UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PLAINTIFF, Individually and on behalf of All Others Similarly Situated, Plaintiff, v. ANAVEX LIFE SCIENCES CORPORATION and CHRISTOPHER U. MISSLING, Defendants	Case No. **COMPLAINT FOR VIOLATIONS OF FEDERAL SECURITIES LAWS** CLASS ACTION DEMAND FOR JURY TRIAL

Plaintiff, individually and on behalf of all others similarly situated, by undersigned counsel, alleges the following based upon personal knowledge as to himself and his own acts, and upon 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: (a) regulatory filings by Anavex Life Sciences Corporation ("Anavex" or the "Company") including with the U.S. Securities and Exchange Commission ("SEC"); (b) press releases and other public statements disseminated by Anavex, as well as transcripts of earnings calls between Anavex executives and securities analysts; (c) media coverage concerning Anavex, including analyst reports; and (d) other publicly available information.

NATURE OF THE ACTION

1. This is a securities fraud class action on behalf of all persons who purchased or otherwise acquired Anavex stock between June 21, 2021 and January 1, 2024, inclusive (the "Class Period"), against Anavex and its Chief Executive Officer ("CEO") for violations of the Securities Act of 1934 (the "1934 Act"). As set forth below, Defendants violated Section 10(b) of the 1934

Act by failing to disclose pertinent information relevant to the Company or, alternatively, providing information about the Company which was misleading or deceptive.

2. Anavex is a clinical stage biopharmaceutical company that engages in the development of therapeutics for the treatment of central nervous system ("CNS") disorders. Its lead product candidate is blarcamesine, known as ANAVEX 2-73. Blarcamesine aims to modify specific genetic pathways associated with some CNS disorders. Anavex has sponsored several research studies concerning blarcamesine's suitability to treat various CNS disorders, and the drug is undergoing clinical trials for the treatment of Alzheimer's disease and Parkinson's disease, as well as other CNS diseases, including rare diseases, such as Rett syndrome, a rare severe neurological monogenic disorder primarily affecting females.

3. Throughout the Class Period, Defendants misled investors about the primary and secondary endpoints by which the Company evaluated blarcamesine as a treatment for Rett syndrome, both in adults and children, in Anavex's clinical trials. As analysts observed, the primary and secondary "outcome measures" in the Rett syndrome studies were moving targets manipulated by Defendants to serve their message.

4. Prior to the start of the Class Period, Anavex sponsored the AVATAR Phase II and III ("AVATAR") clinical trials which tested ANAVEX 2-73 as a treatment for adults with Rett syndrome. According to the study protocol Defendants posted on "clinicaltrials.gov" ("ClinicalTrials"), an FDA-sponsored online resource for pertinent information about pharmaceutical trial research protocols – a website where trial information is updated routinely – Anavex intended to use several "Primary Outcome Measures" and "Secondary Outcome Measures" to evaluate AVATAR's efficacy and overall clinical benefit. However, contrary to the

protocol described on ClinicalTrials, when Anavex later reported its trial results, it revealed that it used alternative measures to assess the drug's success.

5. Throughout the AVATAR study, Defendants represented that Anavex would use certain primary and secondary research outcomes for its testing of ANAVEX 2-73 as a treatment for Rett syndrome in adults. These research outcomes, or endpoints, were listed on the ClinicalTrials website, where Anavex routinely updated the status of the study.

6. On February 1, 2022, the Company released its AVATAR study results. At that time, investors learned for the first time that the actual methods and outcomes used to analyze the AVATAR study were different from those that Defendants had publicly communicated. Analysts critiqued these methods as being unusual and not clinically validated, and further chided these statistical changes and the Company's lack of candor regarding outcome changes. For instance, on February 1, 2022, after Anavex announced that the AVATAR Phase 3 study met both its primary and secondary endpoints, analyst Charles Duncan of Cantor Fitzgerald wrote:

> [W]e cannot say clinical proof-of-concept has been established until there is ***greater disclosure of the data which demonstrates [Anavex] is using well-defined approvable endpoints*** to underscore clinical utility . . . . We note ***last-minute changes were made to the study endpoints***, within the past two weeks, despite the study completion date being nearly four months prior.[1]

7. Despite criticism from analysts and a negative market reaction when the AVATAR results were issued, Defendants attempted the same sleight of hand when announcing the results of its EXCELLENCE study. (The AVATAR study tested the drug in adults with the condition.) On January 2, 2024, Anavex released the EXCELLENCE study results. Despite its insistence that it would analyze EXCELLENCE in the same manner as AVATAR, Anavex used different outcomes and statistical tests from those deployed in AVATAR. The EXCELLENCE study data

[1] Unless otherwise noted, all emphasis is added.

failed to reach statistical significance, the Company blamed a non-existent statistical powering problem for the study's failure.

8. When, on January 2, 2024, the Company reported the results for the EXCELLENCE study, announcing that ANAVEX 2-73 had failed to achieve statistical significance on all but one measure, the Company revealed an alarming lack of consistency in terms of the primary and secondary endpoints. The Company used the "mixed effect model for repeated measure" ("MMRM") method – a statistical method not used in the AVATAR study – to analyze the EXCELLENCE data, and did not report a number of endpoints for EXCELLENCE that it had used in AVATAR. Moreover, the Company blamed any perceived deficiencies in the EXCELLENCE study on a "large placebo effect" – but failed to substantiate the claim with any data.

9. Upon the release of the EXCELLENCE study results, the market realized the truth: Anavex cherry picked outcomes and used stylized statistics to rope along investor hopes on a drug unlikely to succeed. ANAVEX 2-73, Anavex's primary product, would not be released for Rett syndrome. Investor hopes of a patient expansion had been propped up for two years on shoddy data.

10. Investors reacted strongly to this news. Anavex's stock price fell from $9.31 per share on December 29, 2023, to $6.05 per share on January 2, 2024 – a 35% decline in just one trading day.

11. As set forth herein, Defendants are liable for making false and/or misleading statements or failing to disclose adverse facts known to them about Anavex. Defendants' fraudulent scheme and course of business operated as a fraud or deceit on purchasers of Anavex stock, as it deceived the investing public about Anavex's business and prospects, artificially

inflated the price of Anavex common stock, and caused Plaintiff and the other members of the Class (as defined below) to purchase Anavex stock at artificially inflated prices and suffer economic loss when the revelations set forth herein reached the market.

JURISDICTION AND VENUE

12. Jurisdiction is conferred by Section 27 of the 1934 Act, 15 U.S.C. §78aa. The claims asserted herein arise under Sections 10(b) and 20(a) of the 1934 Act, 15 U.S.C. §§78j(b) and 78t(a), and SEC Rule 10b-5, 17 C.F.R. §240.10b-5.

13. Venue is proper in this District pursuant to Section 27 of the 1934 Act. The violations of law complained of herein occurred in part in this District, including the dissemination of materially false and misleading statements herein into this District.

14. 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

15. Plaintiff purchased shares of Anavex stock during the Class Period, as described in the Certification filed herewith and incorporated by reference. Plaintiff has suffered damages in connection with his purchase of Anavex stock.

16. Defendant Anavex Life Science Corp. is incorporated in Delaware. Anavex's headquarters is 630 5th Avenue, 20th Floor, New York, New York, 10111. Shares of the Company's stock trade on the Nasdaq under the ticker symbol "AVXL."

17. Defendant Christopher U. Missling ("Defendant Missling" or the "Individual Defendant") is and was at all material times CEO, Chair of Anavex's Board of Directors (the "Board"), President, and Secretary of Anavex.

18. Defendant Missling, because of his position with the Company, possessed the power and authority to control the contents of Anavex's quarterly reports, press releases, and presentations to securities analysts, money and portfolio managers, and investors, *i.e.*, the market. He was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of his position with the Company and his access to material information available to him but not the public, the Individual Defendant knew that 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 Defendant is liable for the false statements pleaded herein.

FACTUAL ALLEGATIONS

Background

19. Throughout the Class Period, Anavex posted and updated information about its clinical studies of ANAVEX 2-73 on ClinicalTrials.gov (previously defined as "ClinicalTrials"), an online database of current information about pharmaceutical trial research. According to that website, "[t]he purpose of ClinicalTrials.gov is to provide information about clinical research studies to the public, researchers, and health care professionals." "Rel[ying] on sponsors or investigators to submit and update information about studies," the website claims that it "[l]ists up-to-date information on clinical research studies and their results with new studies added almost every day."

20. On May 6, 2019, Anavex first posted the overview and details for the AVATAR study on ClinicalTrials. At that time, the Company described the "Primary Outcome Measures" for AVATAR as: (1) "Incidence of Adverse Events"; (2) "Maximum Plasma Concentration [Cmax] of ANAVEX 2-73"; (3) "Area Under the Curve [AUC] of ANAVEX 2-73"; and (4) "Lipid panel."

21. Anavax also posted on ClinicalTrials two "Secondary Outcome Measures" for the AVATAR study: (1) "Change from baseline to End of Treatment (EOT) in the Rett Syndrome Questionnaire (RSBQ)"; and (2) "Change from baseline to End of Treatment (EOT) in the Clinical Global Improvement Scale (CGI-I) score."

22. Between May 6, 2019 and July 29, 2021, the Company updated the description and the status of AVATAR on ClinicalTrials no fewer than times, including on May 7, 2019, June 9, 2020, June 30, 2020, October 19, 2020, October 26, 2020, October 30, 2020, November 21, 2020, April 26, 2021, and July 29, 2021. Upon each update, the Company listed the same Primary Outcome Measures and Secondary Outcome Measures.

23. Likewise, between May 6, 2019 and January 12, 2022 the Company participated in a total 14 quarterly calls, special calls, and inventor conference presentations. The Company never disclosed an intent to change primary outcomes of the AVATAR study at any of these events.

24. On September 4, 2019, Anavex issued a press release announcing the EXCELLENCE study, evaluating blarcamesine as a treatment for pediatric Rett syndrome.

25. On March 8, 2020, the Company first posted the EXCELLENCE study on ClinicalTrials. At that time, the Company listed two Primary Outcome Measures: (1) "Change from baseline to End of Treatment (EOT) in the Rett Syndrome Behaviour [sic] Questionnaire

(RSBQ);" and (2) "Change from baseline to End of Treatment (EOT) in the Clinical Global Impression Improvement Scale (CGII) score."

26. On ClinicalTrials, the Company also listed five Secondary Outcome Measures for the EXCELLENCE study: (1) Anxiety, Depression, and Mood Scale (ADAMS); (2) Motor Behavioral Assessment-7 dynamic pediatric items (MBA-Ped7); (3) Children's Sleep Habits Questionnaire (CSHQ); (4) Seizure Frequency via seizure diary; and (5) Incidence of Adverse Events.

27. Between March 8, 2020 and July 29, 2021, the study underwent six status updates on ClinicalTrials, including on March 11, 2020, April 11, 2020, June 17, 2020, June 25, 2020, September 1, 2020, and July 29, 2021. Upon each update, the Company reported the same primary and secondary endpoints.

Defendants' False and/or Misleading Statements and Omissions During the Class Period

28. The Class Period begins on June 21, 2021. On that date, Anavex announced "convincing biomarker correlating efficacy data" for the AVATAR study. In a press release entitled "Anavex Life Sciences Announces ANAVEX®2-73 (Blarcamesine) Biomarker Correlated with Efficacy Endpoints in Placebo-Controlled U.S. Phase 2 Clinical Trial for the Treatment of Adult Patients with Rett Syndrome," the Company reported "strong and consistent data demonstrating biomarker-correlated rapid and clinically meaningful improvement in key measures of Rett syndrome symptoms in the Anavex 2-73 treatment group compared to placebo."

29. The June 21, 2021 press release framed the significance of the data as follows:

> This study demonstrates for the first-time that a biomarker correlates with clinical efficacy in Rett syndrome. ANAVEX®2-73 treatment resulted in increases in the mRNA expression of SIGMAR1, the gene coding for the receptor targeted by ANAVEX®2-73, which ***correlated with clinical efficacy as measured by both primary efficacy endpoints (ITT population), namely RSBQ*** (p = 0.035) ***and CGI-I*** (p = 0.029).

Anavex described RSBQ and CGI-I as "primary efficacy endpoints," despite both being listed at the time as Secondary Outcome Measures. Analysts did not pick up on the inconsistency, and investors reacted favorably. Shares of Anavex rose $3.03 per share, more than 13.5%, to close at $25.17 on June 21, 2021, on abnormally high volume.

30. In a Form 8-K filed with the SEC on June 22, 2021, Anavex announced that it had entered into a securities purchase agreement with Deep Track Capital. The prospectus supplement filed on the same day contained a "Clinical Studies Overview" that addressed, *inter alia*, the development of ANAVEX 2-73 to treat Rett Syndrome and referenced both the AVATAR and the EXCELLENCE studies. In pertinent part, the Company represented that:

> The second Phase 2 study of ANAVEX®2-73 for the treatment of Rett syndrome, called the AVATAR study, commenced in June 2019. This study is taking place in Australia and the United Kingdom using a higher dose than the U.S. based Phase 2 study for Rett syndrome. The study will evaluate the safety and efficacy of ANAVEX®2-73 in approximately 33 patients over a 7-week treatment period including ANAVEX®2-73 specific precision medicine biomarkers. All patients who participate in the study will be eligible to receive ANAVEX®2-73 under a voluntary open label extension protocol.
>
> In July 2020, we commenced the third study of ANAVEX®2-73 for the treatment of Rett syndrome, called the EXCELLENCE study. This Phase 2/3 study in pediatric patients with Rett syndrome will evaluate the safety and efficacy of ANAVEX®2-73 in at least 69 pediatric patients, aged 5 to 18, over a 12-week treatment period incorporating ANAVEX®2-73 specific precision medicine biomarkers. All patients who participate in the study will be eligible to receive ANAVEX®2-73 under a voluntary open label extension protocol.

31. Neither the 8-K nor the prospectus supplement filed with the SEC on June 22, 2021 referenced any changes to the primary or secondary outcome measures for either the AVATAR or EXCELLENCE study.

32. On August 12, 2021, Anavex filed with the SEC its quarterly report on Form 10-Q for the quarter ended June 30, 2021 ("Q3 2021"). In the Q3 2021 disclosures, the Company provided an update on the clinical testing of ANAVEX 2-73 as a treatment for Rett syndrome

using language substantially identical to that referenced in paragraph 30, *supra*. The Q3 2021 did not reference any changes to the primary or secondary outcome measures for either the AVATAR or EXCELLENCE study.

33. On September 24, 2021, Anavex filed with the SEC a registration statement on Form S-3 and prospectus for the issuance of up to $150 million in common stock (the "September 2021 Registration Statement"). The September 2021 Registration Statement and accompanying prospectus contained substantially identical language regarding the clinical testing of ANAVEX 2-73 for the treatment of Rett syndrome as referenced in paragraph 30, *supra*. The September 2021 Registration Statement did not reference any changes to the primary or secondary outcome measures for either the AVATAR or EXCELLENCE study.

34. On September 27, 2021, the EXCELLENCE study underwent an update. While the RSBQ remained a primary endpoint, "incidents of adverse events" became the other primary outcome. The CGI-I was downgraded to a secondary outcome.

35. On November 24, 2021, the Company hosted its 2021 earnings call. During that call, Missling announced "full enrollment" of the AVATAR study. He further announced:

> We expect topline results from the second placebo-controlled AVATAR study for the treatment of our patients with Rett syndrome, which are expected to be announced around calendar year end 2021. This study took place in Australia and the United Kingdom using a higher dose than the U.S.-based Phase II study and enrolled 33 patients over a 7-week treatment period, including ANAVAX 2-73 precision medicine biomarkers.

36. Despite AVATAR's conclusion and readiness for topline announcement within weeks of this late November announcement, Missling did not announce changes to the study design or primary outcomes.

37. Also on the November 2021 earnings call, Missling opined on the then-concurrently run EXCELLENCE study. During the question-and-answer period, Missling engaged

in the following exchange with Peter Stravropoulous of Cantor Fitzgerald about the EXCELLENCE study's endpoints:

> Stravropoulous: We also saw that you made a few changes to the primary and secondary endpoints in the EXCELLENCE study. Can you give us a – help us understand what drove those decisions? Was it a result of advice or interactions with the FDA or other regulatory agency?
>
> Missling: Right. So we have noticed that ***the RSBQ is really the most – more rigorous endpoint***. It is really going through 45 very dedicated and detailed questions, which can be answered very precisely. There's also the ability, which we have seen and have demonstrated in our presentation doing sub-analysis of the subscores of the entire score of the RSBQ score. ***However, when we looked at the CGI-I, we noticed that there was a weaker ability to make this because it's really a global assessment. And it also has a very known and its published weak, I would say, reliability***. But we basically are including that still, but we don't want to overemphasize that score. So that was the background for the focus on the RSBQ.

38. Further, during the November 2021 earnings call, Yun Zhong of BTIG then queried the manner in which the Company intended to analyze its data and compare the AVATAR and EXCELLENCE studies. During the question-and-answer segment, Zhong asked:

> Zhong: And so the definition of responder, is that – on each efficacy standpoint, is that going to be the same in pediatric patients as compared to in adult patients? And also, the definition of a responder, is that consistent with how clinicians are viewing as a clinically meaningful improvement?
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> Missling: That's correct. It's consistent with the first study and its consistent with the assessment of a physician. That's correct.

39. On January 15, 2022, the Company updated the AVATAR study design for the tenth time. The same "Primary Outcome Measures" remained listed as had been listed since 2019: "Incidence of Adverse Events;" "Maximum Plasma Concentration [Cmax] of Anavex 2-73;" "Area Under the Curve [AUC] of ANAVEX 2-73;" and, "Lipid panel."

40. Three days later, however, on January 18, 2022, the Company revised the ClinicalTrials description for AVATAR and now listed two "Primary Outcome Measures": "Drug exposure-dependent response of the Rett Syndrome Behaviour [sic] Questionnaire (RSBQ) Total

score" and "Incidence of Adverse Events." Likewise, the Company revised the "Secondary Outcome Measures" on ClinicalTrials, which now read as: (1) "Drug exposure-dependent response of the Clinical Global Impression of Improvement (CGI-I) score"; (2) "Drug exposure-dependent response of the Anxiety, Depression, and Mood Scale (ADAMS)"; (3) "Maximum Plasma Concentration [Cmax] of ANAVEX 2-73"; and (4) "Area Under the Curve [AUC] of ANAVEX 2-73."

41. The Company issued no press release nor issued any comment on the change in primary design, despite having participated in the JP Morgan Annual Health Conference just days before, on January 13, 2022.

Investors First Learn the Partial Truth

42. On February 1, 2022, investors first learned the truth about Defendants' manipulation of the endpoints for the AVATAR trial. On that date, the Company issued a press release announcing "AVATAR Phase 3 Trial met Primary and Secondary Efficacy Endpoints" in which the Company:

> [R]eported positive top-line results from the Phase 3 randomized, double-blind, placebo-controlled AVATAR trial of ANANEX 2-73 (blarcamesine) in adult female patients with Rett syndrome and demonstrated a statistically significant improvement over placebo for the primary efficacy endpoint as well as for all secondary efficacy endpoints.

43. The Company's discussion revealed "the primary endpoint, RSBQ AUC, AVANEX 2-73 induced a statistically significant and clinical meaningful improvement in 72.2% of patients as compared to 38.5 on placebo; ($p = 0.037$)."

44. RSBQ AUC refers to "area under the curve." In pharmacology research, AUC studies examine the relationship between an individual's blood plasma concentration of a drug versus that individual's observed response to the drug. Presumably, as a drug's blood concentration diminishes, so, too, should the observed response. The "curve" is the line of points relating plasma

concentration and observed response. The greater the "area under the curve," the more observed response to the drug.

45. The Company filed a Form 8-K presentation on February 1, 2022. The presentation described the AVATAR results and revealed ***the RSBQ scores were "anchor-based," using CGI-I scores as an anchor***.

46. In the presentation, the Company explained its use of the CGI-I as an RSBQ anchor, since:

> As a stand-alone care giver reported primary outcome assessment, ***the RSBQ does not appear optimally suited, on its own, for the determination of a clinical trial outcome*** (e.g., could lead to either a type 1 or type 2 error). [Emphasis in original.]

47. In the presentation, the Company failed to note it previously described the RSBQ as the "more rigorous endpoint" and that it did not want to "over-emphasize" the CGI-I.

48. An "anchor-based method" (also called an "external reference method") determines clinical significance. It "anchors" scores on one metric ("the target metric") to measure perceived "clinically significant" changes on another metric ("the anchor metric"), based on what researchers define as "minimally important differences" on the anchor metric. It thus renders the continuous "target metric" into a discrete variable. It also renders, by definition, the "anchor metric" as being a clinically valid means of evaluating changes on the "target metric."

49. In its presentation, the Company again failed to explain why the CGI-I, a metric which only several weeks prior the Company "[did]n't want to overemphasize," was now the anchor for the primary outcome in the AVATAR. It also failed to explain why the RSBQ, the "more rigorous" outcome, was now in need of anchoring.

50. Analysts expressed confusion about the AVATAR outcomes, analyses, and results.

51. For instance, on February 1, 2022, Yun Zhong of BTIG wrote the change of a "surprising primary endpoint change and the question on what is the true clinical benefit from ANAVEX 2-73 treatment." Zhong further wrote, "***[t]here could have been less investor confusion if Anavex had chosen to report the RSBQ total score from the AVATAR study as well [as RBSQ AUC].***"

52. Also on February 1, 2022, Charles Duncan of Cantor Fitzgerald wrote "AVATAR P3 Read Makes Us Wonder About Clinical Endpoints in RETT," and lowered the target on AVXL shares from $27 to $16. There he wrote:

> Although the primary endpoint of drug exposure-dependent response Rett Syndrome Behavior Questionnaire (RSBQ) AUC meets statistical significance (p=0.037), ***we cannot say clinical proof-of-concept has been established until there is greater disclosure of the data which demonstrates it using well-defined approvable endpoints to underscore clinical utility***.
>
> . . .
>
> Given these observations, and challenges in interpreting some of the efficacy endpoints, we note inconsistency with our prior diligence with KOLs on RSBQ, which is what we had thought was the primary endpoint, as given on clinicaltrials.gov. Therefore, we now believe it is prudent to project that this P3 may need to be supported with additional clearly positive clinical data to support an NDA submission, including possibly conducting an additional P3.
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> . . .
>
> ***Another interesting detail is that Anavex anchored its RSBQ response to the CGI-I response***, as a result of communication it had with the FDA in which it was relayed that the Agency wanted to see clinical outcome impressions linked to RSBQ scores. Although this 'concept' makes sense to us, as clinical meaningfulness is a key consideration for efficacy and thus pharmaco-economic value, ***in our view, the conclusion and timing is odd to us given our past KOL diligence indicating that RSBQ is a sufficient pivotal endpoint***, and ***we find the company's execution even more confounding***. ***Rather than redefine the primary endpoint following the conduct of the trial*** (albeit perhaps in advance of unblinding), we would have preferred to see greater transparency on RSBQ and CGI-I scores, along with a regression analysis showing their correlation.

53. Also on February 1, 2022, BTIG's Yun Zhong once again engaged Missling over the Company's plans for measuring efficacy. During a special call, similar to previous conversations, Zhong asked as follows concerning Anavex's protocol for the EXCELLENCE study:

> Zhong: So one question – so follow-up question on the endpoint. And I assume when you report top line data from the EXCELLENCE study, it will be the RSBQ AUC as well? And do you have to go back to the U.S. Phase II study to reanalyze the data using AUC versus the – as compared to the original RSBQ to make everything consistent?
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> Missling: Good question. Thank you. So that's right, the EXCELLENCE study will use the same endpoint because it's just described, it is just the preference of the FDA.

54. Despite the Company announcing its "positive" news about AVATAR, shares lost ground, falling from a closing price of $13.08 per share on January 31, 2022 to a closing price of $10.55 per share on February 2, 2022 over two trading days – a decline of $2.53 per share, or more than 19% – on abnormally high volume.

55. Nevertheless, Defendants continued to mislead investors regarding the outcome measures for its testing of ANAVEX 2-73 on patients suffering from Rett syndrome, particularly in the EXCELLENCE study, which examined the effect of the drug on pediatric patients.

56. On February 4, 2022, Anavex published a press release responding to the critiques about endpoints and transparency concerning the AVATAR study. It claimed that:

> Following the successful completion of U.S. Phase 2 Rett syndrome study (ANAVEX 2-73-RS-001) as announced in December 2020, and the knowledge gained from it, the AVATAR study (ANAVEX2-73-RS-02) appropriately updated endpoints according to ICH guideline were approved by the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) and in Autralia by the Human Research Ethics Committees (HREC), where the AVATAR study was conducted. Subsequently the AVATAR study was updated from a Phase 2 to a Phase 3 study. The January 2022 update to the trial description 'clinicaltrials.gov' was not a real-time communication and may have given the wrong impression of a late change of trial endpoints/phase of the study, which is not the case.

57. On a February 9, 2022 earnings call, Charles Duncan of Cantor Fitzgerald reiterated that question:

> Duncan: Let me turn to EXCELLENCE. I guess I'm wondering if you'll use the same evaluation as was used in AVATAR because I think clin trials has it a little bit different, and you might correct that.

58. Missling never fully addressed the question of whether EXCELLENCE would use the same analysis as AVATAR, instead saying:

> And in regards to ClinicalTrials.Gov, I would like to make, again, a statement here that the ClinicalTrials.gov is not what we refer to as company communication. It will be updated eventually. So I'd like you to – you to be aware of that. So the company communication is – has priority over ClinicalTrials.gov, but it will be updated when we have finalized the study outcome. And then we will also update the ClinicalTrials.gov. Right now, it might not be completely up to date. So I want to make sure people understand that.

59. On June 6, 2023, the Company announced completion of dosing of all participants in the EXCELLENCE study.

60. On August 18, 2023, Anavex updated its study protocol for the seventeenth and final time, retaining the RSBQ and adverse events as primary outcomes. The CGI-I remained a secondary outcome.

61. Despite repeated opportunities to clarify the Company's study protocols outside of ClinicalTrials, Defendants consistently concealed their plans to depart from AVATAR's protocol. Further, despite Missling's assertion, the Company continued to update ClinicalTrials. Defendants' statements created a false impression regarding the Company's Rett syndrome ANAVEX 2-73 research program. Specifically, the Company suggested it was going to use particular endpoints and research methods known to the public in advance. When the Company changed those methods last-minute during the AVATAR research program, it promised investors it would keep those newly-adopted endpoints and methods. It likewise abandoned those endpoints

when it released the EXCELLENCE study data. In fact, the Company's statements about its research methods and analysis were false and misleading. Defendants misled investors by providing a materially flawed and inaccurate impression of the Company's research program and of ANAVEX 2-73's actual likelihood of success in the Rett syndrome trials.

The Full Truth Emerges

62. On January 2, 2024, the Company issued a press release announcing, "Topline Results from Phase 2/3 EXCELLENCE Clinical Study in Pediatric Rett Syndrome."

63. The Company reported "improvement on the key co-primary endpoint Rett Syndrome Behaviour Questionnaire (RSBQ)." However, the "the other co-primary endpoint, the Clinical Global Impression – Improvement (CGI-I) . . . was not met."

64. The Company used a "mixed-effect model for repeated measure (MMRM)" method for analyzing improvement on the RSBQ for ANAVEX 2-73-treated patients versus those on placebo. Of the various MMRM statistics reported result, one reached statistical significance – "ANAVEX 2-73-treated patients demonstrated a rapid onset of action with improvements at 4 weeks after treatment with a RSBQ total score LS Mean (SE) -10.32 (2.086) points in the drug-treated group compared to a LS Mean (SE) -5.67 (2.413) points in placebo-treated patients."

65. The MMRM method was not used in the AVATAR study nor was an LS Mean score reported in AVATAR.

66. The RSBQ AUC was not reported in EXCELLENCE though it had been reported in AVATAR.

67. An anchor-based RSBQ using the CGI-I was not reported in EXCELLENCE though it had been reported in AVATAR.

68. Nonetheless, the Company blamed any perceived deficiencies in the EXCELLENCE study on "large placebo effect which may have masked the compound's therapeutic effect," according to the press release. The Company offered no evidence to support that claim.

69. Later, during a January 11, 2024 presentation at the J.P. Morgan Annual Healthcare Conference, Missling spoke about the EXCELLENCE study. He claimed "this study was not fully powered. Was a Phase II/III. And it is not that we were not happy about it, but we had observed a little bit too high of a placebo effect . . . ." He did not mention the Company's previous press releases announcing the study exceeded enrollment targets.

70. Analysts expressed dismay at the EXCELLENCE study results and the Company's explanation. Raghuram Selvaraju of R.C. Wainwright wrote on January 2, 2024:

> In our view, these results were disappointing in that they may not enable Anavex to secure regulatory approval of blarcamesine in Rett syndrome near-term. While Anavex pointed to an unexpectedly high placebo response in the trial as a potential contributor to missing statistical significance and indicated that it has identified probable causes of this, no further details have been given. We are assuming that at least one additional pivotal study may be required to support approval of blarcamesine in Rett syndrome.

71. Anavex shares tumbled after the Company released the EXCELLENCE results. Shares fell from $9.31 per share on December 29, 2023 to $6.05 on January 2, 2024.

ADDITIONAL SCIENTER ALLEGATIONS

72. 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.

LOSS CAUSATION

73. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Anavex stock and operated as a fraud or deceit on Class Period purchasers of Anavex stock by failing to disclose and misrepresenting the adverse facts detailed herein. When Defendants' prior misrepresentations and fraudulent conduct were disclosed and became apparent to the market on January 2, 2024, the price of Anavex stock fell precipitously. As a result of their purchases of Anavex stock during the Class Period, Plaintiff and the other Class Members suffered economic loss, i.e. damages, under the federal securities laws when the truth about Anavex was revealed through the disclosures specified herein, which removed the false inflation from the price of Anavex common stock.

74. By failing to disclose to investors the adverse facts detailed herein, Defendants presented a misleading picture of Anavex's clinical trial operations. Anavex's false and misleading statements had the intended effect and caused Anavex stock to trade at artificially inflated levels throughout the Class Period.

75. As a direct result of the disclosure identified herein, the price of Anavex stock fell precipitously, causing real economic loss to investors who had purchased Anavex stock at artificially inflated prices during the class period.

76. The decline on January 2, 2024 was a direct result of the nature and extent of Defendants' fraud being revealed to investors and the market through the EXCELLENCE study and the Company's continued failure to abide by the outcomes and methods it previously announced to investors. The timing and magnitude of the price declines in Anavex stock negate any inference that the losses suffered by the Plaintiff and other Class members were caused by changed market conditions, macroeocnomic or industry factors, or Company-specific facts

unrelated to Defendants' fraudulent conduct. The economic loss, i.e., damages, suffered by Plaintiff and the other Class members was a direct result of Defendants' fraudulent scheme to artificially inflate the price of Anavex stock and the subsequent significant decline in the value of Anavex stock when Defendants' prior misrepresentations and other fraudulent conduct were revealed.

THE PRESUMPTION OF RELIANCE

77. At all relevant times, the market for Anavex stock was an efficient market for the following reasons, among others:

(a) Anavex stock met the requirements for listing and was listed and actively traded on the Nasdaq, a highly efficient and automated market;

(b) as a regulated issuer, Anavex filed periodic public reports with the SEC;

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

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

78. As a result of the foregoing, the market for Anavex stock promptly digested current information regarding Anavex from all publicly available sources and reflected such information in the price of the stock. Under these circumstances, all purchasers of Anavex stock during the

Class Period suffered similar injury through their purchase of Anavex stock at artificially inflated prices and a presumption of reliance applies under the fraud-on-the-market doctrine.

79. Alternatively, a Class-wide presumption of reliance is also appropriate in this action under the United States Supreme Court's holding in *Affiliated Ute Citizens v. United States*, 406 U.S. 128 (1972), because the Class's claims include allegations concerning omissions. Because this action at least in part involves Defendants' failure to disclose material adverse information regarding the Company's clinical trial operations, positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of Defendants' material Class Period omissions regarding, among other things, the Company's clinical trial operations, that requirement is satisfied here.

NO SAFE HARBOR

80. The "Safe Harbor" warnings accompanying Anavex's reportedly forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability. To the extent that projected revenues and earnings were included in the Company's financial reports prepared in accordance with Generally Accepted Accounting Principles, including those filed with the SEC on Form 8-K, they are excluded from the protection of the statutory Safe Harbor.

81. Defendants are also liable for any false and misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer of Anavex who knew that the FLS was false. In addition, the FLS were contradicted by existing, undisclosed material facts that were required to be disclosed so that the FLS would not be misleading. Finally, most of the purported Safe Harbor

warnings were themselves misleading because they warned of "risks" that had already materialized or failed to provide meaningful disclosures of the relevant risks.

CLASS ACTION ALLEGATIONS

82. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased or otherwise acquired Anavex stock during the Class Period of June 21, 2021 through and including January 1, 2024 (the "Class"). Excluded from the Class are Defendants and their families; 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.

83. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. Anavex shares trade on the Nasdaq and has more than 82 million shares outstanding, owned by hundreds, if not thousands, of persons.

84. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to members of the Class which predominate over questions that may affect individual Class members include:

a. whether Defendants violated the 1934 Act;

b. whether Defendants omitted and/or misrepresented material facts;

c. whether Defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

d. whether Defendants knew or recklessly disregarded that their statements were false and misleading;

e. whether the price of Anavex stock was artificially inflated; and

f. the extent of damages sustained by Class members and the appropriate measure of damages.

85. Plaintiff's claims are typical of those of the Class because Plaintiff and the other Class members sustained damages from Defendants' wrongful conduct.

86. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

87. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

COUNT I

Defendants Violated Section lO(b) and SEC Rule lOb-5

88. Plaintiff incorporates by reference and realleges each and every allegation above as though fully set forth herein.

89. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

9O. Defendants violated Section lO(b) of the l934 Act and Rule lOb-5 in that they:

(a) employed devices, schemes, and artifices to defraud;

(b) made untrue statements of material facts or 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; or

(c) engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiff and other Class members in connection with their purchases of Anavex stock during the Class Period.

91. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other Class members have suffered damages in connection with their respective purchases and sales of Anavex stock during the Class Period, because, in reliance on the integrity of the market, they paid artificially inflated prices for Anavex stock and experienced loses when the artificial inflation was released from Anavex stock as a result of the revelations and stock price decline detailed herein. Plaintiff and the other Class members would not have purchased Anavex stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

92. By virtue of the foregoing, Anavex and the Individual Defendant have each violated Section 1O(b) of the 1934 Act, and Rule 1Ob-5 promulgated thereunder.

COUNT II

Defendant Missling Violated Section 20(a) of the 1934 Act

93. Plaintiff incorporates by reference and realleges each and every allegation above as though fully set forth herein.

94. The Individual Defendant acted as controlling persons of Anavex within the meaning of Section 2O(a) of the 1934 Act. By reason of his controlling positions with the Company, and their ownership of Anavex common stock, the Individual Defendant had the

power and authority to cause Anavex to engage in the wrongful conduct complained of herein. Anavex

controlled the Individual Defendant and all of its employees. By reason of such conduct, the Individual Defendant is liable pursuant to Section 20(a) of the 1934 Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

A. Declaring that this action is a proper class action, designating Plaintiff as Lead Plaintiff, and certifying Plaintiff as a Class representative under Rule 23 of the Federal Rules of Civil Procedure and Plaintiff's counsel as Lead Counsel;

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

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Awarding such equitable, injunctive, or other relief as deemed appropriate by the Court.

JURY DEMAND

Plaintiff hereby demands a trial by jury.