UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

_____, individually and on behalf of all others similarly situated, Plaintiff, v. MINERVA NEUROSCIENCES, INC. and REMY LUTHRINGER, Defendants.	Case No. **CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS** Jury Trial Demanded

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

NATURE AND SUMMARY 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") common stock between May 15, 2017 and November 30, 2020, inclusive (the "Class Period"). This action is brought on behalf of the Class 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 FDA. In this press release, Defendant 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 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.

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

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

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 plummeted 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.

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. This represents 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 that: (i) the truth about the feedback received from the FDA concerning the "end-of-Phase 2" meeting; (ii) the Phase 2b study did not use the commercial formulation of roluperidone and was conducted solely outside of the United States; (iii) 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) 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) 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) 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 §§ 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 § 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 § 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1931(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 United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

17. Plaintiff _____ acquired and held shares of Minerva at artificially inflated prices during the class period, and has been damaged by the revelation of the Company's material misrepresentations and material omissions.

18. Defendant Minerva Neurosciences, Inc. 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 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 Rémy Luthringer is Minerva's Chief Executive Officer. He served as a consultant for the Company from July 2010, and in May 2014, became an employee. In November 2014, Dr. Luthringer was named Minerva's President and Chief Executive Officer, and he served as President until December 2017.

20. Defendant Luthringer, because of his position at the Company, possessed the power and authority to control the content and form of the Company's annual reports, quarterly reports, press releases, investor presentations, and other materials provided to the SEC, securities

analysts, money and portfolio managers and investors, *i.e.*, the market. Defendant Luthringer authorized the publication of the documents, presentations, and materials alleged herein to be misleading prior to its issuance and had the ability and opportunity to prevent the issuance of these false statements or to cause them to be corrected. Because of his position with the Company and access to material non-public information available to them but not to the public, Defendant Luthringer 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 false and misleading. Defendant Luthringer is liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

21. In November 2013, Cyrenaic Pharmaceuticals, Inc. and Sonkei Pharmaceuticals, Inc. merged and the combined company was renamed Minerva Neurosciences, Inc. Minerva's lead compound candidate is roluperidone, which is in development for the treatment of negative symptoms in patients with schizophrenia.

22. In October 2016, the Company 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."

MATERIALLY FALSE AND MISLEADING STATEMENTS

23. The Class Period begins on May 15, 2017, when as a result of the purportedly successful Phase 2b trial, Minerva announced that it would proceed to a Phase 3 trial. Minerva made this announcement in a press release filed on Form 8-K with the SEC, in which Minerva stated "Minerva Announces Outcome of End-of-Phase 2 Meeting with FDA." The release continued that:

> [F]ollowing a recent "end-of-Phase 2" meeting with the U.S. Food and Drug Administration (FDA), Minerva . . . announced its plans to initiate Phase 3 development of MIN-101, a drug targeting negative symptoms in schizophrenia

patients. A pivotal Phase 3 trial with MIN-101 is expected to be initiated in the second half of 2017.

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The overall design of the planned Phase 3 trial is similar to the Phase 2b trial completed in 2016, in which improvement was observed in schizophrenic patients with negative symptoms treated with MIN-101 compared to placebo.
The Company shared pre-clinical and clinical efficacy and safety data at the FDA meeting, and safety and tolerability of MIN-101 will continue to be assessed during the duration of the Phase 3 trial . . . .

***

"Minerva is finalizing its plan for the Phase 3 development of MIN-101 . . . following our recent meeting with the FDA," said Dr. Remy Luthringer . . . . "Our discussion with the agency 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 MIN-101 to the FDA."

24. On June 29, 2017, Minerva filed a Prospectus Supplement on Form 424B5 with the SEC announcing the public offering of 5 million shares of Minerva common stock at $7.75 each, for total proceeds to the Company, before expenses but after underwriting discounts and commissions, of $36.425 million.[2] This Prospectus Supplement provided, in relevant part:

In May 2017, we announced the outcome of an "end of Phase 2" meeting with the FDA and announced our plans to initiate Phase III development of MIN-101. We expect that a pivotal Phase III trial with MIN-101 will be initiated in the second half of 2017.

The Phase III trial design will be a 12-week, double-blind, randomized, placebo-controlled, monotherapy study testing two doses of MIN-101 in patients with negative symptoms and a diagnosis of schizophrenia. To be eligible for the study, patients will be required to have stable negative and positive symptoms over several months prior to enrollment, with a specified minimum threshold baseline score on the PANSS negative sub-scale. After the double-blind phase, patients may enter a 36-week open label extension phase in which all patients will receive active treatment. This multi-center, international trial is expected to enroll approximately 500 patients at approximately 60 clinical sites across the U.S. and Europe.

[2] https://www.sec.gov/Archives/edgar/data/1598646/000119312517217594/d382980d424b5.htm.

25. On August 3, 2017, the Company held an earnings call with analysts to discuss its second quarter 2017 financial results. On this call, Defendant Luthringer stated:

> Informed by feedback from the end of Phase II meeting with the FDA, we have confirmed the key elements of the Phase III trial design with MIN-101. To a significant degree, these parameters measure the design of our successful Phase IIb trial. So Phase III trial will consist of a 3 months randomized double-blind placebo-controlled core period followed by a 9 months open label extension period. Approximately 500 patients will be randomized 1 to 1 to 1, to 2 doses of MIN-101 monotherapy versus placebo. The primary outcome will be improvement in negative symptoms as measured by the Marder score. The Marder score includes a question from the Positive and Negative Syndrome Scale, or PANSS scale that is well correlated with functional outcome in patients and not contained in the pentagonal score utilized in the Phase IIb trial.
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> In fact, a post-op analysis of our Phase IIb data utilizing the Marder score shows the improved effect sizes and p-values relative to placebo as compared to the pentagonal score. Approximately 1/3 of the patients recruited are expected to come from the U.S. with the remainder from the E.U. A total of approximately 60 clinical sites will be included in the trial. We plan to recruit patients who have been symptomatically stable in terms of positive and negative symptoms for 6 months with moderate-to-severe negative symptoms with a PANSS score of greater than 20. We believe that this eligibility criteria represent a significant portion of schizophrenic patients suffering from negative symptoms, and thus cover most patients who are unable to function well during everyday life. We also recently completed a bridging study in healthy volunteers to identify an improved and final formulation of MIN-101 to be used in the Phase III trial, and in the CMC scale-up activities currently ongoing.
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> In summary, data from this study showed bioequivalent exposed between the improved formulation and the formulation used in Phase IIb study in terms of the parent compound. It is important to note that through PK-PD analysis of drug plasma levels versus negative score performed on our Phase IIb data, shows at MIN-101 efficacy is driven by exposure of parent compound. Reduction of the maximum concentration Cmax of the metabolite associated with transient (inaudible) increases, when a certain level is achieved. We believe this decreased Cmax of this metabolite confers an improved safety margin to MIN-101 (inaudible) cerebral fluid effect, which is a key element when MIN-101 is used in an everyday clinical practice. Following the completion of this study, we're planning to initiate the Phase III trial on schedule in the second half of 2017 with the same doses used in the Phase IIb trial. Again, the improved formulation is expected to show an improved safety profile at equivalent doses. Coming back to our Phase III study safety, we continue to be monitored as it was into Phase IIb with specific attention to the side effects seen in standard of care, which were not observed as MIN-101

> in Phase IIb. We expect top line results from the 3 months double blind phase of this trial in the first half of 2019.
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> With respect to our request for breakthrough therapy designation from MIN-101, the initial feedback we received from the FDA, while denying our request confirmed the treatment of negative symptoms of schizophrenia meets the criteria for a serious or life-threatening disease and consequently for breakthrough therapy designation. The FDA advised that they were not able to grant such designation at this time pending receipt of additional analysis of certain data from the Phase IIb study. We're currently in dialogue with the agency to clarify why we believe the existing data provides the analysis the FDA is seeking.

26. In December 2017, Minerva initiated the Phase 3 trial for MIN-101.[3] In a Jan. 8, 2018 presentation filed with the SEC, the Company stated: "Phase 3 efficacy study: confirmatory study design guided by insights from Phase 2b and dialogue with FDA."

27. On March 12, 2018, Minerva filed its 2017 Annual Report on Form 10-K with the SEC.[4] In this 2017 Annual Report, Minerva stated:

> In May 2017, we announced the outcome of an "end-of-Phase 2" meeting with the FDA and announced our plans to initiate Phase 3 development of roluperidone. This meeting and additional discussions with the FDA on the Phase 3 trial design and operational conduct led to the finalization of the protocol and design for that trial described above.

28. Also, on March 12, 2018, Minerva held an earnings call with analysts to discuss its fourth quarter and full year results for 2017. On this call, Defendant Luthringer stated:

> As you know, I mean, we already have a lot of chance because, at the end of Phase II meeting we had with the FDA, it was clearly discussed that, I mean, the Phase III should be as close as possible to the Phase IIb study we have run. So obviously, we could really learn a lot from the Phase IIb in order to design the right Phase III. This said, as everybody knows, I mean, in the Phase III we will have around 30% of the patients coming from the U.S. And here, we put a lot of efforts in this part in order to ensure that the patients who will be enrolled, we have access to their history because when you're dealing with negative symptoms in schizophrenia, you really need to get a good hint about the history of the patient in order to show the stability of the symptoms. So all this has really focused -- the team has focused a lot on this and I really think that we have the right sites in place in the U.S. in order to come

[3] *See* https://www.sec.gov/Archives/edgar/data/1598646/000119312518005144/d509395dex991.htm (Corporate Presentation filed with the SEC on Jan. 8, 2018).
[4] https://www.sec.gov/Archives/edgar/data/1598646/000156459018005224/nerv-10k_20171231.htm.

up with the right patients, with the same patients as the patients we will include in Europe. So this is really something very important.

29. On November 20, 2018, Minerva held a special call with analysts. On that call, Defendant Luthringer stated:

> So basically, as you know, I mean we really had an extremely good exchange discussion with the FDA at the end of Phase II. And I think we achieved something which is quite unique, which is that, yes, the Phase IIb, if we are able in Phase III to reproduce the results with a study design which is extremely similar, this will be really the ground of moving forward and filing an NDA. So this is what we have obtained and yes, indeed, I mean the Phase III is really, I would like to say, copy paste of the Phase IIb.
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> So this is the study design. So as you know, this is a study in monotherapy. So the patients who are treated with antipsychotics and have not a good response in terms of functioning, in terms of negative symptoms, are switched to 2 doses of our molecule, 32 milligram and 64 milligram, basically the same dose strengths as in the Phase IIb.
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> The comparator is placebo, and I will address the reason why in developing a drug for negative symptoms you need to use placebo and not positive control. Because there is no basically positive control. And second, because we know very well that antipsychotics have side effects, which can be picked up. It is not a good control at the end of the day.
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> But so clearly, I mean, it is a 12-week double-blind study. And afterwards, the patients can go into an extension. And this extension is covering 12 months, the idea being here that, I mean, you need to have around 100 patients exposed for 12 months. So this is the reason why we have this duration of extension. But this is obviously, also to check again if once a patient is responding, how long the effect is maintained.
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> Now so these are the key highlights of the study. And I will address all of these questions I had over the last few months since, I mean, we have started the study. So first one is a primary endpoint, yes. As you know, we moved in terms of the primary endpoint. We use, obviously, always the PANSS scale, which is the gold standard in assessing schizophrenia and negative symptoms. But we have moved from the pentagonal score to the model score, and in my next slide will really elaborate on this in order to just explain you why we came to this agreement with the FDA to use a model score.

30. On March 18, 2019, Minerva held an earnings call with analysts to discuss the Company's fourth quarter and full year 2018 results. On that call, Defendant Luthringer stated:

> Our study design and endpoint selection have been informed by insights gained in the recent Phase IIb trial and continuous dialogue with the FDA. We are working closely with approximately 60 clinical sites in the U.S. and Europe to ensure adherence to critical aspects of the conduct of the study. For example, we are working to minimize rating variability among clinical sites by carefully assessing on a regular basis throughout the study intra- and inter-rater variability, which is kept as low as possible. Achieving this goal, we helped reproduce the same separation between roluperidone and placebo observed in the Phase IIb study. We expect completion of enrollment during the first half of 2019 and top line results from the 12-week, double-blind period in mid-2019.
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> In parallel with the conduct of the Phase III study, we are working on key activities, the results of which will be integrated into our NDA submission package. This include, for example, clinical pharmacology trials and CMC scale-up. Furthermore, we are working with input of several KOLs on postapproval studies in schizophrenia and beyond.

31. On October 1, 2019, Minerva announced that its Phase 3 trial would be delayed "[d]ue to a cyber-attack on one of the Company's external contractors that resulted in a disruption to patient recruitment in the study . . . ." As a result, the Company said it expected to "complete enrollment at approximately year-end and anticipates results from the 12-week, double-blind portion of the study to be available in the first half of 2020."[5]

32. On January 6, 2020, Minerva issued a press release on Form 8-K with the SEC in which it announced the completion of patient screening in its Phase 3 trial of roluperidone for the treatment of negative symptoms in schizophrenia.[6] Minerva stated:

> A total of 857 patients have been screened, and the enrollment of at least 501 patients is expected to be completed before the end of January 2020. Top-line results from the 12-week, double-blind portion of the trial are expected in the second quarter of 2020.
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> This trial is a multicenter, randomized, double-blind, parallel group, placebo-controlled, 12-week study to evaluate the efficacy and safety of 32 milligram (mg) and 64 mg doses of roluperidone as measured by the Positive and Negative Syndrome Scale Marder negative symptoms factor score, the primary endpoint. Secondary endpoints include the Personal and Social Performance Scale and Clinical Global Impression of Severity. Patients are being randomized 1:1:1 to the

[5] https://www.sec.gov/Archives/edgar/data/1598646/000119312519259276/d813246dex991.htm.
[6] https://www.sec.gov/Archives/edgar/data/1598646/000119312520002240/d862817dex991.htm.

> 32 mg and 64 mg doses of roluperidone and to placebo. The core 12-week phase of the trial is followed by a 40-week, open-label extension period during which patients on the drug continue receiving their original dose and patients on placebo receive one of the two doses of roluperidone.

33. In addition, Dr. Luthringer stated in the release: "[w]e are pleased to have achieved the important milestone of having completed patient screening in the Phase 3 trial with roluperidone. . . . Our consistent objectives throughout the trial have been to ensure the highest quality of patient selection and the rigorous evaluation of the symptoms of schizophrenia, including negative symptoms. We look forward to randomizing the last patient in January, 2020 and to having top-line results in the second quarter of 2020."

34. On February 5, 2020, Minerva issued a press release on Form 8-K with the SEC in which it announced the completion of patient enrollment in its Phase 3 trial of roluperidone for the treatment of negative symptoms in schizophrenia.[7] Minerva stated:

> A total of 515 patients have been randomized in this trial, compared to the original goal of 501 patients. The trial, which is being conducted at clinical sites in the U.S. and Europe, is a randomized, double-blind, parallel-group, placebo-controlled, 12-week study to evaluate the efficacy and safety of 32 milligram (mg) and 64 mg doses of roluperidone as measured by the Marder negative symptoms factor score of the Positive and Negative Syndrome Scale, the primary endpoint. Secondary endpoints include the Personal and Social Performance Scale and Clinical Global Impression of Severity. Patients are being randomized 1:1:1 to the 32 mg and 64 mg doses of roluperidone and placebo. The core 12-week double-blind phase of the trial is followed by a 40-week, open-label extension period during which patients on the drug continue receiving their original dose and patients on placebo receive one of the two doses of roluperidone. Top-line results from the 12-week, double-blind portion of the trial are expected in the second quarter of 2020.

35. In addition, Defendant Luthringer stated in the release: "[t]he completion of patient enrollment marks a major milestone in the Phase 3 trial with roluperidone . . . We believe the data from this trial have the potential to lead to a significant new treatment option for schizophrenia, as

[7] https://www.sec.gov/Archives/edgar/data/1598646/000119312520024917/d884459dex991.htm.

no pharmacological agent is approved to treat negative symptoms, which is the single greatest unmet need for patients with this disease, their families and their physicians."

36. On March 6, 2020, Minerva held a special conference call presentation with several analysts. On this call, Defendant Luthringer stated:

> I will not bother you again with our Phase IIb data. But this is coming out from the publication in the American Journal of Psychiatry. On the left side, you have the results we obtained during the Phase IIb study, 12-week, double-blind, placebo monotherapy. So these patients are getting off antipsychotics. They are really treated in monotherapy. So you see that after 2 weeks, we already see an improvement of negative symptoms compared to placebo. And the things are becoming highly significant after 12 weeks. I have read in a paper recently that the effect sizes are not really very impressive. I think here we have to mention that the effect size we have here is more than 0.5, yes, I mean, overall. And when you're going to the younger population, we have an effect size which are above 1.5. So I think we have here really a very, very important effect.

37. Defendant Luthringer added: "[s]o these are the Phase IIb results. Very quickly, also, we had secondary endpoints, which were focusing on cognition, and we published this as well. So definitely, there is an effect on cognition. It's the third line."

38. Defendant Luthringer further stated: "We have really not changed the study design between the Phase IIb and the Phase III. So it's again monotherapy. It's again – primary endpoint will be after 12 weeks. Again, placebo versus 2 doses. The randomization is 1:1:1. The difference is that, I mean, we have a longer extension, so the possibility to the patients to go into a 9 months extension to have 12 months exposure."

39. Last, Defendant Luthringer stated on this March 6, 2020 call:

> I'm coming back from visiting sites in Ukraine last week. A lot of patients have completed 12 months, and I have a little bit of problem currently because the clinicians, the caregivers and the patients are telling me, so should I give up this drug because I'm good. But – so this is how it is in clinical development. But what I think – my key message here is that we are not reinventing the wheel for the Phase III. We are really doing something which is in line with what we have done in the Phase IIb.

40. In addition, Dr. Philip Harvey, the Leonard M. Miller Professor of Psychiatry and director of the Division of Psychology at the University of Miami Miller School of Medicine and a VA Senior Health Scientist, participated in the call. Dr. Harvey was asked: "what treatment effect would you consider to be clinically meaningful on the PANSS Marder scores?" He responded, in relevant part:

> In terms of a clinically significant improvement on the Marder scale, what the FDA is going to require is a statistically significant improvement relative to placebo, which in most of these studies tends to be an effect size of about half a standard deviation, which is a moderate effect. That converges with other research in other areas suggesting that an improvement of 0.5 standard deviation in a behavioral trait is the threshold for observers being able to notice that something is different. So there is some clinical validity to that. Obviously, there are functional measures that are being collected in this trial, too. It would be surprising to me if you're seeing this big and this rapid effect on a reduced emotional experience or avolition in the sample that you wouldn't see an improvement in social functioning in the same time frame.

41. On March 9, 2020, Minerva filed its 2019 Annual Report on Form 10-K with the SEC.[8] In this Form 10-K, Minerva stated:

> We believe the scientifically supported and innovative mechanisms of roluperidone may potentially address the unmet needs of schizophrenic patients, which include negative symptoms and cognitive impairment, without the side effects of existing therapies. Negative symptoms are lifelong debilitating symptoms and include: asociality, or the lack of motivation to engage in social interactions; anhedonia, or the inability to experience positive emotions; alogia, or failure to engage in normal conversation; avolition, or loss of energy and interest in activities; and blunted affect, or diminished emotional expression. We plan to seek approval of roluperidone initially as a first line treatment of negative symptoms in patients diagnosed with schizophrenia, and we also may study its use to treat all aspects of the disease, including positive symptoms and relapse prevention.

42. This Form 10-K continued:

> *Phase 3 Clinical Trial*
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> In December 2017, the first patient was screened in the pivotal Phase 3 clinical trial of roluperidone (Study "MIN-101C07") as monotherapy for negative symptoms in patients diagnosed with schizophrenia. The trial is a multicenter, randomized,

[8] https://www.sec.gov/Archives/edgar/data/1598646/000156459020009243/nerv-10k_20191231.htm.

double-blind, parallel-group, placebo-controlled, 12-week study to evaluate the efficacy and safety of 32 milligrams ("mg") and 64 mg of roluperidone as compared to placebo in adult patients with negative symptoms of schizophrenia. The 12-week study is being followed by a 40-week, open-label extension period during which patients on roluperidone will continue receiving their original dose and patients on placebo will receive either 32 mg or 64 mg doses of roluperidone.

We have completed enrollment and a total of 515 patients were randomized in this trial at clinical sites in the U.S. and Europe. We anticipate top-line results from the 12-week, double-blind portion of the study to be available in the second quarter of 2020.

The primary endpoint of this trial is improvement in negative symptoms in patients treated with roluperidone compared to placebo as measured by the change in the Positive and Negative Syndrome Scale, or PANSS, Marder negative symptoms factor score ("NSFS") over the 12-week double-blind treatment period. The key secondary endpoint is the effect of roluperidone compared to placebo as measured by the Personal and Social Performance, or PSP, total score over the same period. Additional secondary endpoints include the effect of roluperidone compared to placebo on the Clinical Global Impression of Severity ("CGI-S") score, the PANSS total and subscale scores, the remaining Marder 4 factor scores, and safety and tolerability.

Patients admitted into the trial had a documented diagnosis of schizophrenia for at least one year and been symptomatically stable for at least 6 months with moderate to severe negative symptoms (>20 on the PANSS negative symptom subscale) and stable positive symptoms. Patients without moderate to severe symptoms of excitement/hyperactivity, suspiciousness/persecution, hostility, uncooperativeness, or poor impulse control were recruited. We believe these eligibility criteria represent the real-world patient population who may benefit when the drug is used in clinical practice. In addition, patients treated with psychotropic agents needed to undergo a wash-out period of a few days before receiving study drug. These parameters were applied in screening the population enrolled in the Phase 2b trial.

Chemistry, Manufacturing and Controls program

The chemistry, manufacturing and controls ("CMC") scale-up program for roluperidone is ongoing to ensure consistency between the drug batches used during Phase 3 testing and those that will be available for potential marketing and commercialization pending the completion of our Phase 3 trial and subsequent regulatory submission and review of a New Drug Application ("NDA") for roluperidone. The CMC program requires validation of all aspects of the manufacturing processes required to result in a drug product that consistently meets approved quality standards.

On September 23, 2019, we announced that we have entered into a long-term commercial supply agreement for roluperidone with Catalent, Inc. ("Catalent"), a leading global provider of advanced delivery technologies, development, and manufacturing solutions for drugs, biologics, gene therapies, and consumer health products. Under the terms of the agreement, Catalent will manufacture and package the finished dose form of roluperidone at its facility in Schorndorf, Germany. To date, Catalent has worked with us to enable the transfer from pilot to commercial-scale production. This has included analytical methods transfer and validation, process optimization, stability studies, and registration batch manufacturing, as well as packaging studies and the assessment of the influence of formulation factors on the product's critical quality attributes as required by Quality by Design process.

43. The Form 10-K continued:

We have completed a prospective, double-blind, placebo-controlled, randomized single-escalating dose study in healthy subjects to evaluate the investigational drug roluperidone as monotherapy administered at nine ascending doses (16, 32, 64, 96, 128, 160, 192, 224 and 256 mg). The highest dose tested is 4 multiples of the highest dose (64 mg) being used in the ongoing Phase 3 trial.

The trial included a total of 90 subjects. 72 received 9 different doses of roluperidone, and 18 received placebo. All subjects who were dosed completed the study as planned except for one male subject who received placebo and subsequently withdrew his consent.

Data from this trial demonstrated the following:

- The pharmacokinetics of roluperidone and its metabolites were dose proportional.
- No QTcF duration > 480 milliseconds ("msec") or increases > 60 msec compared to baseline values were observed in any subject.
- 160 mg was the only roluperidone dose to show an adjusted QTcF mean increase from baseline of 10.7 msec. All other doses showed means below 10 msec that ranged from -1.3 to 5 msec.
- No significant change in repolarization was observed.
- Two subjects (11%) in the placebo group and nine subjects (13%) in the roluperidone group reported adverse events that were mild to moderate in severity and resolved without sequelae.
- Doses up to 160 mg or 2.5 multiples of the highest dose being tested in the ongoing Phase 3 trial had no effect on any cardiac safety parameters.
- Slight but not clinically relevant increases in heart rate were observed in the placebo group and some of the roluperidone doses.
- No serious adverse events were reported.

We believe these findings suggest an expanded therapeutic window and a significantly improved safety margin for roluperidone. They provide further

> evidence that the formulation being used in the Phase 3 trial has a significantly reduced maximum concentration ("Cmax") of the BFB-520 metabolite when compared to the formulation used in the Phase 2b trial, thereby reducing the potential for transient QTc increases at the doses currently tested in the Phase 3 trial. Furthermore, we believe these data suggest the potential for future testing of roluperidone in schizophrenic patients with an exacerbation of psychosis at higher doses than those being used in the Phase 3 trial.

44. Defendant Luthringer signed a certification attesting that based on his knowledge, this Form 10-K report "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

45. In addition, Defendant Luthringer signed a certification stating, in relevant part, that "[t]he information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company."

46. Also on March 9, 2020, the Company held an earnings call with analysts. During this call, Defendant Luthringer stated:

> So clearly, I mean, to really restate the things extremely well. To get to the stage of the NDA and to get, hopefully, the things approved by the FDA, what you have to do is to show that the overall study so from 18 to 55 years of age, that, I mean, you show a p-value on the Marder negative score out of the PANSS. So this is really what you need. Yes. So clearly, we will do some additional analysis as we have done post hoc with the Phase IIb in order to see if we confirm the fact that the age has an effect -- on the effect size, we are not speaking here about p-values, we are speaking about the effect sizes. And this will obviously be done, but this is not at all related to what we need in order to get the drug approved. But we will definitely do it because more speaking with KOLs, more speaking with clinicians, it is true that, I mean, one of the sweet spots of roluperidone would be to really go after even adolescents at risk who have not developed as a complete disease. But I mean, we can also think about the first episode patients, where you have really, I think, with a drug like roluperidone, an extremely good chance to completely reverse the course of the disease. So yes, it did, obviously -- if I mean, we reconfirmed that the effect size in the younger population or the younger part of the patients who are in the Phase III are showing an effect size. Remember, it was above 1.5 in terms of effect size in the younger part of the population. We will definitely think about running a trial, really concentrating on this younger population. So now and more practically, I mean, to your questions. Definitely, I mean, we are in the study, it's a

> Phase III study, below the 40% dropout. So we are completely, how to say, ticking the box.

47. On this March 9, 2020 earnings call, Defendant Luthringer was asked "is there anything other than the clinical components of the [NDA] submission that would be time gating following the Phase III results to NDA submission?" He responded:

> [T]he short answer is, there is no limiting factor, yes, because we are extremely advanced in the preparation of the NDA filing. And obviously, we need to have the clinical data, yes, but for the rest, I mean, the things are really moving according to plan. We are extremely well advanced in terms of CMC. We are – we did a very, very, very careful review of all the preclinical data. We have even – because some data – or the guidelines have changed over time. So we have repeated some data to be according to the most recent guidelines. So I think I can say this very loud and clear. We are completely ready outside of waiting for the clinical data.

48. Luthringer added on this March 9, 2020 call: "obviously, we are in Phase III, so we cannot provide more than this. But clearly, I mean, incredible feedbacks of some patients who have really recovered this, basically. So it's obviously not general. It's not all the patients. And I do not know, obviously, that's history of all the patients, but some of the feedbacks are really, really very, very positive and very encouraging."

49. On March 31, 2020, Minerva held another special call with several analysts. On this call, Defendant Luthringer stated: "what is clear is that the FDA is definitely clear on it that, I mean, they will approve a drug based on the improvement of the Marder negative score coming out from the PANSS. But if you can show functional improvement, it would be better. . . . So I think we will be more precise or we will have more hints towards a functional improvement."

50. On this call, Defendant Luthringer continued:

> [Y]ou really come to the conclusion that this drug might have not only an effect on negative symptoms, which is specific, there seem the Phase IIb has shown this, and hopefully, the Phase III will show this as well. But it shows also that, I mean, you might be able to control positive symptoms in a way or another. I'm not saying that, I mean, it will be a first choice drug for an acute episode of psychosis or positive

symptoms and agitation, but what I think it might be able to control positive symptoms.

51. On April 1, 2020, the Company filed a presentation with the SEC on Form 8-K, entitled "Roluperidone: A potential novel mechanism to treat the negative symptoms of schizophrenia."[9] This presentation provided, *inter alia*:

- "Roluperidone demonstrated a statistically significant reduction in negative symptoms and total PANSS score: Results of the Phase 2b trial"

***

- "Overall Phase 2b study results: Both doses of Roluperidone demonstrated statistically significant superiority to placebo in improving negative symptoms."

***

- "Roluperidone was demonstrated to be superior on both PANSS-derived negative symptoms sub-scale as well as on the BNSS, a scale specifically design [sic] to measure negative symptoms"

52. On May 4, 2020, Minerva issued its financial results from the first quarter of 2020 on Form 10-Q with the SEC.[10] This Form 10-Q contained statements similar to those in Minerva's March 9, 2020 Form 10-K Annual Report. In addition, the Company stated that it had "completed enrollment and a total of 515 patients were randomized in th[e Phase 3] trial in the United States and Europe," and that "[i]n total, 362 patients have completed the double-blind phase, 333 patients from the double-blind phase have elected to transition into the open-label extension period, and 932 patients have completed the extension phase as of April 30, 2020."

53. As exhibits to the May 4, 2020 Form 10-Q, Defendant Luthringer signed a certification similar to the one he signed that accompanied the March 9, 2020 Annual Report on Form 10-K.

[9] https://www.sec.gov/Archives/edgar/data/1598646/000119312520094671/d857702dex991.htm.
[10] https://www.sec.gov/Archives/edgar/data/1598646/000156459020020617/nerv-10q_20200331.htm.

54. Also on May 4, 2020, Minerva held an earnings call with analysts to discuss these first quarter 2020 financial results. On this call, Minerva discussed that the last patient visit took place in the Phase III trial, and that the Company "look[ed] forward to the database log and beginning of data analysis late this month."

55. On this May 4, 2020 earnings call, Defendant Luthringer stated:

> The design of the Phase III trial has been informed by feedback from the FDA, beginning with our end of Phase II meeting and subsequent communication with the agency. . . . We are excited about the possibility of the Phase III data addressing this significant unmet medical need and pointing the way to a new treatment paradigm for negative symptoms beginning with schizophrenia.

56. Luthringer also stated on this May 4, 2020 call: "we shared our statistical analysis plan with the FDA, yes? And we received a feedback, which already confirmed the way we would like to analyze the data. We will analyze the data because it's not becoming clear reality but the statistical analysis plan is ITT."

57. Luthringer further stated:

> As you know, the primary objective of this extension is to tick the box of 100 patients exposed to the drug for 1 year. So this is really the safety aspect, but this is what you have to do to tick the box to go for the NDA – or to go to the FDA. So I think this is really extremely good news because we still have a lot of patients going on, and we have already 92 have completed. So I think we are really in good shape for ticking this box now. We're obviously following these patients in terms of safety and efficacy. And without having as much details as for the double blind phase, I think that the things are behaving in terms of efficacy like it was in the Phase IIb as well. So far, so good, yes, and very reassuring, yes.

58. On this May 4, 2020 call, Luthringer was asked if Minerva could give an update on the baseline characteristics observed in the Phase 3 trial on a blinded basis versus what they saw in the Phase 2b trial. Luthringer responded:

> [W]hat we had in the Phase IIb was for negative symptoms around 25 points at baseline. And it is true that, I mean, we are monitoring, obviously, the Phase III completely blinded by merging together all the patients who enter the study. And I have to say that we are ending up with exactly the same entry score in terms of

> negative symptoms, which is obviously great news. And I can even give you a little bit more granularity, telling you that, I mean, what we see over the first 12 weeks during the double-blind phase in terms of the behavior and the dynamic of the negative score is really overlapping between the 2 studies, the Phase IIb and the Phase III.

59. The statements described above were materially false and misleading and failed to disclose material adverse facts about the Company's business, operations, and prospects. As discussed below, the Defendants misled investors by misrepresenting and/or failing to disclose that: (i) the truth about the feedback received from the FDA concerning the "end-of-Phase 2" meeting; (ii) the Phase 2b study did not use the commercial formulation of roluperidone and was conducted solely outside of the United States; (iii) 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) 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) 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) as a result, the Company's public statements were materially false and misleading at all relevant times.

60. The statements described in ¶¶ 23-30, 36-39, and 43-58 were materially false and misleading and failed to disclose material adverse facts about the Company's business, operations, and prospects.

61. On May 29, 2020, Minerva issued a press release on Form 8-K with the SEC in which it announced the results of its critical Phase 3 trial of roluperidone for the treatment of negative symptoms in schizophrenia.[11] The Company stated in the release, in relevant part, that "[t]he 64 mg and 32 mg doses were not statistically significantly different from placebo at Week

[11] https://www.sec.gov/Archives/edgar/data/1598646/000119312520155824/d935488dex991.htm.

12 on the primary endpoint, the PANSS Marder Negative Symptoms Factor Score (p ≤0.064 and 0.259, respectively), or the key secondary endpoint, the Personal and Social Performance Scale Total Score (p ≤0.021 and p ≤0.542, respectively)."

62. This release continued:

> In total, 515 patients were enrolled into the trial, and 513 patients received treatment and were included in the safety and Intent-To-Treat population. The trial was conducted in the USA, Europe and Israel. There were 172 patients who received placebo, 172 patients who received roluperidone 32 mg, and 171 patients who received roluperidone 64 mg. Demographic and baseline disease characteristics were comparable across all treatment arms.
>
> The results for both roluperidone doses versus placebo across both the primary and the key secondary endpoints to Week 12 were corrected for multiplicity using the truncated Hochberg procedure.
>
> The primary objective of the trial was to evaluate the change from baseline to Week 12 of NSFS with 32 mg and 64 mg doses of roluperidone compared to placebo in patients diagnosed with schizophrenia presenting with moderate to severe negative symptoms. Neither the 32 mg nor 64 mg dose of roluperidone showed a statistically significant separation from placebo (32 mg: p ≤0.256, effect size [ES]=0.1; 64 mg: p ≤0.064, ES=0.2).
>
> Furthermore, neither dose showed a statistically significant separation from placebo on the key secondary endpoint, the change from baseline to Week 12 in PSP (32 mg: p ≤0.542, ES=0.1; 64 mg: nominal p ≤0.021, ES=0.3).

63. On this news, the Company's stock price plummeted, 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. This represents a one day drop of approximately 72.5%.

64. Yet Defendants continued to mislead the investing public about the viability of roluperidone to treat negative symptoms of schizophrenia. Indeed, in the very release announcing the failure of the Phase 3 trial, Defendant Luthringer stated:

> We are encouraged by the results obtained in this study which expand upon the outcome of the Phase 2b study that showed improvements in the primary endpoint and in multiple secondary endpoints . . . . Even though this study didn't achieve its primary and key secondary endpoints, primarily due to a larger than expected

> placebo effect at Week 12, results obtained with the 64 mg dose including the early onset of effect and functional improvement as measured by PSP suggest roluperidone merits continued investigation for the treatment of primary negative symptoms. We intend to consult with the US FDA about the next steps in the development of roluperidone for this indication after we complete the analysis of the study data. I would like to express our sincere appreciation to all of the patients, caregivers, the investigators and their staff who participated in this trial.

65. On June 5, 2020, Minerva held a special call with analysts to discuss the Phase 3 trial results. During this call, Defendant Luthringer stated:

> Based on the recent Phase III data and all the data we have accumulated over the last years, roluperidone has really the potential to be the first approved drug to treat negative symptoms. Whilst we did not reach the statistical requirements for the primary endpoint, I'm extremely excited that roluperidone has now shown a real clinical benefit in 2 late stage trials.
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> ***
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> What is interesting to notice here is that, when you're looking to the level of improvement with roluperidone in the 2 studies, I think the level of improvement is very similar. And the time course is extremely similar as well. So clearly, the 2 doses of roluperidone behave exactly in the same was as what we have seen in the Phase IIb.

66. Moreover, Dr. Harvey added:

> Now the FDA has required that all treatments that are targeting symptoms of schizophrenia, other than psychosis, provide evidence of what they would call a co-primary functional outcome. And the FDA has, in fact, approved one major treatment for major depression, vortioxetine, for improving cognition and everyday functioning based on changes in a performance-based measure of functioning. So this is a tremendously important finding. And it is completely congruent with the observational data published beforehand.
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> ***
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> So let's talk about the receptivity of the FDA to data like this. The FDA has allowed other sponsors to combine data from trials to create an aggregate outcome that they would then consider for approval. The fact that the drug improves everyday functioning is going to be highly positive in terms of their deliberations.

67. Again on the June 5, 2020 call, an analyst asked Defendant Luthringer: "can you just talk about what their guidance view is in terms of approaching the FDA meeting and

specifically for the regulatory consultants, what they think are the likely outcomes?" Luthringer replied:

> So definitely we spoke with them, and we continue to speak with them. And as we generate additional data, sorry, we will speak with them. So again, and I do not want to, how to say, to say something, which is not final because, I think what we have to do here, what is a recommendation is that the data are definitely good enough to go to approach the FDA. You heard that, because we have a specific effect on negative symptoms and the functional improvement this will be considered extremely carefully by the FDA because the mechanism of action is, how to say, completely innovative, as you know. I think we have to come to the FDA with an extremely good file and with an extremely good understanding of our data. So this is what -- this is a recommendation. And afterwards, I cannot decide and they cannot decide for the agency, but I think we have a fair chance that the agency will look into this very carefully, with a positive eye. And we discussed about 2 or 3 different possibilities of outcomes. And I think as of today, it's too early to say what would be the best -- not the best, the most probable outcome because there are several outcomes. And yes, indeed, one outcome is just proceed. One is do an additional study. You can also discuss is the study before approval or after approval, all this, I think, again, I do not want to speak in place of the agency because they have their own view. But I think we have a very robust file to present that we need to really put all what we know about the drug. As you know, the company is extremely transparent as well as we are transparent with the FDA. And as we have already established a very good relationship. And so we will present all of what we know about the drug and see what comes out. But there is no final answer from our experts or from our advisers. Because, this is also -- keep in mind, this is something which is unprecedented, in terms of what we are addressing here. We're addressing the huge unmet medical need. And I think this is important. So I cannot give you a better answer. So stay with us a little bit that we see more and we have more understanding. But at the end of the day, it is the FDA who will decide. But I think we have a good file.

68. Also on June 5, 2020, Minerva published a presentation on Form 8-K with the SEC entitled: "Roluperidone: Topline results from the Phase 3 trial: A Multicenter, Randomized, Double-blind, Parallel Group, Placebo-Controlled, Monotherapy, 12-Week Study to Evaluate the Efficacy and Safety of 2 Fixed Doses of MIN-101 in Adult Patients with Negative Symptoms of Schizophrenia, Followed by 40-Week Open-Label Extension."[12]

[12] https://www.sec.gov/Archives/edgar/data/1598646/000119312520162243/d940195dex991.htm.

69. On August 3, 2020, Minerva released its financial results for the second quarter of 2020 on Form 10-Q with the SEC. In this Form 10-Q, the Company stated:

Roluperidone (MIN-101)

Phase 3 Clinical Trial

On May 29, 2020, we announced that the Phase 3 trial of roluperidone to treat negative symptoms in schizophrenia did not meet its primary (reduction in PANSS Marder Negative Symptoms Factor Score, or NSFS) and key secondary (improvement in the Personal and Social Performance Scale Total Score, or PSP) endpoints.

In total, 515 patients were enrolled into the trial, and 513 patients received treatment and were included in the safety and Intent-To-Treat population. The trial was conducted in the United States, Europe and Israel. There were 172 patients who received placebo, 172 patients who received roluperidone 32 mg, and 171 patients who received roluperidone 64 mg. Demographic and baseline disease characteristics were comparable across all treatment arms.

The results for both roluperidone doses versus placebo across both the primary and the key secondary endpoints to Week 12 were corrected for multiplicity using the truncated Hochberg procedure.

The primary objective of the trial was to evaluate the change from baseline to Week 12 of NSFS with 32 mg and 64 mg doses of roluperidone compared to placebo in patients diagnosed with schizophrenia presenting with moderate to severe negative symptoms. Neither the 32 mg nor 64 mg dose of roluperidone showed a statistically significant separation from placebo at Week 12 (32 mg: $p \leq 0.256$, effect size [ES]=0.1; 64 mg: $p \leq 0.064$, ES=0.2).

Furthermore, neither dose showed a statistically significant separation from placebo on the key secondary endpoint, the change from baseline at Week 12 in PSP (32 mg: $p \leq 0.542$, ES=0.1; 64 mg: nominal $p \leq 0.021$, ES=0.3).

Although limited inferences can be drawn from this data, unadjusted statistically significant separations from placebo were observed in NSFS at Week 4 for both doses (32 mg: nominal $p \leq 0.036$, ES=0.2; 64 mg: nominal $p \leq 0.007$, ES=0.3), and at Week 8 for the 64 mg dose (nominal $p \leq 0.027$, ES=0.3), and the 64 mg dose was statistically significantly different from placebo as measured by change in PSP at all other assessment timepoints (Week 4, nominal $p \leq 0.005$, ES=0.3; Week 8: nominal $p \leq 0.018$, ES=0.3).

Overall, subgroup analyses by region (United States and rest of the world) and by age groups were similar.

> Roluperidone was generally well tolerated, and the incidences of patients who reported treatment-emergent adverse events over the duration of 12 weeks of treatment were 37% for the 64 mg group, 42% for the 32 mg group, and 33% for placebo. Only 42 patients discontinued from the study due to adverse events, 16 (9%) in 64 mg arm, 18 (10%) in 32 mg arm, and 8 (5%) in placebo arm. Two treatment-unrelated deaths were reported in the 32 mg treatment arm.
>
> Patients admitted into the trial had a documented diagnosis of schizophrenia for at least one year and been symptomatically stable for at least six months with moderate to severe negative symptoms (>20 on the PANSS negative symptom subscore) and stable positive symptoms. Patients without moderate to severe symptoms of excitement/hyperactivity, suspiciousness/persecution, hostility, uncooperativeness, or poor impulse control were recruited. We believe these eligibility criteria represent the real-world patient population who may benefit when the drug is used in clinical practice. In addition, patients treated with psychotropic agents needed to undergo a wash-out period of a few days before receiving study drug. These parameters were applied in screening the population enrolled in the Phase 2b trial.
>
> We believe the results obtained in the Phase 3 study expand upon the outcome of the Phase 2b study that showed improvements in the primary endpoint and in multiple secondary endpoints. We believe the Phase 3 study's inability to achieve statistically significant (adjusted for multiplicity) improvement at Week 12 on its primary and secondary endpoints may be primarily due to a larger than expected placebo effect. Results obtained with the 64 mg dose included an early onset of effect and functional improvement as measured by PSP and suggest that roluperidone merits continued investigation for the treatment of negative symptoms in patients with schizophrenia. We are completing additional detailed analyses of data from this trial, following which we plan to request a meeting with the U.S. FDA to consult about the potential next steps in the development of roluperidone.

70. As exhibits to the August 3, 2020 Form 10-Q, Defendant Luthringer signed a certification similar to the one he signed that accompanied the March 9, 2020 Annual Report on Form 10-K and the May 4, 2020 Form 10-Q.

71. Also, on August 3, 2020, Minerva held an earnings call with analysts to discuss the Company's second quarter 2020 financial results. During this call, Defendant Luthringer stated:

> But I think the – so the bottom line is that we are more and more convinced that this drug is doing what it had to do. It's clear that in the Phase III, we had this effect

> on placebo, which was more important than in the Phase IIb. And it's basically not a surprise, yes, because if you have a highly positive Phase IIb study, the expectation from the PIs, the sites and even the patients or the caregiver is higher. So this is, obviously, one explanation. . . . I'm very confident that we will have a good meeting with the FDA.
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> But I think the most important of our data, and I think this is something which will be very helpful when we are going to present all this and what we will put, obviously, in a briefing book. But all what we will go to present to the FDA is to really show and demonstrate that between the Phase IIb and the Phase III the improvement we have seen with 32 and more particularly with 64-milligram is the same between the 2 studies. We will again demonstrate that avolition is an extremely important driver. And here, the things are very, very clear when you're looking to the data we have today in hand. And obviously, we will also more and more go into the details about PSP, yes, which, as you know, is a functional improvement. So all these pieces are fitting extremely well together and are definitely not influenced as they have been by the placebo effect or by the placebo inflation as the primary endpoint has been influenced. And you're right, it's not really a surprise because as I tried to explain before, negative symptoms is a construct of different aspects and different dimensions. And when you're going more into the details, you see that, I mean, the Phase III is extremely positive and discriminating very well treatment from placebo. So this will be the full package we will present to the FDA.

72. On November 2, 2020, just eight days before the Type C Meeting to be held with the FDA, Minerva issued its third quarter 2020 financial results on Form 10-Q with the SEC. In this Form 10-Q, the Company made similar statements to those contained in its August 3, 2020 Form 10-Q as alleged *supra*. In addition, the Company stated:

> We have completed additional detailed analyses of data from this trial, following which we requested a meeting with the FDA to consult about the potential next steps in the development of roluperidone. On September 2, 2020, the FDA granted us a Type C meeting, which is currently scheduled to take place via teleconference on November 10, 2020. In preparation for this meeting, we have provided the Type C Meeting Package to the FDA that contains detailed analyses of the Phase 3 trial results and background information on roluperidone. It is possible that the FDA could cancel or reschedule this meeting, and we do not expect to receive the official minutes of the meeting until mid or late December 2020.

73. As exhibits to the November 2, 2020 Form 10-Q, Defendant Luthringer signed a certification similar to the one he signed that accompanied the March 9, 2020 Annual Report on Form 10-K, the May 4, 2020 Form 10-Q, and the August 3, 2020 Form 10-Q.

74. Also, on November 2, 2020, Minerva held an earnings call with analysts to discuss the Company's third quarter 2020 financial results. During this call, Minerva stated that they had presented their materials to the FDA in September. Then Defendant Luthringer stated:

> In summary, the recent Phase III data combined with all of the data accumulated over the last few years, continue to support our belief that roluperidone can become an important treatment for schizophrenia patients.
>
> ***
>
> [W]ith 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. . . . But indeed, obviously, we are anticipating any outcome, and we are also working currently on what would be the next steps if, I mean, the FDA is requested us to do another study. Again, we don't expect this or we are doing all what we can that this will not happen and we have already also anticipated, obviously, the analysis of the extension phase or the extension part of the study, which will end in the first quarter of next year.

THE TRUTH EMERGES

75. Before the markets opened on December 1, 2020, Minerva issued a press release in which the Company announced the outcome of its Type C Meeting with the FDA concerning roluperidone. In this announcement, Minerva stated that it had "received official meeting minutes from the November 10, 2020 Type C meeting with the" FDA. In this release, 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."

76. 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. This represents a one day drop of approximately 25.7%.

77. The statements described in ¶¶ 64-65, 67, and 69-74 were materially false and misleading and failed to disclose material adverse facts about the Company's business, operations, and prospects. As discussed below, the Defendants misled investors by misrepresenting and/or failing to disclose that: (i) the truth about the feedback received from the FDA concerning the "end-of-Phase 2" meeting; (ii) the Phase 2b study did not use the commercial formulation of roluperidone and was conducted solely outside of the United States; (iii) 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) 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) 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) as a result, the Company's public statements were materially false and misleading at all relevant times.

CLASS ACTION ALLEGATIONS

78. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of a class of all persons and entities who purchased or otherwise acquired Minerva common stock between May 15, 2017 and November 30, 2020, inclusive. Excluded from the Class are Defendants, directors and officers of the Company, as well as their families and affiliates.

79. 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.

80. 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 the members of the Class which predominate over questions which may affect individual Class members include:

a. Whether Defendants violated the Exchange 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 the Company's stock was artificially inflated; and

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

81. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages from Defendants' wrongful conduct alleged herein.

82. 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 that conflict with those of the Class.

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

FRAUD ON THE MARKET

84. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine that, among other things:

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

b. The omissions and misrepresentations were material;

c. The Company's common stock traded in efficient markets;

d. The misrepresentations alleged herein would tend to induce a reasonable investor to misjudge the value of the Company's common stock; and

e. Plaintiff and other members of the class purchased the Company's common stock between the time Defendants misrepresented or failed to disclose material facts and the time that the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

85. At all relevant times, the markets for the Company's stock were efficient for the following reasons, among others: (i) the Company filed periodic public reports with the SEC; and (ii) the Company regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures such as communications with the financial press, securities analysts, and other similar reporting services. Plaintiff and the Class relied on the price of the Company's common stock, which reflected all information in the market, including the misstatements by Defendants.

NO SAFE HARBOR

86. The statutory safe harbor provided for forward-looking statements under certain conditions does not apply to any of the allegedly false statements pleaded in this Complaint. The specific statements pleaded herein were not identified as forward-looking statements when made.

87. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

LOSS CAUSATION

88. On December 1, 2020, prior to the commencement of trading, Minerva announced the results of its November 10, 2020 Type C meeting with the FDA concerning roluperidone. 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. This represents a one day drop of approximately 25.7%.

89. These revelations contradicted statements made by Defendants during the Class Period and were a causal element of the concurrent decline in the Company's share price.

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

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

91. During the Class Period, Defendants Minerva and Luthringer 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 to make the statements made, in light of the circumstances under which they were made, not misleading.

92. Defendants Minerva and Luthringer violated § 10(b) of the Exchange Act and Rule 10b-5 in that they (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a

fraud and deceit upon those who purchased or otherwise acquired the Company's securities during the class period.

93. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for the Company's common stock. Plaintiff and the Class would not have purchased the Company's common stock at the price paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

Count Two
Violation of § 20(a) of the Exchange Act
(Against Defendant Luthringer)

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

95. Defendant Luthringer acted as a controlling person of the Company within the meaning of § 20(a) of the Exchange Act as alleged herein. By virtue of his high-level positions at the Company, Defendant Luthringer had the power and authority to cause or prevent the Company from engaging in the wrongful conduct complained of herein. Defendant Luthringer was provided with or had unlimited access to the documents described above that contained statements alleged by Plaintiff to be false or misleading both prior to and immediately after their publication, and had the ability to prevent the issuance of those materials or to cause them to be corrected so as not to be misleading.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(a) determining that this action is a proper class action pursuant to Rule 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of the Class as defined herein, and a

certification of Plaintiff as class representative pursuant to Rule 23 of the Federal Rules of Civil Procedure and appointment of Plaintiff's counsel as Lead Counsel;

(b) awarding compensatory and punitive 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 pre-judgment and post-judgment interest thereon.

(c) awarding Plaintiff and other members of the Class their costs and expenses in this litigation, including reasonable attorneys' fees and experts' fees and other costs and disbursements; and

(d) awarding Plaintiff and the other Class members such other relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury in this action of all issues so triable.