.S. and other geographies. We are funded well beyond our projected date for the release of topline LEVEL data, positioning us to advance the development of TNX-103 and improve the quality of life for patients living with PH-HFpEF.”***

38. On March 25, 2025, Tenax filed with the SEC an annual report on Form 10-K, reporting its financial results for the fiscal year ended December 31, 2023, and issued a press release announcing the same. In that annual report, Tenax provided investors with an update concerning the LEVEL trial, touting the “promising evidence” that showed TNX-103 “may significantly improve the lives of patients, and Defendants’ **“derisked approach”** to developing the drug, stating in relevant part:

We are currently actively conducting the LEVEL clinical trial to evaluate levosimendan as our prioritized product candidate, and have deprioritized a Phase 3 clinical trial of imatinib, ***two drugs supported by promising evidence that they may significantly improve the lives of patients with pulmonary hypertension***. Importantly, both levosimendan and imatinib have already been approved in other indications and prescribed around the world for more than 20 years, and we believe their mechanisms of action are uniquely suitable to target and treat pulmonary hypertension. ***We believe this derisked approach of using already-approved drugs*** that provide well-established safety profiles from millions of patients, combined with a development path led by preeminent cardiology and pulmonary hypertension experts, ***puts us in a strong position to deliver breakthrough cardiopulmonary therapies designed to improve patients’ function and quality of life.***

39. On May 14, 2025, Tenax filed with the SEC a quarterly report on Form 10-Q, reporting its financial and operating results for the quarter ended March 31, 2025, and issued a press release announcing the same. That press release quoted Defendant Giordano as stating Defendants expected to “establish TNX-103 as a powerful therapeutic option” after sharing topline data from the LEVEL study, stating in relevant part:

“2025 is off to a strong start. We continued to make meaningful progress in both the ongoing LEVEL study as well as preparations to commence our second registrational Phase 3 study, LEVEL-2,” said Chris Giordano, President and Chief Executive Officer of Tenax Therapeutics. “We also continued to engage with key stakeholders over the past quarter to discuss how levosimendan can control splanchnic blood volume and reduce blood

flow to the left ventricle, potentially providing desirable effects for patients suffering from PH-HFpEF. ***We expect to share topline data from our first Phase 3 study, LEVEL, in the middle of 2026 and establish TNX-103 as a powerful therapeutic option for this disease currently without any available treatments.***

40. On August 13, 2025, Tenax filed with the SEC a quarterly report on Form 10-Q, reporting its financial and operating results for the quarter ended June 30, 2025, and issued a press release announcing the same. That press release quoted Defendant Giordano reiterating Defendants' expectation that LEVEL would "satisfy the requirements, including safety data expectations, to file for approval in the U.S. and other geographies", stating in relevant part:

"We are pleased with the progress achieved in the second quarter, and remain in a strong position to execute and advance our lead program, TNX-103, in patients with PH-HFpEF," said Chris Giordano, President and Chief Executive Officer of Tenax Therapeutics. "Our sites in North America continue recruiting toward the expanded target of 230 patients, which increased the statistical powering of the LEVEL study. We now anticipate completing enrollment in the first half of 2026. Importantly, we remain on track to initiate our global Phase 3 study, LEVEL-2, this year. ***Together, both registrational studies are expected to satisfy the requirements, including safety data expectations, to file for approval in the U.S. and other geographies.***"

41. On November 13, 2025, Defendants Giordano and Rich appeared on behalf of Tenax at its Virtual KOL Call. During that appearance, Defendant Rich acknowledged that Defendants had frequently been asked "how has the Phase III LEVEL study been derisked to assure a positive outcome." In support of Defendants' claim that LEVEL was "derisked", Defendant Rich referenced results from the Phase II HELP study, the fact that Defendants designed LEVEL based around the Phase II patients who responded positively

to TNX-103, and the fact that Defendants had leveraged data concerning the use of TNX-103 in patients with other conditions, stating in relevant part:

Now we are often asked how has the Phase III [LEVEL] study been derisked to assure a positive outcome. So there's three points I'd like to make. The first one is that the Phase II HELP study that we did confirmed that levosimendan produces a reduction in wedge pressure with exercise in these patients. . . .

Secondly, we've enriched our Phase III trial based on the hemodynamic profile of the patients in the Phase II HELP study that responded to the drug. And so *we're kind of assuring ourselves that the patients we're enrolling are ones that have the best opportunity to have a favorable response to the drug.*

Finally, I want to point out that all of the LEVEL data that preceded the trial came from the use of intravenous levosimendan. *The patients in the HELP study got an infusion of levosimendan once a week, knowing that the drug would wear off as the week went on.* The active drug is this metabolite 1896. And when we did our 6-minute walk assessment after 6 weeks, it was done towards the end of the week when the level of 1896 was low, and *we received a 29-meter treatment effect, which was considered remarkable, in fact, the only positive study in this group of patients.* We then are going to an oral formulation, as you probably know, in our Phase III program. . . . We have legacy studies with oral levosimendan administered chronically for over 6 months in patients with heart failure and 12 months in patients with ALS, and that has provided us with a great amount of data on the optimal daily dosing, the efficacy and safety of the trial. *So one would assume that if the patients now are taking daily drug, with a therapeutic level of drug, they would respond better to the oral rather than the IV.*

42. The statements referenced in ¶¶ 25–27, 30–41 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) TNX-103 was less effective than Defendants had led investors to believe; (ii) accordingly, TNX-103's overall clinical, regulatory, and commercial prospects were

overstated; and (iii) as a result, the Company’s public statements were materially false and misleading at all relevant times.

The Truth Emerges

43. The truth began to emerge on August 10, 2026, when Tenax issued a press release reporting topline results from its Phase 3 LEVEL clinical trial, and held a conference call to discuss the same. In its press release, Tenax stated that TNX-103 “did not meet its primary endpoint of improvement in the 6-minute walk distance versus placebo, or the key secondary endpoint of improvement in Kansas City Cardiomyopathy Questionnaire total symptom score.”

44. In the related conference call, Defendant Giordano told investors that “***Tenax did not anticipate the impact disease burden would have on the treatment response***”, stating in relevant part:

LEVEL was a well-conducted trial. It was executed on time, randomizing 241 patients in about 24 months with a reassuring 2% rate of missingness on the primary endpoint, very high patient retention and therapy adherence and no site-specific problems or 6-minute walk test performance anomalies we’re going to point to as a culprit behind the primary miss.

[...]

Is chronic oral levosimendan safe in the population tested? The answer is yes. Do we have a clear and robust set of evidence of a dose that is biologically active with NT-proBNP and pulmonary pressures both responding in the way this mechanism predicts they should? Yes. The Phase 2 efficacy results from HELP were unprecedented in Group 2 patients, but were they reliable? Would we be able to validate the treatment effect we saw in those 36 advanced PH-HFpEF patients? Again, yes. Can the sites and the clinical operations team execute? Yes.

The reason those answers did not convert to a win on the primary is apparent. It actually jumps off the page at us in the first hours of our review

of the data. Tenax did not anticipate the impact disease burden would have on the treatment response. In patients whose baseline walk is below the median of 333 meters, the result is not 8 meters or 3.5 meters, the placebo-corrected improvement below the median is 26.3 meters with a 95% confidence interval of 6 to 47 meters and a nominal p-value of 0.0112. Above that line, healthier placebo patients outwalked healthier levosimendan patients by 17.6 meters.

45. On this news, Tenax’s stock price fell approximately \$12.06 per share, or 89.77%, to close at approximately \$1.38 per share on August 10, 2026.

46. Following Defendants’ revelations, several analysts lowered their price targets for Aardvark’s stock. On August 11, 2026, Guggenheim Securities reduced its price target 90%, from \$40 to \$4, writing that “many questions remain” and “[g]iven the obvious uncertainty, we are lowering our PT . . . driven by lower PoS, [total addressable market], and penetration forecasts.” On the same date, Chardan Research downgraded Tenax’s stock from Buy to Neutral, and reduced its price target approximately 81.5%, from \$27 to \$5, writing “[w]e are downgrading out rating to Neutral until we see more data and a path forward for LEVEL-2”, and that LEVEL results “rais[e] the possibility that TNX-103 is not merely diluted in healthier patients but actively counterproductive — a contraindication rather than a design flaw[.]” Also on August 11, 2026, Leerink Partners reduced its price target 84.6%, from \$26 to \$22, citing “significant revis[i]ons to] our model following the Ph3 LEVEL trial failure”, and writing that even though it saw “a potential path forward”, that path required “additional clarification” to “the subgroup dataset”, “FDA/EMA feedback” on the Company’s registration strategy, and a follow-up LEVEL-2 trial “would likely need succeed with a $p < 0.01$ to justify approval with a single trial.” And Evercore ISI downgraded Tenax’s stock from Outperform to In Line and reduced its price target

approximately 87.2%, from \$39 to \$5, writing that the “[h]eadline takeaway is that LEVEL failed in the overall population and path forward is less clear”.

47. 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.

SCIENTER ALLEGATIONS

48. During the Class Period, Defendants had both the motive and opportunity to commit fraud. For example, during the Class Period, while disseminating the materially false and misleading statements alleged herein to maintain artificially inflated prices for Tenax securities, Defendants sold millions of the Company’s common shares, as well as warrants to purchase tens-of-millions of the Company’s common shares, both to the public and directly to institutional investors, for gross proceeds to the Company of ***\$134 million*** via: (i) the February 2024 Offering, as alleged *supra* ¶¶ 28–29, (ii) the August 2024 Placement, as alleged *supra* ¶ 32, and (iii) a private placement that closed on March 5, 2025 and yielded gross proceeds to the Company of approximately \$25 million.

49. Defendants 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. TNX-103 was Defendants’ lead product candidate and Defendants repeatedly spoke to its efficacy, as alleged *supra* ¶¶ 26, 31–32, 35, 39–40, their confidence in their “*derisked*” approach to development, as alleged *supra* ¶¶ 4, 38, 41, and their working relationship with the FDA in connection with their IND for TNX-103, as alleged *supra* ¶¶ 25, 30, 34, 37. 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

50. 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 Tenax 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.

51. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Tenax 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 Tenax 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.

52. 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.

53. 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.

54. 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 Tenax;
- whether the Individual Defendants caused Tenax 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 Tenax 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.

55. 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.

56. 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;
- Tenax 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 Tenax 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.

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

58. 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)

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

60. 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.

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

62. 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 Tenax 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 Tenax's finances and business prospects.

63. By virtue of their positions at Tenax, 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.

64. 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 Tenax, the Individual Defendants had knowledge of the details of Tenax's internal affairs.

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

66. During the Class Period, Tenax 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 Tenax 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 Tenax

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

67. 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.

68. 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)

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

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

71. 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

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

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

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

74. 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 Tenax.

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.