UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

YUTING AO, individually and on behalf of all others similarly situated, Plaintiff, v. MINERVA NEUROSCIENCES, INC. and REMY LUTHRINGER, Defendants.	Case No. 1:21-cv-10051 **CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS** Jury Trial Demanded

Plaintiff Yuting Ao ("Plaintiff"), by and through Plaintiff's attorneys, alleges upon personal knowledge as to Plaintiff's own acts, and upon information and belief as to all other matters, based upon the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of documents filed by Defendants (as defined below) with the United States ("U.S.") Securities and Exchange Commission (the "SEC"), news reports, press releases issued by Defendants, and other publicly available documents, as follows:

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all investors who purchased or otherwise acquired Minerva Neurosciences, Inc. ("Minerva" or the "Company") securities between May 15, 2017 and November 30, 2020, inclusive (the "Class Period"). This action is brought on behalf of the Class (as defined below) for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (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.

2. According to its most recent annual report filed on Form 10-K with the SEC, Minerva purports to be a clinical-stage biopharmaceutical company focused on the development

and commercialization of a portfolio of product candidates to treat patients suffering from central nervous diseases. The Company's lead product candidate is roluperidone (also known as MIN-101). Minerva common stock trades on the NASDAQ stock exchange under the ticker "NERV." The Company is headquartered in Waltham, Massachusetts.

3. Minerva's drug candidate roluperidone, MIN-101, is in development for the treatment of negative symptoms in patients with schizophrenia. In October 2016, the Company had previously reported positive results from a Phase 2b trial of roluperidone for this treatment, asserting that the "[d]ata show continuous improvement in negative symptoms, stable positive symptoms and extended safety profile."[1]

4. On May 15, 2017, the start of the Class Period, Minerva announced via press release that it would proceed to a Phase 3 clinical trial for MIN-101 following a successful "end-of-Phase 2" meeting with the U.S. Food and Drug Administration ("FDA"). In this press release, Defendant Rémy Luthringer ("Luthringer") was quoted as saying that "[o]ur discussion with the [FDA] has helped to confirm our Phase 3 trial design, which is similar to our previous Phase 2b trial design. We believe that positive data from the Phase 3 trial, along with the positive data from the Phase 2b trial, may form the basis for the future submission of a New Drug Application for [roluperidone] with the FDA."

5. The FDA, however, did not agree with Minerva that positive data from the Phase 2b trial could form the basis of a future New Drug Application ("NDA") for MIN-101, or that the Phase 3 trial was a well-designed trial. Thus, Luthringer's statements about FDA feedback were materially misleading.

[1] https://www.sec.gov/Archives/edgar/data/1598646/000119312516747326/d255045dex991.htm.

6. On May 29, 2020, Minerva released the results of its Phase 3 clinical trial. The Company announced that the studied "doses were not statistically significantly different from placebo at Week 12 on the primary endpoint . . . or the key secondary endpoint." In other words, the Phase 3 clinical trial failed.

7. On this news, the Company's stock price fell from a May 28, 2020 closing price of $13.47 per share to a May 29, 2020 closing price of just $3.71 per share, representing a one day drop of approximately 72.5%.

8. On a November 2, 2020 earnings call, Luthringer, in discussing an upcoming November 10, 2020 meeting with the FDA to discuss whether the Phase 2b study combined with the data from the Phase 3 study could form the basis of an NDA, said: "with all the data we have generated and we put in the briefing book, we are extremely confident that the FDA will understand that we have really very compelling data as you already have seen, when you combine the 2 studies, Phase IIb and Phase III . . . ."

9. On December 1, 2020, before the markets opened, Minerva issued a press release revealing that it had "received official meeting minutes from the November 10, 2020 Type C meeting with the" FDA. Minerva disclosed for the first time that the "FDA advised that the Phase 2b study is problematic because it did not use the commercial formulation of roluperidone and was conducted solely outside of the United States. In addition, FDA commented that the Phase 3 study does not appear to be capable of supporting substantial evidence of effectiveness . . . ." Indeed, the "FDA cautioned that an NDA submission based on the current data from the Phase 2b and Phase 3 studies ***would be highly unlikely to be filed*** and that at a minimum, there would be substantial review issues due to the lack of two adequate and well-controlled trials to support efficacy claims for this indication."

10. On this news, Minerva's stock price fell from its November 30, 2020 closing price of $3.89 per share to a December 1, 2020 closing price of $2.89 per share, representing a one day drop of approximately 25.7%.

11. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business. Specifically, Defendants made false and/or misleading statements and/or failed to disclose: (i) the truth about the feedback received from the FDA concerning the "end-of-Phase 2" meeting; (ii) that the Phase 2b study did not use the commercial formulation of roluperidone and was conducted solely outside of the U.S.; (iii) that the failure of the Phase 3 study to meet its primary and key secondary endpoints rendered that study incapable of supporting substantial evidence of effectiveness; (iv) that the Company's plan to use the combination of the Phase 2b and Phase 3 studies would be "highly unlikely" to support the submission of an NDA; (v) that reliance on these two trials in the submission of an NDA would lead to "substantial review issues" because the trials were inadequate and not well-controlled; and (vi) that, as a result, the Company's public statements were materially false and misleading at all relevant times.

JURISDICTION AND VENUE

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

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

14. This Court has jurisdiction over each Defendant named herein because each Defendant is an individual or corporation who has sufficient minimum contacts with this District

so as to render the exercise of jurisdiction by the District Court permissible under traditional notions of fair play and substantial justice.

15. 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), as the Company has its principal executive offices located in this District and conducts substantial business here.

16. In connection with the acts, omissions, conduct and other wrongs in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to the U.S. mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

17. Plaintiff, as set forth in the attached Certification, purchased or otherwise acquired Minerva securities at artificially inflated prices during the Class Period, and has been damaged by the revelation of the Company's material misrepresentations and omissions.

18. Defendant Minerva purports to be a clinical-stage biopharmaceutical company focused on the development and commercialization of a portfolio of product candidates to treat patients suffering from central nervous diseases. The Company's lead product candidate is roluperidone, in development for the treatment of negative symptoms in patients with schizophrenia. Minerva common stock trades in an efficient market on the NASDAQ stock exchange under the ticker "NERV." The Company's headquarters are located at 41601 Trapelo Rd., Suite 286, Waltham, MA 02451, and the Company is incorporated under the laws of the State of Delaware.

19. Defendant Luthringer is Minerva's Chief Executive Officer ("CEO"). He served as a consultant for the Company from July 2010, and in May 2014, became an employee. In

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