UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number 001-36517

Minerva Neurosciences, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**26-0784194**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1601 Trapelo Road, Suite 286 Waltham, MA	**02451**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 600-7373

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	NERV	The NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definition of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate value of the Company's Common Stock held by non-affiliates of the Company was approximately $141.1 million as of June 30, 2020, when the last reported sales price was $3.61 per share.

The number of shares of Registrant's Common Stock outstanding as of March 4, 2021 was 42,721,566.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement relating to the 2021 Annual Meeting of Stockholders to be filed pursuant to Regulation 14A with the Securities and Exchange Commission are incorporated by reference into Part III of this Report. Such proxy statement will be filed with the Securities and Exchange Commission not later than 120 days following the end of the Registrant's fiscal year ended December 31, 2020.

MINERVA NEUROSCIENCES, INC.

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All trademarks, trade names, service marks, and copyrights appearing in this Annual Report on Form 10-K are the property of their respective owners.

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These forward-looking statements reflect our plans, estimates and beliefs. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "would" and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Because of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not transpire. These risks and uncertainties include, but are not limited to, the risks included in this Annual Report on Form 10-K under Part I, Item IA, "Risk Factors."

Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our estimates and assumptions only as of the date of this document. You should read this document with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we do not undertake any obligation to publicly update or revise any forward-looking statements contained in this report, whether as a result of new information, future events or otherwise.

Summary of Risks Associated with Our Business

The summary of risks below provides an overview of the principal risks that we are exposed to in the normal course of our business activities. The below summary of risks is not exhaustive, and such summary should be considered in addition to the other risks described elsewhere in this report:

- We have incurred significant losses since our inception. We expect to continue to incur losses over the next several years and we will require additional capital to finance our operations;
- We are subject to risks and uncertainties as a result of the ongoing COVID-19 pandemic;
- Changes in estimates regarding fair value of intangible assets may result in an adverse impact on our results of operations;
- We cannot give any assurance that any of our product candidates will receive regulatory approval in a timely manner or at all. The results of clinical trials conducted at sites outside the U.S. may not be accepted by the FDA and the results of clinical trials conducted at sites in the U.S. may not be accepted by international regulatory authorities;
- If we experience delays in clinical testing, we will be delayed in commercializing our product candidates, our costs may increase and our business may be harmed. If we are unable to enroll subjects in clinical trials, we will be unable to complete these trials on a timely basis or at all. Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which could prevent or delay regulatory approval and commercialization, and also increase costs;
- We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success;
- Even if we complete the necessary clinical trials, we cannot predict when or if we will obtain marketing approval to commercialize a product candidate or the approval may be for a narrower indication than we expect. We have no experience in advancing product candidates beyond Phase 3, which makes it difficult to assess our ability to develop and commercialize our product candidates;
- Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties, including ongoing regulatory obligations and continued regulatory review. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to administrative sanctions or penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products;
- The regulatory pathway for our product candidate, MIN-301, has not yet been determined. Depending on the pathway, we may be subject to different regulatory requirements;
- If the market opportunities for any product that we or our collaborators develop are smaller than we believe, our revenue may be adversely affected and our business may suffer;
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do;
- Recently enacted and future legislation may increase the difficulty and cost for us to commercialize our product candidates and affect the prices we may obtain;

- Our business and operations would suffer in the event of system failures. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud;
- We currently rely and continue to expect to rely on third parties to conduct our future clinical trials. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business;
- We contract with third parties for the manufacturing of our product candidates for pre-clinical and clinical testing and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products, or such quantities at an acceptable cost;
- We depend on collaborations with certain of our licensing partners, and could be seriously harmed if our license agreements are terminated or breached;
- Substantial potential future milestone payments to the Company depend on the development and commercialization of seltorexant, and we may be obligated to make related payments to certain of our contractual partners even if certain of our other contractual partners breach their obligations to pay us;
- We may not be successful in establishing new collaborations, which could adversely affect our ability to develop future product candidates and commercialize future products;
- One or more of our owned or licensed patents directed to our proprietary products or technologies may expire or have limited commercial life before the proprietary product or technology is approved for marketing in a relevant jurisdiction;
- We have in-licensed or acquired a portion of our intellectual property necessary to develop our product candidates, and if we fail to comply with our obligations under any of these arrangements, we could lose such intellectual property rights;
- We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful;
- We cannot predict what the market price of our common stock will be and, as a result, it may be difficult for you to sell your shares of our common stock;
- Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval;
- Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall;
- Securities litigation could result in substantial damages and may divert management’s time and attention from our business; and
- We have never paid dividends on our capital stock, and because we do not anticipate paying any cash dividends in the foreseeable future, capital appreciation, if any, of our common stock will be your sole source of gain on an investment in our common stock.

Part I

ITEM 1. Business

Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of proprietary product candidates to treat patients suffering from central nervous system ("CNS") diseases. Leveraging our scientific insights and clinical experience, we have acquired or in-licensed compounds that we believe have innovative mechanisms of actions and therapeutic profiles that potentially address the unmet needs of patients with these diseases.

We are developing roluperidone (f/k/a MIN-101) for the treatment of negative symptoms in patients with schizophrenia and MIN-301 for the treatment of Parkinson's disease. In addition, we previously co-developed seltorexant (f/k/a MIN-202 or JNJ-42847922) with Janssen Pharmaceutica NV ("Janssen") for the treatment of insomnia disorder and adjunctive treatment of Major Depressive Disorder ("MDD"). During 2020, we exercised our right to opt out of a joint development agreement with Janssen for the future development of seltorexant. As a result, we will be entitled to collect royalties in the mid-single digits on potential future sales of seltorexant worldwide in certain indications, with no further financial obligations to Janssen. In January 2021, we sold our rights to these potential royalties to Royalty Pharma plc ("Royalty Pharma").

We believe our product candidates have significant potential to improve the lives of a large number of affected patients and their families who are currently not well-served by available therapies. According to Datamonitor, an independent market research firm, in 2020 approximately 2.9 million people suffered from schizophrenia and 2.1 million suffered from Parkinson's disease in the United States ("U.S."), Japan and the five major European Union ("EU") markets of France, Germany, Italy, Spain and the United Kingdom. There is no approved treatment to address negative symptoms in patients with schizophrenia in the U.S., which is a significant driver of the cost burden of that disease. An estimated 69% of treated patients with schizophrenia have predominant/persistent negative symptoms. Negative symptoms also exist in other CNS diseases beyond schizophrenia, the existing treatments for which we believe are poorly addressed in a broad range of indications such as Alzheimer's disease, Parkinson's disease and depression.

Our Strategy

Our strategy is to develop and commercialize first-in-class products that address critical unmet medical needs in the CNS therapeutic area. We are pursuing this strategy based on the following principles: selection of differentiated products with novel mechanisms of action that target therapeutic areas of high unmet need and significant disease burden; attention to patient safety and compliance; scientific rigor applied to patient selection and clinical trial conduct; engagement of highly trained clinical trial investigators; incorporation of patient and caregiver insights to drive clinical advancements; and integrity. With the experience and knowledge base of our clinicians and physicians, we have generated substantive data from randomized, double blind, placebo-controlled trials that support the clinical advancement of these products in defined patient populations and in multiple regulatory jurisdictions. In summary, key elements of our strategy are to:

- ***Identify, acquire and develop differentiated products with innovative mechanisms of action based on biological and clinical insights into the unmet needs of patients;***
- ***Leverage the randomized, double-blind, placebo-controlled data from completed trials to advance the clinical development of our product candidates in multiple regulatory jurisdictions;***
- ***Prepare for the commercialization of our lead product, roluperidone, which will potentially be the first product approved to treat negative symptoms in patients with schizophrenia in the U.S. and, in the longer term as a potential treatment for other neuro-degenerative brain disorders in which negative symptoms represent a significant debilitating, unmet need;***
- ***Selectively explore collaborations with leading pharmaceutical companies to maximize the value of our current product candidate portfolio, particularly in connection with pivotal clinical trials and subsequent regulatory review, approval and commercialization;***
- ***Apply our management team's expertise and current intellectual property portfolio to identify and explore additional indications to investigate with our current portfolio of compounds and to acquire additional product candidates.***

Our History

Minerva Neurosciences, Inc. was formed in November 2013 from the merger of Cyrenaic Pharmaceuticals, Inc. and Sonkei Pharmaceuticals, Inc. These two predecessor companies had exclusively licensed roluperidone and another compound from Mitsubishi Tanabe Pharma Corporation, or MTPC. In February 2014 we acquired Mind-NRG Sarl, or Mind-NRG, which owns exclusive rights to develop and commercialize MIN-301 globally. In addition, in February 2014 we entered into a co-development and license agreement with Janssen, one of the Janssen Pharmaceutical Companies of Johnson & Johnson, in connection with the co-development and commercialization of seltorexant. During 2020, we exercised our right to opt out of the agreement with Janssen. As a result, we will be entitled to collect royalties in the mid-single digits on potential future sales of seltorexant worldwide in certain indications, with no further financial obligations to Janssen. In January 2021, we sold our rights to these potential royalties to Royalty Pharma.

We have not received regulatory approvals to commercialize any of our product candidates, and we have not generated any revenue from the sales or license of our product candidates. We have incurred significant operating losses since inception. We expect to incur net losses and negative cash flow from operating activities for the foreseeable future in connection with the clinical development and the potential regulatory approval, infrastructure development and commercialization of our product candidates

Our Clinical-Stage Programs

Roluperidone (MIN-101)

Introduction

Roluperidone is a compound that has been shown to block serotonin, sigma, and α-adrenergic receptors that are involved in the regulation of mood, cognition, sleep and anxiety. We are developing roluperidone to treat patients with schizophrenia. Roluperidone has been designed to block a specific subtype of serotonin receptor called 5-HT_{2A}. When 5-HT_{2A} is blocked, certain symptoms of schizophrenia, such as hallucinations, delusions, agitation and thought and movement disorders, as well as the side effects associated with antipsychotic treatments, can be minimized. Additionally, blocking 5-HT_{2A} promotes slow wave sleep, a sleep stage often disrupted in patients with schizophrenia. Roluperidone has also been designed to block a specific subtype of sigma receptor called $sigma_2$, which is involved in movement control, psychotic symptom control and learning and memory. Blocking $sigma_2$, along with blocking the α-adrenergic subtypes α_{1A}, and to a lesser extent α_{1B}, also increases calcium levels in neurons in the brain, which can improve memory. Pre-clinical findings provide evidence of the effect of roluperidone on Brain-Derived Neurotrophic Factor (“BDNF”), which has been associated with neurogenesis, neuroplasticity, neuroprotection, synapse regulation, learning and memory.

We believe the scientifically supported and innovative mechanisms of action 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. We believe that roluperidone, if approved, could treat the majority of patients diagnosed with schizophrenia. An estimated 69% of patients diagnosed with schizophrenia have negative symptoms, with at least 42% of patients diagnosed with schizophrenia having prominent negative symptoms.

Beyond schizophrenia, we believe roluperidone may possess therapeutic utility in brain disorders where negative symptoms are a core feature of the disease associated with a range of poor clinical outcomes. These potential indications include apathy in dementia, for which we have filed an Investigational New Drug (“IND”) application, the majority of schizophrenia spectrum and other psychotic disorders, autism spectrum disorders, Alzheimer’s disease, Parkinson’s disease and depression.

Clinical and Regulatory Developments

Type C Meeting

On November 30, 2020 we received official meeting minutes from our November 10, 2020 Type C meeting with the U.S. Food and Drug Administration (“FDA”) regarding the development of roluperidone for treatment of negative symptoms of schizophrenia. The objective of this meeting was to obtain FDA input regarding the roluperidone data package and its readiness to support a New Drug Application (NDA) submission. The two main topics addressed during the meeting were:

1. *Readiness for submission of NDA*

We requested confirmation from FDA that, based on the totality of evidence, the data from the MIN-101C03 ("Phase 2b") and MIN-101C07 ("Phase 3") studies constitute substantial evidence of the effectiveness of the 64 milligrams ("mg") dose of roluperidone for the treatment of negative symptoms of schizophrenia and would warrant review of an NDA submission.

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, because neither dose of roluperidone showed a statistically significant separation from placebo at Week 12 in the intent-to-treat ("ITT") analysis set. 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.

FDA acknowledged that the data from the Phase 2b and Phase 3 studies appear to show promising signals and encouraged us to continue the development of roluperidone for treatment of negative symptoms of schizophrenia, which FDA confirmed is an unmet need.

We believe FDA's comments can be addressed based on published regulatory guidance and precedents. We have comparable pharmacokinetic data for the formulations used in Phase 2b and Phase 3 and intend to perform a pivotal bioequivalence study in healthy volunteers to bridge the two formulations as well as at least one new formulation designed in conjunction with our commercial supply partner, Catalent, Inc., to facilitate large scale manufacturing. In addition, we believe the Phase 3 study has shown that U.S. data and ex-U.S. data are comparable, and that many precedents exist where drugs were approved by FDA based solely on ex-U.S. data. We believe that, in the Phase 3 study, results from the modified ITT ("mITT") analysis set that excludes patients with implausible behavioral and physiological data from one site (17 of a total of 513 patients) address the lack of separation at Week 12.

2. *FDA's consideration of both ITT and mITT data analyses from Phase 3 study*

In the briefing book for the Type C meeting, we highlighted that the exclusion of implausible behavioral and physiological data from 17 patients at one site forms the basis of the mITT analysis set as outlined in the Statistical Analysis Plan submitted to FDA before unblinding the study.

For the mITT analysis set, the 64 mg dose of roluperidone achieved a nominal statistically significant result (p-value ≤ 0.044) on the primary endpoint, the Marder Negative Symptoms Factor Score ("NSFS") of the Positive and Negative Syndrome Scale ("PANSS"). The details of both the ITT and mITT results for the primary ("NSFS") and key secondary endpoint, the Personal and Social Performance (PSP) total score, can be found in the table below.

Roluperidone Phase 3: ITT and mITT NSFS & PSP total score change from baseline scores and p-values						
Timepoint	**Intent-to-Treat**			**Modified Intent-to-Treat (Excluding patients from 1 site)**		
Timepoint	**Placebo (N=172)**	**64 mg Roluperidone (N=171)**	**p-value**	**Placebo (N=167)**	**64 mg Roluperidone (N=162)**	**p-value**
Primary Endpoint: Marder Negative Symptoms Factor Score						
Week 2	-1.6 (0.22)	-1.9 (0.22)	***NS***	-1.6 (0.22)	-1.9 (0.22)	***0.311***
Week 4	-2.0 (0.26)	-2.9 (0.26)	***0.007***	-2.0 (0.26)	-3.0 (0.27)	***0.005***
Week 8	-2.9 (0.30)	-3.8 (0.32)	***0.027***	-2.9 (0.31)	-3.9 (0.32)	***0.021***
Week 12	-3.5 (0.34)	-4.3 (0.38)	***0.064***	-3.5 (0.35)	-4.5 (0.35)	***0.044***
Key Secondary Endpoint: Personal and Social Performance Total Score						
Week 4	1.3 (0.56)	3.2 (0.56)	***0.005***	1.2 (0.58)	3.3 (0.59)	***0.004***
Week 8	2.8 (0.66)	4.8 (0.66)	***0.019***	2.8 (0.68)	4.9 (0.68)	***0.014***
Week 12	3.9 (0.73)	6.1 (0.73)	***0.021***	3.8 (0.75)	6.2 (0.77)	***0.017***

FDA advised that their consideration of both the mITT and ITT results would be a matter of review and that in principle all sites should be included in the primary analysis set, and FDA cannot determine at this time whether data from the referenced site should be removed without a thorough evaluation. FDA indicated that we should include justification for exclusion of these data in the future NDA package and provide primary results both with and without these data.

In addition to the two main agenda items described above, the use of the PSP total score in the label and the adequacy of the PANSS and PSP instruments and related constructs to assess the efficacy of roluperidone were also discussed with the FDA. We intend to provide requested literature to support both instruments' psychometric properties to FDA.

Future development of roluperidone

We intend to continue development and NDA activities consistent with FDA's December 2019 draft guidance titled "Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products." As stated in this draft guidance document, where the target indication is an unmet need such as negative symptoms in schizophrenia, the FDA is allowed to consider one adequate and well-controlled study and confirmatory evidence as an alternative to two adequate and well-controlled studies to establish effectiveness.

Patient evaluation in the open-label extension phase of the Phase 3 trial of roluperidone was achieved on February 15, 2021, with a total of 202 patients completing this phase. Data are expected to be available in the first half of 2021. We intend to initiate a pivotal bioequivalence study in approximately 48 healthy volunteers comparing the formulations employed in the Phase 2b and Phase 3 trials as well as at least one new formulation designed in conjunction with our commercial supply partner, Catalent, Inc., to facilitate large scale manufacturing. In addition, we are moving forward with activities we believe are necessary to support the submission of a NDA for this compound.

Following the completion of the bioequivalence study, we plan to request a pre-NDA meeting with the FDA to discuss certain matters including data from the Phase 3 open-label extension, data from the pivotal bioequivalence study and potential NDA submission of roluperidone for the treatment of negative symptoms of schizophrenia

Phase 3 Trial Results

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.

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.

In total, 515 patients were enrolled into the trial, and 513 patients received treatment and were included in the ITT and safety populations. The trial was conducted in the United States, Europe and Israel. There were 172 patients who received placebo, 170 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 ≤0.542, ES=0.1; 64 mg: nominal p ≤0.021, ES=0.3).

Although limited inferences can be drawn from these data, unadjusted statistically significant separations from placebo were observed in NSFS at Week 4 for both doses (32 mg: nominal p ≤0.036, ES=0.2; 64 mg: nominal p ≤0.007, ES=0.3), and at Week 8 for the 64 mg dose (nominal p ≤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 ≤0.005, ES=0.3; Week 8: nominal p ≤0.019, 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.

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 adjusted statistically significant improvement at Week 12 on its primary and key secondary endpoint 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.

Patient evaluation in the open-label extension phase of the Phase 3 trial of roluperidone was achieved on February 15, 2021, with a total of 202 patients (61%) completing this phase. Data are expected to be available in the first half of 2021.

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 and subsequent regulatory submission and review of an 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.

In September 2019 we 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.

Drug-Drug Interaction Studies

We completed certain pharmacology trials that include a Drug-Drug Interaction study, which comprise a standard part of the NDA. We have studied interactions separately with molecules inhibiting two subtypes of the cytochrome P450 (CYP2D6 and CYP3A4). The data from this study show minimal to no interaction with the strong CYP3A4 inhibitor, and some interaction (< 1.6-fold increase in exposure) with the moderate CYP2D6 inhibitor.

Dose Escalation Study with formulation employed in Phase 3 clinical trial

We 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) used in the 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.

We believe the findings from the trial suggest an expanded therapeutic window and a significantly improved safety margin for roluperidone. 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 used in the Phase 3 trial.

Brain-Derived Neurotrophic Factor ("BDNF") Findings

We completed non-clinical studies that provide evidence of the effect of roluperidone on Brain-Derived Neurotrophic Factor ("BDNF") and on Glial Cell-Derived Neurotrophic Factor ("GDNF"). BDNF is the most widely distributed member of neurotrophins in the brain and has been associated with neurogenesis, neuroplasticity, neuroprotection, synaptic regulation and learning and memory. Its involvement in schizophrenia has also been described. GDNF is another neurotrophin known to promote the survival of different types of brain cells and has been shown to be essential for the maintenance and survival of dopamine neurons.

Data from this study were presented at the 2019 Congress of the Schizophrenia International Research Society on April 11, 2019. These findings demonstrate that administration of roluperidone significantly increased BDNF release by astrocytes and hippocampal neurons obtained from the cerebral cortex of newborn rats, as well as the release of GDNF in cultured astrocytes. Furthermore, data showed that roluperidone enhanced BDNF gene expression at drug concentrations comparable to those observed in humans at tested doses. Based on these results, we believe that the effect of roluperidone on BDNF and GDNF may indicate its potential for disease modification and improved neuroplasticity, in addition to its observed effects on the serotoninergic 5-HT_{2A}, $sigma_2$, and α_{1A}- and α_{1B}- adrenergic neurotransmitter pathways.

Roluperidone License Agreement with MTPC

We have entered into a license agreement with MTPC dated as of August 30, 2007, as amended, or the Roluperidone License Agreement. Under the terms of the Roluperidone License Agreement, we acquired an exclusive license to the lead compound known as CYR-101 (subsequently renamed MIN-101 and roluperidone), and other compounds with a similar structure and intended purpose and other data included within the valid claims of certain patents licensed to us under the Roluperidone License Agreement. The license is for world-wide rights other than certain countries in Asia, including China, Japan, India and South Korea. We will pay MTPC a tiered royalty for net sales of product by us or any of our affiliates or sublicensees containing the licensed compound at a range of percentages of the high single digits to the low teens depending on net sales of products under the Roluperidone License Agreement. We were also required to make certain milestone payments upon the achievement of certain development and commercial milestones, potentially up to $57.5 million for roluperidone and up to $59.5 million for additional products.

In January 2014 we renegotiated the structure of the license for roluperidone such that we are required to make milestone payments upon the achievement of one development milestone totaling $0.5 million and certain commercial milestones, which could total up to $47.5 million, in the aggregate, as well as the tiered royalty payments described above. In addition, in the event that we sell the rights to the license, MTPC will be entitled to a percentage of milestone payments in the low teens and a percentage of royalties received by us in the low double digits. This license agreement has a term of the later of 12 years from the launch of the product in each country in our territory, or the expiration of our obligation to pay royalties, upon which we will have a fully paid-up, non-exclusive, perpetual, irrevocable license. Our obligation to pay royalties continues, on a country-by-country basis, until the expiration of the last-to-expire patent that covers roluperidone in each country in our territory.

Seltorexant (MIN-202)

Seltorexant is an innovative selective orexin 2 receptor antagonist that we co-developed with Janssen for the treatment of insomnia and aMDD. Insomnia is the repeated difficulty with sleep initiation, maintenance or quality that occurs despite adequate time and opportunity for sleep, resulting in daytime impairment. Insomnia can be the primary condition for patients or a secondary symptom of, and contributor to, another medical or psychiatric condition, such as MDD or schizophrenia.

On June 30, 2020, we exercised our right to opt out of our agreement with Janssen for the future Phase 3 development and commercialization of seltorexant. Under the opt-out agreement, we will be entitled to collect royalties in the mid-single digits on potential future sales of seltorexant worldwide in certain indications, with no further financial obligations to Janssen. In January 2021, we sold our rights to these potential royalties to Royalty Pharma.

In October 2019 we announced top-line results from a Phase 2b clinical trial in which flexibly dosed seltorexant (20 mg or 40 mg) was compared to flexibly dosed quetiapine XR (150 mg or 300 mg) for adjunctive treatment of patients with MDD. There were 102 patients enrolled, each with MDD not responding adequately to SSRIs and SNRIs. The primary endpoint was all cause discontinuation

of therapy over 6 months. Mood improvement, measured using the MADRS, and safety and tolerability were evaluated. The primary intent of this exploratory trial was to generate data to assist with the planning of Phase 3 studies; it was not powered to detect statistical significance. Quetiapine XR was used as a comparator, because it is the only medication approved for the adjunctive treatment of MDD in both the U.S. and Europe.

In May 2019 we announced positive top-line results from a Phase 2b trial of seltorexant as adjunctive therapy to antidepressants in adult patients with MDD who have responded inadequately to antidepressant therapy, including selective serotonin reuptake inhibitors ("SSRIs") and/or serotonin-norepinephrine reuptake inhibitors ("SNRIs"). We believe these results represent the first clinical observation in a large, late-stage study that a selective orexin molecule can achieve a positive effect as an adjunctive treatment in patients with MDD who have an inadequate response to SSRIs and SNRIs. We believe these findings, if confirmed in Phase 3 studies, will suggest a novel approach to treating MDD with an improved safety profile compared to existing therapies. Approximately 60%-70% of patients diagnosed and treated with first-line therapies, including SSRIs and/or SNRIs, do not experience adequate treatment response, and seltorexant potentially represents a unique opportunity to improve treatment response rates safely in most of these patients.

MIN-301

We are developing MIN-301, a soluble recombinant form of the Neuregulin-1b1, or NRG-1b1, protein, for the treatment of Parkinson's disease and potentially for other neurodegenerative disorders. We believe MIN-301 has the potential to slow the onset of, and restore the brain tissue damage caused by, the disease. MIN-301 is produced by recombinant technology, which is a type of process that modifies the genetics of a biological organism to cause it to produce a particular product. MIN-301 is a peptide that contains the extracellular domain of the human neureglin-1 beta 1 protein and is produced using an Escherichia coli organism that is genetically engineered to express this peptide. Once administrated, this peptide binds to a particular receptor, ErbB4, which produces certain biological effects. For instance, binding to ErbB4 modulates the levels of certain neurotransmitters such as Gamma-Aminobutyric Acid ("GABA") and glutamate in the brain, which are often unbalanced in individuals with Parkinson's disease. Further, ErbB4 promotes oxygenation and metabolism of neurons and it is involved in the control of brain inflammation, which may indicate that MIN-301 could reverse the damage caused by Parkinson's disease.

Current treatments for Parkinson's disease improve the symptoms of patients, but none have been proven to delay the onset of the disease, slow or prevent the progression of the disease or reverse its effects. Due to MIN-301's novel mechanism of action that targets neurological deficits, we believe MIN-301 has the potential to address these unmet needs of patients and, if approved, may be used as an early-stage monotherapy as well as a complementary therapy to existing treatments.

Non-clinical Development

Results from a non-human primate study showed that treatment with an analog of MIN-301 resulted in improvements in a range of symptoms associated with a Parkinson's disease model in primates. The results confirmed the beneficial effects of MIN-301 in non-primate pre-clinical models. We believe these data provide support for advancing MIN-301 into clinical trials for the treatment of Parkinson's disease in humans. Building upon these data, we are continuing to conduct pre-clinical studies in preparation for an IND or Investigational Medicinal Product Dossier ("IMPD") filing, with a Phase 1 study expected to commence thereafter.

Optimization of the bioanalytical method was accomplished during 2020 following the completion of a rat pharmacokinetic study. The new bioanalytical method facilitates the detection of MIN-301 concentrations at very low levels which we believe will enable our further non-clinical testing of this compound.

Competition

Roluperidone: Competition in the Pharmaceutical Market for the Treatment of Schizophrenia

Current drug therapies for the treatment of schizophrenia mainly target the positive symptoms of the disease. When patients present positive symptoms and require treatment, they are typically given either conventional "first-generation" antipsychotic medication, such as GlaxoSmithKline's Thorazine Sanofi-Aventis' Largactil (chlorpromazine) and Janssen's Haldol (haloperidol), or second-generation "atypical antipsychotics," such as Novartis' Clozaril (clozapine), Janssen's Risperdal (risperidone), AstraZeneca's Seroquel (quetiapine), Eli Lilly's Zyprexa (olanzapine) and Bristol-Myers Squibb's Abilify (aripiprazole).

Both types of existing therapies have limited ability to improve negative symptoms and cognitive symptoms. In addition, existing therapies have extensive side effects such as weight gain, metabolic syndrome, sedation, nausea, movement disorders, restlessness, insomnia, impairment of cognitive skills, and prolactin increase. Since schizophrenia has a wide range of symptoms, multiple therapeutics are often prescribed in an attempt to address all aspects of the disease, compounding these side effects.

Given the focus of currently approved drug therapies for positive symptoms and their side effect profiles, we believe these therapies are unlikely to be directly competitive with roluperidone, which is intended to target primarily negative symptoms and cognitive impairment. However, new drug therapies in addition to roluperidone are being developed to address the limitations of current therapies. Several new pharmacological approaches have been investigated. One targets a neurotransmitter called glutamate and the other targets a neurotransmitter called nicotine. Glutamate is the most predominant neurotransmitter system in maintaining the brain in an active state and is involved in maintaining accurate vigilance, attention and contributing to some cognitive skills. Nicotine is among the most predominant neurotransmitter system involved in learning and some other cognitive skills.

Specific compounds under late-stage development that include negative symptoms as a target include Acadia Pharmaceuticals' Pimavanserin, a selective serotonin $5HT_{2A}$ inverse agonist ("SSIA") that is approved for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis. A phase 3 to evaluate the efficacy and safety of Pimavanserin as adjunctive treatment for the negative symptoms of schizophrenia was initiated in August 2020. In January 2019, Lundbeck indicated they would begin proof-of-concept studies for Lu AF11167, a PDE-10 inhibitor for the treatment of persistent negative symptoms in schizophrenia. In August 2020, Lundbeck announced they were discontinuing the trial based on the results of a futility interim analysis, which concluded that the trial was unlikely to achieve statistical significance on its primary endpoint, mean change from baseline to week 12 on the Brief Negative Symptom Scale (BNSS).

Other products in clinical development, as a monotherapy or as an adjunctive treatment, whose targets include negative symptoms, (although not necessarily defined as a primary outcome of their clinical trials) are Roche's RO6889450/RG-7906, Neurocrine's NBI-1065844 (formerly Takeda's TAK-83), SyneuRx's NaBen, Avanir Pharmaceuticals' AVP-786, and Karuna Therapeutics' KarXT. In addition, a number of academic groups are conducting studies with existing compounds for the treatment of negative symptoms of schizophrenia.

MIN-301: Competition in the Pharmaceutical Market for the Treatment of Parkinson's Disease

Current treatments for Parkinson's disease are intended to improve the symptoms of patients. The cornerstone of Parkinson's therapy is levodopa, as it is the most effective therapy for reducing symptoms of Parkinson's disease. However, levodopa may cause unpleasant systemic side effects, such as dyskinesias, and is often used with dopaminergics to manage these side effects. While initially effective, symptoms become increasingly difficult to control over time, and patients experience a pattern of motor complications that include motor fluctuations, dyskinesias, off-period dystonia, freezing and falls. Accordingly, there are advantages to deferring their use to later stages of the disease, or using them with other therapies to reduce the side effects of motor fluctuations and dyskinesia that 50% of levodopa patients experience.

Unlike currently available therapies, MIN-301, if approved, is intended to delay the onset of the disease, slow or prevent the progression of the disease or reverse its effects. Since MIN-301 is expected to target Parkinson's disease, rather than merely its symptoms, and current therapies are not fully effective at improving the symptoms of Parkinson's disease without side effects, we believe that levodopa and other currently available generic products may not be directly competitive with MIN-301. While there are other drug therapies in development that will target the disease, such as gene and stem cell therapy and A2A receptor agonists, the majority of products in development for Parkinson's disease are still in the pre-clinical stage.

Intellectual Property

We strive to protect the proprietary products and technologies that we believe are important to our business, including seeking and maintaining patent protection intended to cover the composition of our product candidates, their methods of use, related technology and other inventions that are important to our business. We also rely on trade secrets and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

The patent portfolios for our product candidates, which we own or are exclusively licensed to us, are summarized below.

Roluperidone

Compound

Under our agreement with MTPC, we have an exclusive license to U.S. Patent No. 7,166,617, which claims the roluperidone compound, as well as to corresponding patents in the following countries: Australia, Canada, Europe (Albania, Austria, Belgium, Republic of Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia, Monaco, Netherlands, Portugal, Romania, Slovenia, Spain, Sweden, Switzerland, Turkey, and United Kingdom), Israel, New Zealand, and Russia. The U.S. patent is scheduled to expire no earlier than May 17, 2021, and a patent term extension of up to 5 years may be available. The foreign patents are scheduled to expire no earlier than February 26, 2021.

In addition to U.S. Patent No. 7,166,617, Minerva also owns numerous other granted patents and patent applications worldwide that provide strong protection for roluperidone. These include patents and applications directed to pharmaceutical compositions comprising roluperidone and methods of using roluperidone.

Pharmaceutical Compositions

We own three granted U.S. patents, U.S. Patent Nos. 9,458,130, 9,730,920 and 10,258,614, and pending applications in the U.S., Australia, Brazil, Canada, Chile, Colombia, Eurasia, Europe, Israel, Mexico, New Zealand, Peru, Ukraine, and South Africa that cover a novel formulation comprising roluperidone. This novel formulation provides improved therapeutic response and minimizes the potential for transient QTc increases – and thus safety issues - when compared to previous formulations. Because of this improved safety profile, it is this formulation of roluperidone that is being used in Phase 3 clinical trials, and it is this formulation that we expect will be the basis for approval in the US and EU. The granted U.S. patents, as well as any other U.S. or foreign patents that may grant from these applications, will expire no earlier than November 30, 2035. These patents are listable in the FDA's Orange Book and would, we believe, bar generic competition during their terms. In addition to the patent terms referenced above, a patent term extension of up to 5 years may also be available.

We also own pending applications in the U.S., Australia, Brazil, Canada, Chile, Colombia, Eurasia, Europe, Israel, Mexico, New Zealand, Peru, Ukraine, and South Africa that cover gastro-resistant, controlled release dosage formulations of roluperidone. The terms of any future granted patents in this patent family would expire no earlier than June 21, 2038.

Methods of Use

We own U.S. Patent No. 9,732,059, two granted patents in Russia, and a single patent in Europe (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Norway, Poland, Portugal, Spain, Sweden, Switzerland, Turkey, and United Kingdom), as well as pending applications in United States, Brazil, Canada, Europe, and Russia across two patent families that are directed to methods of use of roluperidone to treat negative and other symptoms of schizophrenia, sleep disorders, depression, and other sigma-2 disorders or conditions. U.S. Patent No. 9,732,059 covers the use of roluperidone to treat one or more negative symptoms of schizophrenia and will not expire until 2033. This patent is listable in the FDA's Orange Book and would, we believe, bar generic competition during their terms. A patent term extension of up to 5 years may also be available. The foreign patents, as well as any future U.S. or foreign patents granting in these families, are scheduled to expire no earlier than July 20, 2031.

We also own U.S. and EP patent applications directed to the use of roluperidone to treat negative symptoms in non-schizophrenic patients. Any patents granting from these applications would expire no earlier than May 23, 2037.

In addition, we own U.S. and PCT applications directed to the use of roluperidone to treat negative symptoms, various disorders (including autism disorders, amblyopia, personality disorders, traumatic brain injury), as well as increasing neuroplasticity and promoting neuroprotection in subjects in need thereof. Any patents granting from the U.S. application, or any national phase applications that may be filed based upon the PCT application, would expire no earlier than August 21, 2039.

MIN-301

We own a patent family that is directed to the use of MIN-301 for treating neurologic and psychiatric diseases, including Parkinson’s disease. This patent family includes patents granted in the U.S., Australia, Canada, Europe (Austria, Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, Turkey and United Kingdom), Japan, Mexico and Russia. Applications are also pending in the United States and Brazil. Any existing and future granted patents in this family will expire no earlier than November 17, 2028. A patent term extension of up to five years may be available in the United States.

Data and Marketing Exclusivity

In addition to patent protection, our product candidates may also be eligible for data and marketing exclusivity protection in the U.S., EU and certain other countries. If this protection is available, no competitor may use the data in our marketing application to obtain marketing approval of a generic product during the exclusivity period.

For small molecules, such as roluperidone and seltorexant, the data and marketing exclusivity period is generally five years in the U.S. and ten years in the EU, measured from the FDA and EU approval dates, respectively. If MIN-301 is approved as a biologic product, it may be eligible for a data and marketing exclusivity period of twelve years in the U.S. and ten years in the EU. The data and marketing exclusivity periods in the U.S. may be extended by 6 months of pediatric exclusivity if a qualifying pediatric study is performed or in the EU by 12 months if approval for a new indication is obtained during the initial 8 year data exclusivity period and there are no existing therapies for that indication, or there are existing therapies for that indication, but there is a significant clinical benefit to using the drug for which the extra market protection is sought.

Manufacturing

We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third parties for the manufacturing of our product candidates for pre-clinical and clinical testing, as well as for commercial manufacturing if our product candidates receive marketing approval. Our product candidates are manufactured in reliable and reproducible synthetic processes from readily available starting materials. The chemistry does not require unusual equipment in the manufacturing process. We expect to continue to develop product candidates that can be produced cost-effectively at contract manufacturing facilities.

Commercialization

Except for most of Asia, we have global commercialization rights for roluperidone. We also own worldwide rights for MIN-301. We believe that it will be possible for us to access European and, in the case of roluperidone and MIN-301, other priority markets including the United States, Asia, and Latin America, through a focused, specialized sales force where the population dynamics would prove efficient. We may enter into sales, distribution or other marketing arrangements with third parties for priority markets or limited to certain territories for any of our drug candidates that obtain marketing approval.

Subject to receiving marketing approvals, we expect to commence commercialization activities by building a focused sales and marketing organization, either alone or through collaborations with third parties, in the United States, EU and Latin America to sell our product candidates. We believe that such an organization will be able to target the community of physicians who are the key specialists in treating the patient populations for which our product candidates are being developed. Additionally, we plan to engage fully with all key constituencies involved in treatment decisions, including payors, patients and others.

Government Regulation and Product Approval

Clinical Trials and Marketing Authorization in the European Union

In Europe, a clinical trial application, or CTA, must currently be submitted to the competent national regulatory authority and to independent ethics committees in each country in which we intend to conduct clinical trials. Once the CTA is approved in accordance with that country's requirements, clinical trial development may proceed in that country. Under the new Regulation on Clinical Trials, there will be a centralized application procedure where one national authority takes the lead in reviewing the application and the other national authorities have only a limited involvement. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be notified to or approved by the relevant competent authorities and ethics committees. In all cases, the clinical trials must be conducted in accordance with good clinical practices and other applicable regulatory requirements and medicines used in clinical trials must be manufactured in accordance with good manufacturing practices. A clinical trial may only be undertaken subject to certain conditions. The relevant ethics committee must give its opinion, before a clinical trial commences, on any issue requested. Clinical trials information must be entered into a European database. There are strict requirements in relation to the labeling and packaging of our product candidates, the verification of compliance with the provisions on good clinical and manufacturing practice and the notification of adverse events and serious adverse reactions.

Under European Union regulatory systems, a company may not market a medicinal product without marketing authorization.

There are four procedures for submitting a Marketing Authorization Application, or MAA, in the EU: (i) the national procedure, (ii) the mutual recognition procedure, or MRP; (iii) the decentralized, or DCP and (iv) the centralized procedure, or CP. The submission strategy for a given product will depend on the nature of the product, the target indication(s), the history of the product, and the marketing plan. The centralized procedure is compulsory for certain medicinal products which are produced by biotechnology processes, advanced therapy medicinal products and for those which are designated as orphan medicinal products. Besides the products falling under the mandatory scope, the centralized procedure is also optional for medicinal products that constitute a significant therapeutic, scientific or technical innovation i.e. new active substances or other medicinal products that constitute a significant therapeutic, scientific or technical innovation that contain an active substance not authorized in the European Union before May 20, 2004 or for which a centralized procedure would be in the interest of patients.

The centralized procedure leads to approval of the product in all 27 EU member states and in Norway, Iceland and Liechtenstein, collectively referred to herein as the EEA. Submission of one MAA thus leads to one assessment process and one authorization that allows access to the market of the entire EEA. The process of the centralized procedure is triggered when the applicant submits an MAA to the EMA. The letter of intent also initiates the assignment of the Rapporteur and Co-Rapporteur, who are the two appointed members of the Committee for Human Medicinal Products, or CHMP, representing two EU member states. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA by the EMA is 210 days. This excludes so-called clock stops, during which additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Human Medicinal Products, or CHMP. At the end of the review period, the CHMP provides an opinion to the European

Commission. If this is opinion favorable, the Commission may then adopt a decision to grant a marketing authorization. In exceptional cases, the CHMP might perform an accelerated review of an MAA in no more than 150 days. This is usually when the product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation.

When using the MRP or DCP, the applicant must select which and how many EU member states in which to seek approval. In the case of an MRP, the applicant must initially receive national approval in one EU member state. This will be the so-called reference member state, or RMS, for the MRP. Then, the applicant seeks approval for the product in other EU member states, the so-called concerned member states, or CMS, in a second step: the mutual recognition process. For the DCP, the applicant will approach all chosen member states at the same time. To do so, the applicant will identify the RMS that will assess the submitted MAA and provide the other selected member states with the conclusions and results of the assessment.

The European Union medicines rules expressly permit the EU Member States to adopt national legislation prohibiting or restricting the sale, supply or use of any medicinal product containing, consisting of or derived from a specific type of human or animal cell, such as embryonic stem cells. While the products we have in development do not make use of embryonic stem cells, it is possible that the national laws in certain EU Member States may prohibit or restrict us from commercializing our products, even if they have been granted an EU marketing authorization.

An innovator company enjoys a period of “data exclusivity” during which their pre-clinical and clinical trials data may not be referenced in the regulatory filings of another company (typically a generic company) for the same drug substance.

Data exclusivity in Europe is 8 years from the date of first authorization in Europe with an additional period of 2 years of “market exclusivity.” This is the period of time during which a generic company may not market an equivalent generic version of the originator’s pharmaceutical product. An additional 1 year may be obtained where the innovator company is granted a marketing authorization within the above 8-year period for a significant new indication for the relevant medicinal product.

The Pediatric Regulation provides that an application for a new marketing authorization must include the results of all trials performed and details of all information collected in compliance with an agreed pediatric investigation plan, or PIP, unless a deferral or waiver applies on the basis that pediatric use is not relevant - also the requirement can be deferred by agreement.

When the application for marketing authorization is made, the competent authority responsible for granting a marketing authorization must verify whether the application complies with the relevant requirements, including compliance with the agreed PIP. Assuming it does, the marketing authorization may be granted and the relevant results are included in the summary of product characteristics, or SmPC, for the product, along with a statement indicating compliance with the agreed PIP. The applicant then receives the six month extension to the SPC. It is not necessary for the product actually to be indicated for use in the pediatric population (for example, if the results show that that would not be appropriate).

U.S. FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDCA, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, approval, labeling, advertising, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. MIN-301, a peptide, may be regulated as a biologic and additionally subject to the Public Health Service Act. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to allow pending Investigational New Drug Applications, or INDs, and approve NDAs, withdrawal of a marketing approval, imposition of clinical holds or termination of clinical trials, or issuance of Warning or Untitled Letters, product recalls, product seizures, refusal to allow imports or exports total or partial suspension of production or distribution, debarment, injunctions, fines, refusal of government contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement, civil penalties and criminal prosecution, including criminal fines and imprisonment.

FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug, can be marketed in the United States. Pharmaceutical product development in the United States typically involves, among other things, pre-clinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and significant financial investment, and the actual time and cost required may vary substantially based upon the type, complexity and novelty of the product or disease indicated for treatment.

Pre-clinical tests include laboratory evaluation of product chemistry, pharmacology, stability, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices. The results of pre-clinical testing are submitted

to the FDA as part of an IND along with other information including information about product chemistry, manufacturing and controls, any available clinical data or literature, and a proposed clinical trial protocol, among other items. Certain pre-clinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may be conducted after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not placed a clinical hold on the IND within this 30-day period, the clinical trial proposed in the IND may begin. Should FDA place a clinical hold on the IND, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial may begin.

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations, good clinical practices, or GCP, which include the ethical principles that all research subjects provide their informed consent in writing for their participation in any clinical trial, and that all trials be approved and monitored on an ongoing basis by an institutional review board, or IRB. Clinical trials must also be conducted under protocols detailing the objectives of the trial, trial procedures, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated, and a statistical analysis plan. Each protocol involving testing in U.S. subjects and subsequent protocol amendments must be submitted to the FDA as part of the IND. The study protocol and informed consent information for subjects in clinical trials, along with all amendments, must also be submitted to an IRB for approval.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or subjects with the target disease or condition, the drug is tested to assess safety, metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a limited subject population with the target disease or condition to evaluate the effectiveness of the drug for a particular indication or indications, dosage tolerance and optimum dosage, and identify possible adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, generally two adequate and well-controlled Phase 3 trials are undertaken to obtain additional information about clinical efficacy and safety in a larger number of subjects, typically at geographically dispersed clinical trial sites, to establish the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In some cases, the FDA may condition approval on the sponsor's agreement to conduct additional clinical trials to further assess the drug's safety and effectiveness after approval. Such post-approval trials are typically referred to as Phase 4 trials. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Information about certain clinical trials, including a description of the study and study results must also be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their clinicaltrials.gov website.

The manufacture of investigational drugs for the conduct of human clinical trials is subject to the Current Good Manufacturing Practices, or cGMPs. Investigational drugs and active pharmaceutical ingredients imported into the United States are also subject to regulation by FDA relating to their labeling and distribution. Further, the export of investigational drug products outside of the United States is subject to regulatory requirements of the receiving country as well as United States export requirements.

The FDA may suspend or terminate a clinical trial, or impose other sanctions, at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk or if it believes that the clinical trials are not being conducted in accordance with FDA requirements. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to subjects, or may impose other conditions on the conduct of the research. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group regularly reviews accumulated data and advises the study sponsor regarding the continuing safety of trial subjects, potential trial subjects, and the continuing validity and scientific merit of the clinical trial. Sponsors may also suspend or terminate a clinical trial based on safety concerns, a lack of evidence of drug efficacy, evolving business objectives and/or competitive climate.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all pre-clinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls, and proposed labeling, among other things. Under federal law, the submission of most marketing applications is subject to a substantial application user fee, and the sponsor of an approved application is also subject to annual program fees.

In addition, under the Pediatric Research Equity Act, or PREA, a marketing application or supplement to a marketing application for a new active ingredient, indication, dosage form, dosage regimen or route of administration must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

The FDA also may require submission of a risk evaluation and mitigation strategy, or REMS, either during the application process or after the approval of the drug to mitigate any identified or suspected serious risks, and to identify any new risks that were not apparent in clinical investigations. The REMS plan could include medication guides, physician communication plans, assessment plans, and elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

Under the Prescription Drug User Fee Act the FDA has agreed to certain performance goals in the review of NDAs. The FDA has a goal of reviewing ninety percent of applications for non-priority drug products within 10 months of the FDA's acceptance of the full application for filing. The review process may be extended by the FDA under certain circumstances.

Under the FDCA and FDA guidance, before approving a drug for which no active ingredient (including any ester or salt of the active ingredients) has previously been approved by the FDA or a first-of-a-kind, first-in-class biologic, FDA must either refer that drug to an external advisory committee or provide in an action letter, a summary of the reasons why FDA did not refer the drug to an advisory committee. The external advisory committee review may also be required for other drugs because of certain other issues, including clinical trial design, safety and effectiveness, and public health questions. An advisory committee is a panel of independent experts, including clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless the facility, and all of its subcontractors and contract manufacturers, demonstrate compliance with cGMPs, and provide adequate assurance that they can consistently produce the product within required specifications, and the NDA contains data that provides substantial evidence that the drug is safe and effective for the indication sought in the proposed labeling. Additionally, the FDA will typically inspect one or more clinical trial sites to assure compliance with GCPs before approving a marketing application. After the FDA evaluates the marketing application and the manufacturing facilities, it may issue an approval letter, or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA may issue an approval letter.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling restrictions, limitations on the approved indications, contraindications, warnings or precautions, such as black boxed warnings, distribution restrictions or other risk-management mechanisms under a REMS which can materially affect the potential market and profitability of the drug. The FDA may prevent or limit further marketing of a product based on the results of post-marketing trials or surveillance programs. Further, if there are any modifications to the drug, including changes in indications, labeling, manufacturing processes or facilities, or new safety issues arise, a new or supplemental NDA or a post-implementation notification or other report may be required or requested depending on the change, which may require additional data or additional pre-clinical studies and clinical trials. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion, and reporting of adverse experiences with the product and drug shortages. After approval, most changes to the approved product, such as adding new indications, manufacturing changes or other labeling claims, are subject to further testing requirements and prior FDA review and approval.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with cGMP and other regulatory requirements. Changes to the manufacturing process are strictly regulated and may require prior FDA approval or notification before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market trials or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, Untitled Letters, Warning Letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of administrative civil or criminal penalties, including fines and imprisonment.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Although physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications if in their professional medical judgment they believe it to be appropriate, pharmaceutical companies may only market and promote their drug products for the FDA approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws prohibiting the marketing and promotion of off-label uses, and a company that is found to have improperly marketed or promoted off-label uses may be subject to significant liability, including, among others, criminal and civil penalties under the FDCA and False Claims Act, exclusion from participation in federal healthcare programs, and mandatory compliance programs.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Moreover, the Drug Quality and Security Act imposes obligations on manufacturers of pharmaceutical products, among others, related to product and tracking and tracing.

In the European Union, holders of a marketing authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, or QPPV, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new European marketing authorization applications must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the European Union. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each EU Member State and can differ from one country to another.

Federal and State Fraud and Abuse, Data Privacy and Security and Transparency Laws

In addition to FDA restrictions on marketing and promotion of pharmaceutical products, other federal and state healthcare laws restrict business practices in the biopharmaceutical industry. These laws include, without limitation, state and federal anti-kickback and false claims laws, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers. Applicable state anti-kickback and false claims laws may be broader in scope than federal law and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs.

We may also be subject to state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by the Health Insurance and Portability and Accountability Act

("HIPAA"), thus complicating compliance efforts. In addition, we may be subject to reporting requirements under state transparency laws, as well as state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government that otherwise restricts certain payments that may be made to healthcare providers and entities.

If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal and civil and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government healthcare programs, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws.

Coverage and Reimbursement

The commercial success of our product candidates and our ability to commercialize any approved product candidates successfully will depend in part on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for our product candidates, once approved.

Government health administration authorities, private health insurers and other third-party payors generally decide which drugs they will pay for and establish reimbursement levels for healthcare. In particular, in the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. Sales of our product candidates will therefore depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be covered by third-party payors. The market for our product candidates will depend significantly on access to third-party payors' formularies without prior authorization, step therapy, or other limitations such as approved lists of treatments for which third-party payors provide coverage and reimbursement. Also, third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. Coverage and reimbursement for therapeutic products can differ significantly from payor to payor. A third-party payors' decision to provide coverage for a medical product or service does not imply that an adequate reimbursement rate will be approved. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that adequate coverage and reimbursement will be obtained.

In the United States, the European Union and other potentially significant markets for our product candidates, government authorities and other third-party payors are developing increasingly sophisticated methods of controlling healthcare costs and are increasingly imposing additional requirements and restrictions on coverage.

Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and utilization, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care organizations, competition within therapeutic classes, availability of generic equivalents or biosimilars, judicial decisions and governmental laws related to Medicare, Medicaid and healthcare reform, pharmaceutical coverage and reimbursement policies and pricing in general. The cost containment measures that healthcare payors and providers are instituting and the effect of any healthcare reform implemented in the future could significantly reduce our revenues from the sale of any approved product candidates. We cannot provide any assurances that we will be able to obtain and maintain governmental or private third-party coverage or adequate reimbursement for our product candidates in whole or in part.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the state level, legislatures are passing increasing amounts of legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Healthcare Reform

The United States and some foreign jurisdictions are considering enacting or have enacted a number of additional legislative and regulatory proposals designed to change the healthcare system in ways that could affect our ability to sell our products profitably.

In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, including the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, which substantially changed healthcare financing and delivery by both governmental and private insurers, and significantly impacted the pharmaceutical industry. The ACA contains provisions that may potentially reduce the profitability of products, including, for example, increased rebates for products sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. There have been judicial and congressional challenges to the ACA, as well as to repeal or replace certain aspects of the ACA. It is unclear how efforts to repeal and replace the ACA will impact the ACA. We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that may be charged for any of our product candidates, if approved.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or the FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and debarment from government contracts.

Human Capital Resources

Employees

As of December 31, 2020, we had 11 full-time employees. In addition, we are or have engaged with a number of consultants and companies, including Pharma Partnering in Research & Strategy SAS, or PPRS, that provide expertise in the key functions involved with the development of our products. None of our employees is subject to a collective bargaining agreement and we consider our relationship with our employees to be good.

Talent Acquisition and Development

We believe the skills and experience of our employees are an essential driver of our business and important to our future prospects. We face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other research institutions, and we believe that our future success will depend in part on our continued ability to attract and retain highly skilled employees. To attract qualified applicants and retain our employees, we offer our employees what we believe to be competitive salaries, comprehensive benefit packages, equity compensation awards, and discretionary bonuses based on a combination of seniority, individual performance and corporate performance.

Available Information

We file reports with the Securities and Exchange Commission ("SEC"), including annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K any other filings required by the SEC. We make available on our website (www.minervaneurosciences.com) our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. These materials are available free of charge on or through our website via the Investor Relations page at www.minervaneurosciences.com. References to our website address in this report are intended to be inactive textual references only, and none of the information contained on our website is part of this report or incorporated in this report by reference.

The SEC maintains an Internet site (http://www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

ITEM 1A. Risk Factors

This Annual Report on Form 10-K contains forward-looking information based on our current expectations. Because our actual results may differ materially from any forward-looking statements that we make or that are made on our behalf, this section includes a discussion of important factors that could affect our actual future results, including, but not limited to, our capital resources, the progress and timing of our clinical programs, the safety and efficacy of our product candidates, risks associated with regulatory filings, risks associated with determinations made by regulatory agencies, the potential clinical benefits and market potential of our product candidates, commercial market estimates, future development efforts, patent protection, effects of healthcare reform, reliance on third parties, and other risks set forth below.

Risks Related to Our Financial Position and Capital Requirements

We have incurred significant losses since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.

We are a clinical development-stage biopharmaceutical company. In November 2013, we merged with Sonkei Pharmaceuticals, Inc., or Sonkei, and, in February 2014, we acquired Mind-NRG, which were also clinical development-stage biopharmaceutical companies. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval or become commercially viable. As an early stage company, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly the biopharmaceutical area. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. Our recent collaborative revenue was due to the recognition of deferred revenue as a result of opting out of an agreement, and is not a recurring source of revenue.

As of December 31, 2020, we had an accumulated deficit of $284.8 million.

We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates. If any of our product candidates fail in clinical trials or do not gain regulatory approval, or if any of our product candidates, if approved, fail to achieve market acceptance, we may never generate revenue or become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will require additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. As a result, we may not complete the development and commercialization of our product candidates or develop new product candidates.

Our operations and the historic operations of Sonkei and Mind-NRG have consumed substantial amounts of cash since inception. As of December 31, 2020, we had cash, cash equivalents, and restricted cash of $25.5 million. We believe that our existing cash, cash equivalents, and restricted cash will be sufficient to meet our cash commitments for at least the next 12 months after the date that the year-end condensed financial statements are issued. The process of drug development can be costly and the timing and outcomes of clinical trials is uncertain. The assumptions upon which we have based our estimates are routinely evaluated and may be subject to change. The actual amount of our expenditures will vary depending upon a number of factors including but not limited to the design, timing and duration of future clinical trials, the progress of our research and development programs, the infrastructure to support a commercial enterprise, the cost of a commercial product launch, and the level of financial resources available.

Our future funding requirements, both short and long-term, will depend on many factors, including:

- the initiation, progress, timing, costs and results of pre-clinical studies and clinical trials for our product candidates and future product candidates we may develop;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the EMA, FDA, and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more studies than those that we currently expect;
- the cost to establish, maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;

- the effect of competing technological and market developments;
- market acceptance of any approved product candidates;
- the costs of acquiring, licensing or investing in additional businesses, products, product candidates and technologies; and
- the cost of establishing sales, marketing and distribution capabilities for our product candidates for which we may receive regulatory approval and that we determine to commercialize ourselves or in collaboration with our partners.

When we need to secure additional financing, such additional fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we raise additional equity financing, our stockholders may experience significant dilution of their ownership interests, and the per-share value of our common stock could decline. If we engage in debt financing, we may be required to accept terms that restrict our ability to incur additional indebtedness and force us to maintain specified liquidity or other ratios. Further, the evolving and volatile global economic climate and global financial market conditions could limit our ability to raise funding and otherwise adversely impact our business or those of our collaborators and providers. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. Any of these events could significantly harm our business, financial condition and prospects.

We are subject to risks and uncertainties as a result of the ongoing COVID-19 pandemic, and could be subject to risks from further health pandemics or epidemics, as well as uncertainty regarding returning to work and phased re-openings.

Our business could be adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 pandemic, which continues to have a negative impact on the local, regional, national and global scale. In response to the pandemic, a number of jurisdictions in which we or our service providers operate implemented shelter-in-place or similar type restrictions, which limited on-site activity to certain service providers. Additionally, our headquarters are located in Massachusetts, which implemented such restrictions. In response, we implemented work-from-home policies for our employees, which continue to be in effect. While certain jurisdictions, including Massachusetts have begun a phased re-opening of businesses and governmental agencies, there remain limitations on the physical operations of businesses and prohibitions on certain non-essential gatherings, and it is unclear if such phased re-openings will continue or be rolled back, and there is uncertainty about when, if, or how our workforce may return. The effects of the state executive order, local shelter-in-place orders, government-imposed quarantines and our work-from-home policies, including the uncertainty about their duration, may negatively impact productivity, disrupt our business and delay our clinical programs and timelines. The magnitude of these negative effects will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course, and our ability to respond with minimal disruptions to the evolving restrictions, reopenings, and any future curtailment. These and similar, and perhaps more severe, disruptions in our operations in response to the ongoing COVID-19 pandemic and any future health pandemics or epidemics could negatively impact our business, operating results and financial condition.

In addition, our clinical trials may be affected by the COVID-19 pandemic. We may face difficulties enrolling or retaining patients in future clinical trials if patients are affected by the COVID-19 virus or are unable to travel to the clinical trial sites or obtain study medication. Our clinical trials may further be delayed due to prioritization of hospital resources toward the COVID-19 pandemic, and some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to the COVID-19 virus, could be delayed or disrupted, which would adversely impact our clinical trial operations. As a result, we could experience delays in the completion of our trials, which could result in a material adverse impact on our clinical trial plans and timelines.

Furthermore, the COVID-19 pandemic has caused a broad negative impact globally on capital markets and economies worldwide, which could have a negative impact on us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic, may be difficult to assess or predict, it is currently resulting in significant disruption of global financial markets. This disruption, if sustained or recurrent, could have a material adverse effect on our operating results, our ability to raise capital needed to develop and commercialize products and our overall financial condition. In addition, a recession or market correction resulting from the spread of the coronavirus could materially affect the value of our common stock.

The extent of the impact of the COVID-19 pandemic on our business is uncertain and difficult to predict, as the pandemic continues to rapidly evolve. The ultimate impact of the COVID-19 pandemic or a similar health pandemic or epidemic is highly uncertain and subject to change. We do not yet know the extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. These effects could have a material impact on our operations, and we will continue to monitor the COVID-19 pandemic closely.

Changes in estimates regarding fair value of intangible assets may result in an adverse impact on our results of operations.

We test goodwill and in-process research and development for impairment annually or more frequently if changes in circumstances or the occurrence of events suggest impairment exists. The test for impairment of in-process research and development requires us to make several estimates about fair value, most of which are based on projected future cash flows. Changes in these estimates may result in the recognition of an impairment loss in our results of operations. An impairment analysis is performed whenever events or changes in circumstances indicate that the carrying amount of any individual asset may not be recoverable. For example, if we or our counterparties fail to perform our respective obligations under an agreement, or if we lack sufficient funding to develop our product candidates, an impairment may result. In addition, any significant change in market conditions, estimates or judgments used to determine expected future cash flows that indicate a reduction in carrying value may give rise to impairment in the period that the change becomes known.

Our ability to use net operating losses ("NOL") carryforwards may be limited.

Our ability to use our federal and state NOL carryforwards to offset potential future taxable income is dependent upon our generation of future taxable income before the expiration dates of the NOL carryforwards, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOL carryforwards. As of December 31, 2020, we had approximately $102.8 million of federal NOL carryforwards and approximately $98.6 million of state NOL carryforwards. Our federal NOL carryforwards will begin to expire in 2030, if not utilized. Under the Tax Cuts and Jobs Act enacted in 2017 (the "Tax Act"), as modified by the Coronavirus Aid, Relief, and Economic Security Act enacted in 2020 ("CARES Act"), federal NOL carryforwards generated in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such NOL carryforwards in taxable years beginning after December 31, 2020 is limited to 80% of taxable income. Many states have similar laws. Accordingly, our federal and state NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), federal NOL carryforwards may become subject to an annual limitation in the event of certain cumulative changes in our ownership. An "ownership change" pursuant to Section 382 of the Code generally occurs if one or more stockholders or groups of stockholders who own at least 5% of the company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. If substantial changes in ownership have occurred, there could be annual limitations on the amount of NOL carryforwards that can be realized in future periods. It is possible that some or all of our existing or future NOL carryforwards could be limited by the provisions of Section 382 of the Tax Code as a result of future changes in ownership, including as a result of subsequent sales of securities by us or our stockholders. Further, state NOL carryforwards may be similarly limited. Any such disallowances may result in greater tax liabilities than we would incur in the absence of such a limitation and any increased liabilities could adversely affect our business, results of operations, financial condition and cash flow.

Risks Related to Our Business and Industry

We cannot give any assurance that any of our product candidates will receive regulatory approval in a timely manner or at all, which is necessary before they can be commercialized.

The regulatory approval process is expensive and the time required to obtain approval from the EMA, FDA or other regulatory authorities in other jurisdictions to sell any product is uncertain and may take years.

Whether regulatory approval will be granted is unpredictable and depends upon numerous factors, including the substantial discretion of the regulatory authorities. Moreover, the filing of a marketing application, including a New Drug Application ("NDA"), or Biologics License Application ("BLA"), requires a payment of a significant user fee upon submission. The filing of marketing applications for our product candidates may be delayed due to our lack of financial resources to pay such user fee.

If, following submission, our application is not accepted for substantive review or approval, the EMA, FDA or other comparable foreign regulatory authorities may require that we conduct additional clinical or pre-clinical trials, provide additional data, manufacture additional validation batches or develop additional analytical tests methods before they will reconsider our application. If the EMA, FDA or other comparable foreign regulatory authorities requires additional studies or data, we would incur increased costs and delays in the marketing approval process, which may require us to expend more resources than we have available. In addition, the EMA, FDA or other comparable foreign regulatory authorities may not consider any additional required trials, data or information that we perform or provide to be sufficient, or we may decide, or be required, to abandon the program.

Moreover, policies, regulations, or the type and amount of pre-clinical and clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. It is possible that none of our existing product candidates or any of our future product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- The EMA, FDA or other regulatory authorities may disagree with the design or implementation of our clinical trials. We have not yet consulted with the EMA or the FDA on the design and conduct of the clinical trials that have already been conducted or that we intend to conduct. Thus, the EMA, FDA and other comparable foreign authorities may not agree with the design or implementation of these trials. We intend to seek guidance from the EMA in relation to the European Union clinical trial program and the FDA on the design and conduct of clinical trials of our compounds when we initiate a clinical program in the United States in the future.
- We may be unable to demonstrate to the satisfaction of the EMA, FDA or other regulatory authorities that a product candidate is safe and effective for its proposed indication.
- The results of clinical trials may not meet the level of statistical significance required by the EMA, FDA or other regulatory authorities for approval.
- We may be unable to demonstrate that a product candidate's clinical and other benefits outweigh any safety risks.
- The EMA, FDA or other regulatory authorities may disagree with our interpretation of data from pre-clinical studies or clinical trials.
- The data collected from clinical trials of our product candidates may not be sufficient to support an NDA or other submission or to obtain regulatory approval in the United States or elsewhere.
- The EMA, FDA or other regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies.
- The approval policies or regulations of the EMA, FDA or other regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Even if we obtain approval for a particular product, regulatory authorities may approve that product for fewer or more limited indications, including more limited patient populations, than we request, may require that contraindications, warnings, or precautions be included in the product labeling, including a black box warning, may grant approval contingent on the performance of costly post-marketing clinical trials or other post-market requirements, including risk evaluation and mitigation strategies, or REMS, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product. Any of the foregoing could materially harm the commercial prospects for our product candidates.

Results of earlier clinical trials may not be predictive of the results of later-stage clinical trials.

The results of pre-clinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Interpretation of results from early, usually smaller, trials that suggest positive trends in some subjects, require caution. Results from later stages of clinical trials enrolling more subjects may fail to show the desired safety and efficacy results or otherwise fail to be consistent with the results of earlier trials of the same product candidate. This may occur for a variety of reasons, including differences in trial design, trial endpoints (or lack of trial endpoints in exploratory studies), subject population, number of subjects, subject selection criteria, trial duration, drug dosage and formulation or due to the lack of statistical power in the earlier trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials.

The results of clinical trials conducted at sites outside the United States may not be accepted by the FDA and the results of clinical trials conducted at sites in the United States may not be accepted by international regulatory authorities.

We plan to conduct our clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data would be subject to certain conditions imposed by the FDA. For example, the clinical trial must be well-designed and conducted and performed by qualified investigators in accordance with ethical safeguards such as institutional review board, or IRB, or ethics committee approval and informed consent. The study population must also adequately represent the applicable United States population, and the data must be applicable to the American population and medical practice in ways that the FDA deems clinically meaningful. In addition, while clinical trials conducted outside of the United States are subject to the applicable local laws, FDA acceptance of the data from such trials will be dependent upon its determination that the trials were conducted consistent with all applicable United States laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside of the United States as adequate support of a marketing application, and it is not unusual for the FDA to require some Phase 3 clinical trial data to be generated in the United States. If the FDA does not accept the data from our international clinical trials, it would likely result in the need for additional trials in the United States, which would be costly and time-consuming and could delay or permanently halt the development of one or more of our product candidates.

If we experience delays in clinical testing, we will be delayed in commercializing our product candidates, our costs may increase and our business may be harmed.

We do not know whether our clinical trials will be completed on schedule, or at all. Our product development costs will increase if we experience delays in clinical testing. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may harm our business, results of operations and prospects.

The commencement and completion of clinical development can be delayed or halted for a number of reasons, including:

- difficulties obtaining regulatory approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;
- delays in reaching or failure to reach agreement on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- deviations from the trial protocol by clinical trial sites and investigators, or failing to conduct the trial in accordance with regulatory requirements;
- failure of our third parties, such as CROs, to satisfy their contractual duties or meet expected deadlines;
- insufficient or inadequate supply or quantity of product material for use in trials due to delays in the importation and manufacture of clinical supply, including delays in the testing, validation, and delivery of the clinical supply of the investigational drug to the clinical trial sites;
- delays in identification and auditing of central or other laboratories and the transfer and validation of assays or tests to be used;
- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- difficulties obtaining IRB or ethics committee approval to conduct a trial at a prospective site, or complying with conditions imposed by IRBs or ethics committees;
- challenges recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including competition from other programs for the treatment of similar conditions;
- severe or unexpected drug-related adverse events experienced by subjects in a clinical trial;
- difficulty retaining subjects who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, which are common among schizophrenia and MDD subjects who we require for our clinical trials of our product candidate roluperidone;
- delays in adding new investigators and clinical sites;
- withdrawal of clinical trial sites from clinical trials;
- lack of adequate funding; and
- clinical holds or termination imposed by the European Union national regulatory authorities, the FDA or IRBs or ethics committees.

Clinical trials may also be delayed as a result of ambiguous or negative interim results. In addition, clinical trials may be suspended or terminated by us, an IRB or ethics committee overseeing the clinical trial at a trial site (with respect to that site), the European Union national regulatory authorities or the FDA due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements, the trial protocols and applicable laws;
- observations during inspection of the clinical trial operations or trial sites by the EMA, FDA or other comparable foreign regulatory authorities that ultimately result in the imposition of a clinical hold;
- unforeseen safety issues; or
- lack of adequate funding to continue the clinical trial.

Failure to conduct a clinical trial in accordance with regulatory requirements, the trial protocols and applicable laws may also result in the inability to use the data from such trial to support product approval. Additionally, changes in regulatory requirements and guidance may occur, and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to the EMA, FDA, IRBs or ethics committees for reexamination, which may impact the costs, timing and successful completion of a clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of a clinical trial may also ultimately lead to the denial of regulatory approval of the associated product candidate. If we experience delays in completion of, or if we terminate any of our clinical trials, our ability to obtain regulatory approval for our product candidates may be materially harmed, and our commercial prospects and ability to generate product revenues will be diminished.

We have no experience in advancing product candidates beyond Phase 3, which makes it difficult to assess our ability to develop and commercialize our product candidates.

We have no experience in progressing clinical trials past Phase 3, obtaining regulatory marketing approvals or commercializing product candidates. We merged with Sonkei and acquired Mind-NRG and have limited operating history since the respective merger and acquisition. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in pursuing our business objectives. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

If we are unable to enroll subjects in clinical trials, we will be unable to complete these trials on a timely basis or at all.

The timely completion of clinical trials largely depends on subject enrollment. Many factors affect subject enrollment, including:

- the size and nature of the subject population;
- the number and location of clinical sites we enroll;
- competition with other companies for clinical sites or subjects;
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;
- inability to obtain and maintain subject consents;
- risk that enrolled subjects will drop out before completion; and
- clinicians' and subjects' perceptions as to the potential advantages or disadvantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials in Europe and, we expect, eventually in the United States and, while we have agreements governing their committed activities, we have limited influence over their actual performance. We may also experience difficulties enrolling subjects for our clinical trials relating to roluperidone due to the mental health of the subjects that we will need to enroll, related diagnoses and drop-out rates.

Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which could prevent or delay regulatory approval and commercialization, and also increase costs.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive pre-clinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication, and failures can occur at any stage of testing. Clinical trials often fail to demonstrate safety and statistically significant efficacy of the product candidate studied for the target indication in later stages of clinical development. For example, a Phase 2b trial in MDD with respect to a drug that we were previously developing, MIN-117, failed to achieve its primary endpoint, and we decided to discontinue development of MIN-117 for MDD. Furthermore, the FDA has expressed certain concerns with respect to roluperidone and our continuing Phase 3 and any future trials with roluperidone may fail to demonstrate safety and efficacy. Regulatory authorities may find that our studies do not support, in combination with other studies, approval of our product candidates for the target indication. In addition, our product candidates may be associated with undesirable side effects or have characteristics that are unexpected, which may result in abandoning their development or regulatory authorities restricting or denying marketing approval. For instance, prior clinical studies indicated that roluperidone and MIN-117 may cause adverse events, including, but not limited to, dizziness, vital sign changes, central nervous system events, cardiac events, including prolongation of the QT/QTc interval, and gastrointestinal events. Most product candidates that commence clinical trials are never approved by the applicable regulatory authorities.

In the case of our product candidate roluperidone, we are seeking to develop a treatment for schizophrenia, which adds a layer of complexity to our clinical trials and may delay regulatory approval. The cause and pathophysiology of schizophrenia are not fully understood, and our results will rely on subjective feedback from patients, caregivers and healthcare providers, which is inherently difficult to evaluate, can be influenced by factors outside of our control and can vary widely from day to day for a particular subject, and from subject to subject and site to site within a clinical study. The placebo effect may also have a more significant impact on our clinical trials.

If our product candidates are not shown to be both safe and effective in clinical trials, we will not be able to obtain regulatory approval or commercialize our product candidates.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and management resources, we focus on a limited number of research programs and product candidates. For instance, at the present time we are prioritizing the clinical trials and development of the most advanced of our product candidates, roluperidone. As a result, we may forego or delay pursuit of opportunities with other product candidates, including MIN-301, or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

Even if we complete the necessary clinical trials, we cannot predict when or if we will obtain marketing approval to commercialize a product candidate or the approval may be for a narrower indication than we expect.

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our product candidates demonstrate safety and efficacy in clinical trials, the regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain marketing approval from the relevant regulatory agencies. Additional delays may result if the EMA, FDA, an FDA Advisory Committee, or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials and the review process.

Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties, including ongoing regulatory obligations and continued regulatory review. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to administrative sanctions or penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Even if we obtain regulatory approval for a product candidate, product candidates may be approved for fewer or more limited indications, including more limited subject populations, than we request, and regulatory authorities may require that contraindications, warnings, or precautions be included in the product labeling, including a black box warning, may grant approval contingent on the performance of costly post-marketing clinical trials or other post-market requirements, such as REMS, may require post-marketing surveillance, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. For instance, in 2007, the FDA requested that makers of all antidepressant medications update existing black box warnings about increased risk of suicidal thoughts and behavior in young adults, ages 18 to 24, during initial treatment. If approved for marketing, our drugs may be required to carry warnings similar to this and other class-wide warnings.

Any approved products would further be subject to ongoing requirements imposed by the EMA, FDA, and other comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, marketing, recordkeeping and reporting of safety and other post-market information. If there are any modifications to the drug, including changes in indications, labeling, manufacturing processes or facilities, or if new safety issues arise, a new or supplemental NDA, post-implementation notification or other reporting may be required or requested, which may require additional data or additional pre-clinical studies and clinical trials.

The EMA, FDA and other comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the EMA, FDA or other comparable foreign regulatory authorities become aware of new adverse safety information after approval of any of our product candidates, a number of potentially significant negative consequences could result, including:

- we may suspend marketing of, or withdraw or recall, such product;
- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings or otherwise restrict the product’s indicated use, label, or marketing;
- the EMA, FDA or other comparable foreign regulatory bodies may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- the FDA may require the establishment or modification of a REMS or the EMA or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, require us to issue a

medication guide outlining the risks of such side effects for distribution to subjects or restrict distribution of our products and impose burdensome implementation requirements on us;
- regulatory authorities may require that we conduct post-marketing studies or surveillance;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

In addition, manufacturers of drug products and their facilities, including contracted facilities, are subject to continual review and periodic inspections by national regulatory authorities in the European Union, the FDA and other regulatory authorities for compliance with current Good Manufacturing Practices, or cGMP, regulations and standards. The European Union cGMP guidelines are as set forth in Commission Directive 2003/94/EC of October 8, 2003. If we or a regulatory agency or authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, the product's stability (changes in levels of impurities or dissolution profile) or problems with the facility where the product is manufactured, we may be subject to reporting obligations, additional testing and additional sampling, and a regulatory agency or authority may impose restrictions on that product, the manufacturing facility, our suppliers, or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates, the manufacturing facilities for our product candidates, our CROs, or other persons or entities working on our behalf fail to comply with applicable regulatory requirements either before or after marketing approval, a regulatory agency may, depending on the stage of product development and approval:

- issue adverse inspectional findings;
- issue Warning Letters or Untitled Letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- amend and update labels or package inserts;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil, criminal and/or administrative penalties, damages or monetary fines or imprisonment;
- suspend or withdraw regulatory approval;
- suspend or terminate any ongoing clinical studies;
- bar us from submitting or assisting in the submission of new regulatory applications;
- refuse to approve pending applications or supplements to applications filed by us;
- refuse to allow us to enter into government contracts;
- suspend or impose restrictions on operations, including restrictions on marketing or manufacturing of the product, or the imposition of costly new manufacturing requirements or use of alternative suppliers; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

Our product candidates and the activities associated with their development and commercialization in the United States, including, but not limited to, their advertising and promotion, will further be heavily scrutinized by the FDA, the United States Department of Justice, the United States Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress and the public. Violations of applicable law, including advertising, marketing and promotion of our products for unapproved (or off-label) uses, are subject to enforcement letters, inquiries and investigations, and civil, criminal and/or administrative sanctions by regulatory agencies. Additionally, comparable foreign regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval outside of the United States. In this regard, advertising and promotion of medicines in the European Union is governed by Directive 2001/83 EC, as amended, and any such activities which we may undertake in the European Union will have to be in strict compliance with the same. Any advertising of a prescription medicinal product to the public and any promotion of a medicinal product that does not have marketing authorization or is not promoted in accordance with that marketing authorization is prohibited. Advertisements and promotions of medicinal products are monitored nationally in the European Union, and each country will have its own additional advertising laws and industry governing bodies, whose obligations may go further than those set out in Directive 2001/83. For instance, in the United Kingdom the code of practice of the Association of the British Pharmaceutical Industry (the lead United Kingdom trade association) is considerably stricter than applicable legislative requirements. Any violations and sanctions will similarly be decided and administered by the relevant country's national authority.

In the United States, engaging in the impermissible promotion of products for off-label uses can also subject the entity engaging in such conduct to false claims litigation under federal and state statutes, which can lead to civil, criminal and/or administrative penalties, damages, monetary fines, disgorgement, exclusion from participation in Medicare, Medicaid and other federal healthcare programs, curtailment or restructuring of its operations and agreements that materially restrict the manner in which it promotes or distributes drug products. Accordingly, we are subject to the federal civil False Claims Act, which prohibits persons and entities from knowingly filing, or causing to be filed, a false claim, or the knowing use of false statements, to obtain payment from the federal government. Certain suits filed under the civil False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "whistleblowers," may share in certain amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the civil False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Various states have also enacted laws modeled after the federal civil False Claims Act. We are also subject to the federal criminal False Claims Act, which imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing

such claim to be false, fictitious, or fraudulent. Additionally, we may be subject to civil monetary penalties that may be imposed against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to substantial civil and criminal settlements regarding certain sales practices, including promoting off-label drug uses. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claims action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and/or be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our products, we may become subject to such litigation, which may have a material adverse effect on our business, financial condition and results of operations.

While no definition of "off-label use" exists at the European Union level, promotion of a medicinal product for a purpose that has not been approved is strictly prohibited. Such promotion also gives rise to criminal prosecution in the European Union, and national healthcare supervisory authorities may impose administrative fines. Engaging in such promotions in the European Union could also lead to product liability claims, in accordance with EU product liability regime under Directive 85/374.

The EMA's, FDA's, and other applicable government agencies' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval and marketing authorization, and the sale and promotion of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and be subject to civil, criminal and administrative enforcement, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

The regulatory pathway for our product candidate, MIN-301, has not yet been determined. Depending on the pathway, we may be subject to different regulatory requirements.

MIN-301 is a peptide, and, as a peptide, may be subject to the Public Health Service Act, or PHSA, and the Food, Drug, and Cosmetic Act, or FDCA. We have yet to meet with the FDA regarding the approval pathway for this product candidate. Based on the definition of a biologic in the PHSA, we believe that MIN-301 meets the definition of a biologic and, thus, we will need to submit a Biologics License Application, or BLA, for product approval. Moreover, based on an FDA intercenter agreement, we believe that MIN-301 will be regulated by the FDA's Center for Drug Evaluation and Research. However, we intend to discuss jurisdiction with the FDA to determine the appropriate regulatory pathway and corresponding requirements. Depending on the pathway, we may be subject to different regulatory requirements, including different regulatory and testing requirements, shorter or longer periods of market exclusivity, and different approval processes for generic drug and biosimilar competitors.

If the market opportunities for any product that we or our collaborators develop are smaller than we believe, our revenue may be adversely affected and our business may suffer.

Our product candidates are intended for the treatment of schizophrenia, MDD, and Parkinson's disease. Our projections of both the number of people who have these disorders or diseases, as well as the subsets of people who have the potential to benefit from treatment with our product candidates and who will pursue such treatment, are based on our beliefs and estimates that may prove to be inaccurate. For instance, with respect to schizophrenia and MDD, our estimates are based on the number of patients that suffer from schizophrenia and MDD, but these disorders are difficult to accurately diagnose and high rates of patients may not seek or continue treatment. Our estimates and beliefs are also based on the potential market of other drugs in development for schizophrenia and MDD, which may prove to be inaccurate and our advantages over such drugs may not be, or may not be perceived to be, as significant as we believe they are. If our estimates prove to be inaccurate, even if our products are approved, we may not be able to successfully commercialize them. In addition, the cause and pathophysiology of schizophrenia and MDD are not fully understood, and additional scientific understanding and future drug or non-drug therapies may make our product candidates obsolete.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates are developed through pre-clinical to late stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or future clinical trials to be conducted with the altered materials. Such changes may also require additional testing, EMA or FDA notification or EMA or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and/or jeopardize our ability to commence product sales and generate revenue.

Our failure to obtain regulatory approval in additional international jurisdictions would prevent us from marketing our product candidates outside the European Union and the United States.

We plan to seek regulatory approval to commercialize our product candidates in the European Union and the United States. We also expect to seek regulatory approval in additional foreign countries. To market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain EMA or FDA approval. The regulatory approval process outside the European Union and United States generally includes risks substantially similar to those associated with obtaining EMA or FDA approval. In addition, in many countries outside the United States, we must secure product price and reimbursement approvals before regulatory authorities will approve the product for sale in that country or within a short time after receiving such marketing approval. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Also, regulatory approval for any of our product candidates may be withdrawn. If we fail to comply with the regulatory requirements in international markets or do not receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all, especially because some foreign jurisdictions require prior approval of a treatment by the domestic regulatory agency. Our failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business prospects could decline.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than us.

The biopharmaceutical industry is intensely competitive and subject to rapid and significant technological change. We face competition with respect to our current product candidates and will face competition with respect to any future product candidates from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our competitors may obtain regulatory approval of their products more rapidly than us or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used, less costly and/or have a better safety profile than our products, and competitors may also be more successful than us in manufacturing and marketing their products.

Our competitors will also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

There are numerous currently approved therapies for treating the same diseases or indications for which our product candidates may be useful and many of these currently approved therapies act through mechanisms similar to our product candidates. Many of these approved drugs are well-established therapies or products and are widely accepted by physicians, patients and third-party payors. Some of these drugs are branded and subject to patent protection and regulatory exclusivity, while others are available on a generic basis. Insurers and other third-party payors may encourage the use of generic products or specific branded products. Moreover, it is difficult to predict the effect that introduction of biosimilars into the market will have on sales of the reference biologic product, which will depend on the FDA's standards for interchangeability, the structure of government and commercial managed care formularies, and state laws on substitution of biosimilars. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generics and biosimilars. This may make it difficult for us to differentiate our products from currently approved therapies, which may adversely impact our business strategy. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability, and safety in order to overcome price competition and to be commercially successful. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer. Moreover, many companies are developing new therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development.

Even if any of our drug candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our drug candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant revenue from drug sales and we may not become profitable. Our commercial success also depends on coverage and adequate reimbursement of our products by third-party payors, including government payors, which may be difficult or time-consuming to obtain, may be limited in scope or may not be obtained in all jurisdictions in which we may seek to market our products. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and perceived and potential advantages compared to alternative treatments, including any similar generics and biosimilars;
- the timing of market introduction relative to alternative treatment;
- our ability to offer our drugs for sale at competitive prices relative to alternative treatments;
- the clinical indications for which the product candidate is approved;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of our marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for our products or the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors;
- unfavorable publicity relating to the products;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our drugs together with other medications.

Our focus on CNS disorders, in particular, exposes us to an increased risk that serious side effects and disease events, including suicide, will occur during patient use of our products, even if such side effects and disease events are unrelated to the use of our products. Most approved CNS medicines carry boxed warnings for clinically significant adverse events, and our products may categorically need to carry such warnings as well.

We currently have a limited marketing and sales organization. If we are unable to establish greater marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to effectively market and sell our product candidates, if approved, or generate product revenues.

We currently have a limited marketing or sales organization for the marketing, sales and distribution of pharmaceutical products. In order to commercialize any product candidates, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We may not be successful in doing so on commercially reasonable terms or at all.

If our product candidates receive regulatory approval, we intend to establish our sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time consuming and may require substantial investments prior to any product candidate being granted regulatory approval. In selling, marketing and distributing our products ourselves, we face a number of additional risks, including:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the clinical benefits of our products to achieve market acceptance;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- the costs associated with training sales personnel on legal compliance matters and monitoring their actions;
- liability for sales personnel failing to comply with the applicable legal requirements; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products.

We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we enter into arrangements with third parties to perform sales, marketing and distribution services for our products, the resulting revenues or the profitability from these revenues to us are likely to be lower than if we had sold, marketed and distributed our products ourselves. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval. Depending on the nature of the third party relationship, we may have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell, market and distribute our products effectively.

If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

Even if we commercialize any of our product candidates, these products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The laws that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. In many countries, the pricing review period begins after marketing or product licensing approval is granted. Some countries require approval of the sale price of a drug before it can be marketed or soon thereafter. Additionally, in some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates even if our product candidates obtain marketing approval.

In the European Union, the pricing and reimbursement of prescription drugs is controlled by each member state. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures in the current economic climate in Europe. There is very limited harmonization on member state pricing and reimbursement practices in the European Union.

Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In particular, Germany, Portugal and Spain have all introduced a number of short-term measures to lower healthcare spending, including mandatory discounts, clawbacks and price referencing rules, which could have a material adverse effect on our business.

Our ability to commercialize any products successfully will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities and other third-party payors, such as private health insurers and health maintenance organizations. Government authorities and other third-party payors determine which medications they will cover and establish reimbursement levels. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

Government authorities and other third-party payors are developing increasingly sophisticated methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices as a condition of coverage, are using restrictive formularies and preferred drug lists to leverage greater discounts in competitive classes, and are challenging the prices charged for medical products. In addition, in the United States, federal programs impose penalties on drug manufacturers in the form of mandatory additional rebates and/or discounts if commercial prices increase at a rate greater than the Consumer Price Index-Urban, and these rebates and/or discounts, which can be substantial, may impact our ability to raise commercial prices. Further, in the United States there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. We expect that additional U.S. federal healthcare

reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Additionally, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the EMA, FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Prices paid for a drug also vary depending on the class of trade. Prices charged to government customers and certain customers that receive federal funds are subject to price controls, and private institutions may obtain discounts through group purchasing organizations or use formularies to leverage discounts. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the state level, legislatures are passing increasing amounts of legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Recently enacted and future legislation may increase the difficulty and cost for us to commercialize our product candidates and affect the prices we may obtain.

In the United States and many foreign jurisdictions, the legislative landscape continues to evolve. There have been a number of enacted or proposed legislative and regulatory changes affecting the healthcare system and pharmaceutical industry that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidate for which we obtain marketing approval.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the ACA, broadened access to health insurance, reduced or constrained the growth of healthcare spending, enhanced remedies against healthcare fraud and abuse, add imposed new transparency requirements for healthcare and health insurance industries, imposed new taxes and fees on pharmaceutical manufacturers and imposed additional health policy reforms. Since the ACA's enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. It is unclear how efforts to repeal and replace the ACA will impact the ACA and our business.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities

can take considerable time after the receipt of marketing approval for a drug. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a health technology assessment that compares the cost-effectiveness of our drug candidate to other available therapies. There can be no assurance that our products will be considered cost-effective, that an adequate level of reimbursement will be available or that a foreign country's reimbursement policies will not adversely affect our ability to sell our products profitably.

If reimbursement of our drugs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

Our international operations are subject to foreign currency and exchange rate risks.

Because we plan to continue to conduct our clinical trials in Europe, we are exposed to currency fluctuations and exchange rate risks. The costs of our CROs may be incurred in Euros and we may pay them in Euros, however, we expect to keep the substantial portion of our cash, cash equivalents, marketable securities and private placement transactions, in United States Dollars. Therefore, fluctuations in foreign currencies, especially the Euro, could significantly impact our costs of conducting clinical trials. In addition, we may have to seek additional funding earlier than expected, which may not be available on acceptable terms or at all. Changes in the applicable currency exchange rates might negatively affect the profitability and business prospects of the third parties conducting our future clinical trials. This might cause such third parties to demand higher fees or discontinue their operations. These situations could in turn increase our costs or delays our clinical development, which could have a material adverse effect on our business, financial condition and results of operations.

A variety of risks associated with international operations could materially adversely affect our business.

We own one Swiss subsidiary, expect to engage in significant cross-border activities, and we will be subject to risks related to international operations, including:

- different regulatory requirements for maintaining approval of drugs in foreign countries;
- reduced protection for contractual and intellectual property rights in certain countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, political instability in particular foreign economies and markets, or public health issues or pandemics, such as the coronavirus;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- compliance with tax laws of various jurisdictions, including with respect to intercompany transfer pricing arrangements and taxable nexus;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in North America;
- tighter restrictions on privacy and the collection and use of patient data; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including pandemics, earthquakes, typhoons, floods and fires.

If any of these issues were to occur, our business could be materially harmed.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, especially Dr. Remy Luthringer, whose services are critical to the successful implementation of our product candidate development and regulatory strategies. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. In order to induce valuable employees to continue their employment with us, we have provided stock options that vest over time. The value to employees of stock options that vest over time is significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies.

Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Pursuant to their employment arrangements, each of our executive officers may voluntarily terminate their employment at any time by providing as little as thirty days advance notice. Our employment arrangements, other than those with our executive officers, provide for at-will employment, which means that any of our employees (other than our executive

officers) could leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, financial condition and prospects. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior scientific and medical personnel.

We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical, biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we have to offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize product candidates will be limited.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2020, we had 11 full-time employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including:

- managing our clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, collaborators, contractors and other third parties;
- improving our managerial, development, operational and finance systems; and
- developing our compliance infrastructure and processes to ensure compliance with complex regulations and industry standards regarding us and our product candidates.

As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, collaborators, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

Future acquisitions, mergers or joint ventures could disrupt our business and otherwise harm our business.

We actively evaluate various strategic transactions on an ongoing basis and may acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures or investments in complementary businesses. We merged with Sonkei in November 2013 and acquired Mind-NRG in February 2014, but otherwise do not have any substantial experience integrating or managing acquired businesses or assets. Strategic transactions expose us to many risks, including:

- disruption in our relationships with collaborators or suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- retention of key employees;
- diversion of management time and focus from operating our business to management of strategic alliances or joint ventures or acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses; and
- possible write-offs or impairment charges relating to acquired businesses.

Foreign acquisitions, such as the acquisition of Mind-NRG, a Swiss company, involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

Also, the anticipated benefit of any strategic alliance, joint venture or acquisition may not materialize. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt (including on terms that are unfavorable to us that we are unable to repay or that may place burdensome restrictions on our operations), contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties brought by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates, if approved. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or products that we may develop;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling revisions, marketing or promotional restrictions;
- loss of revenues from product sales; and
- the inability to commercialize our product candidates.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We do not currently carry any product liability insurance. Although we anticipate obtaining and maintaining such insurance in line with our needs for our upcoming trials, such insurance may be more costly than we anticipate and any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by such insurance or that is in excess of the limits of such insurance coverage. We also expect our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, outbreaks of contagious diseases, such as coronavirus, terrorism, war and telecommunication and electrical failures. For example, a cyber-attack on one of our external contractors during the summer of 2019 resulted in a disruption to patient recruitment in our Phase 3 clinical trial of roluperidone. Further similar events could occur and cause interruptions in our operations, and could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

We are required to comply with the SEC's rules that implement Section 404 of the Sarbanes-Oxley Act and the Committee on Sponsoring Organizations, or COSO, Report on Internal Control – Integrated Framework, which require, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. Under Section 404 of the Sarbanes-Oxley Act, we are required to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment must include disclosure of any material weaknesses identified by management in our internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

Our compliance with Section 404 requires that we compile the system and process documentation necessary to perform an appropriate evaluation. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. While we have established certain procedures and control over our financial reporting processes, we cannot assure you that these efforts will prevent restatements of our financial statements in the future. If we identify any future significant deficiencies or material weaknesses, the accuracy and timing of our financial reporting may be adversely affected and we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and business prospects. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. We designed our disclosure controls and procedures to reasonably assure us that the information we disclose in reports we file in accordance with the Exchange Act is accurate, complete, reviewed by management and reported within the required time period. We believe that any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Prior to November 2013, we operated without full-time employees, relying on the services of consultants, including representatives of our former affiliate, Care Capital LLC, to provide certain accounting and finance functions. We have since hired personnel and continue to develop our disclosure control procedures; however, if we are unsuccessful in building an appropriate infrastructure, or unable to develop procedures and controls to ensure timely and accurate reporting, we may be unable to meet our disclosure requirements under the Exchange Act, which could adversely affect the market price of our common stock and impair our access to the capital markets.

Our employees, independent contractors, principal investigators, CROs, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees and independent contractors, such as principal investigators, CROs, manufacturers, consultants, commercial partners and vendors, could include failures to comply with EMA or FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with European, federal and state healthcare fraud and abuse laws, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including, but not limited to certain activities related to research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee and independent contractor misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in sanctions, monetary penalties, and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct.

We have adopted a code of business ethics and conduct, but it is not always possible to identify and deter employee and independent contractor misconduct, and the precautions we take to detect and prevent improper activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

Any relationships with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third-party payors in connection with our current and future business activities may and may continue to be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, marketing expenditure tracking and disclosure (or "sunshine") laws, government price reporting, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations.

Our business operations and activities may be directly, or indirectly, subject to various federal, state and local healthcare laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as proposed and future sales, marketing and education programs. In addition, we may be subject to patient data privacy and security regulation by the federal government, state governments and foreign jurisdictions in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the referral of an individual for the furnishing or arranging for the furnishing of any item or service, or the purchase, lease, order, arrangement for, or recommendation of the purchase, lease, or order of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs.
- The federal civil False Claims Act, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; conspiring to defraud the government by getting a false or fraudulent claim paid or approved by the government; or knowingly making, using or causing to be made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government.
- The federal criminal False Claims Act, which imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false, fictitious or fraudulent.
- The civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.
- The Veterans Health Care Act of 1992 that requires manufacturers of "covered drugs" to offer them for sale to certain federal agencies, including but not limited to, the Department of Veterans Affairs, on the Federal Supply Schedule, which requires compliance with applicable federal procurement laws and regulations and subjects manufacturers to contractual remedies as well as administrative, civil and criminal sanctions.
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their respective business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements.
- The federal Physician Payments Sunshine Act and its implementing regulations requires manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace and other activities that potentially harm consumers.

- State law equivalents of each of the above federal laws, such as anti-kickback, false claims, consumer protection and unfair competition laws which may apply to our business practices, including but not limited to our research, distribution, sales and marketing arrangements and our practices for submitting claims involving healthcare items or services reimbursed by any third-party payors, including commercial insurers. State laws may also (1) require that pharmaceutical companies comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restrict the payments that may be made to healthcare providers, (2) require that drug manufacturers file reports with states regarding marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on a pharmaceutical company's business and/or increase enforcement scrutiny of its activities), (3) require the reporting of information related to drug pricing, ,and (4) govern the privacy and security of health information in certain circumstances. State laws are not uniform, may differ from each other in significant ways and may be applied with differing effects.

In addition, any sales of our products or product candidates once commercialized outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws such as, for instance, the UK Bribery Act 2010 other national anti-corruption legislation made as a consequence of a member states' adherence to the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, the European Union data protection regime set out in Directive 95/46/EC as implemented nationally by the member states, and European Union consumer laws protecting against defective products, including Directive 85/374/EEC. In addition, there are national laws and codes which are comparable to the United States "sunshine laws," including certain provisions under the UK ABPI Code of Practice and French disclosure requirements on manufacturers to publicly disclose interactions with French health care professionals.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to, without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

We are subject to the Foreign Corrupt Practices Act.

The Foreign Corrupt Practices Act, or the FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and debarment from government contracts.

We and our service providers are subject to EU data protection laws. Failure to comply with such laws could harm our financial condition and operating results and involve distraction from other aspects of our business.

In October 2015, the Court of Justice of the European Union (CJEU) invalidated the EU-U.S. Safe Harbor Framework, which had established a means for legitimating the transfer of personal data, as the term is used in the context of the EU Data Protection Directive, to the U.S. and required U.S.-based companies that have certified with the Department of Commerce as part of the Safe Harbor Framework to provide assurance that they are adhering to relevant European standards for data protection. As Minerva is not Safe Harbor certified, the CJEU's ruling invalidating the Safe Harbor has no direct effect on Minerva's own compliance with EU data protection laws; however, in light of the CJEU's recent decision, we are reviewing the practices of third party service providers with whom we work, which include the transfer of personal data between the European Economic Area ("EEA") and the U.S. to ensure that all data transfers to us comply with EU data protection laws. In February 2016, the EU Commission announced that it had reached agreement with the U.S. replacement regime to the Safe Harbor Framework. We require our EEA-based services providers, and U.S.-based service providers undertaking clinical trials on our behalf in the EEA, to confirm that all of the personal data which we receive from them is legitimately transferred to us. In many cases we believe that patients and subjects consent to the transfer of their data in a

manner which satisfies the requirements of EU data protection law. Where appropriate and pending the ratification of the replacement regime, we may require third party service providers to adopt an alternative means of legitimizing data transfers from the EEA, such as the Standard Contractual Clauses which have been approved by the EU Commission as a means of transferring data to the U.S. These confirmations and, if necessary, additional actions may involve substantial time and expense to both Minerva and its third party service providers, and could divert management's attention and resources from other aspects of our business. If data transfers to the U.S. are not legitimized, the EU data protection authorities can impose a number of different sanctions, including fines and, ultimately, a prohibition on transfers, any of which could harm our business, financial condition and operating results.

Risks Related to Our Dependence on Third Parties

We currently rely and continue to expect to rely on third parties to conduct our future clinical trials. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may not obtain regulatory approval for or commercialize our product candidates in a timely manner or at all.

We plan to rely upon third-party CROs to monitor and manage data for our future clinical programs. We will rely on these parties for execution of our clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with current GCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the EMA, FDA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, we must conduct our clinical trials with product produced under cGMP requirements. Failure to comply with these regulations may require us to repeat pre-clinical and clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and pre-clinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If necessary, switching or adding CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, prospects, financial condition and results of operations.

If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, we may need to conduct additional trials, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be adversely affected.

We contract with third parties for the manufacturing of our product candidates for pre-clinical and clinical testing and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products, or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities. For our product candidates, we rely, and expect to continue to rely, on third parties for the manufacturing of our drug candidates for pre-clinical and clinical testing, as well as for commercial manufacture if any of our drug candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates or drugs, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our ability to timely conduct our clinical trials or our other development or commercialization efforts.

We also expect to rely on third-party manufacturers or third-party collaborators for the manufacturing of commercial supply of any other drug candidates for which we or our collaborators obtain marketing approval. We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- disruption and costs associated with changing suppliers, including additional regulatory filings; and
- the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for us.

Moreover, the facilities used by our contract manufacturers to manufacture our products must be approved by the FDA pursuant to inspections that will be conducted after we submit our marketing application to the FDA. Other national regulatory authorities have comparable powers. While we are ultimately responsible for the manufacture of our product candidates, other than through our contractual arrangements, we do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP requirements, for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, other than through our contractual agreements, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved.

Further, our suppliers are subject to regulatory requirements, covering manufacturing, testing, quality control, and record keeping relating to our product candidates, and subject to ongoing inspections by the regulatory agencies. Failure by any of our suppliers to comply with applicable regulations may result in long delays and interruptions to our manufacturing capacity while we seek to secure another supplier that meets all regulatory requirements, as well as market disruption related to any necessary recalls or other corrective actions.

Third-party manufacturers may not be able to comply with cGMP, regulations or similar regulatory requirements outside the United States. Additionally, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical hold or termination, fines, imprisonment, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures, refusal to allow product import or export, Warning Letters, Untitled Letters, or recalls of drug candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our drugs.

Our drug candidates and any drugs that we may develop may compete with other drug candidates and drugs for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacturing of our drug candidates or drugs may adversely affect our future profit margins and our ability to commercialize any drugs that receive marketing approval on a timely and competitive basis.

If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. Our manufacturers are or will be subject to federal, state and local laws in the United States and in Europe governing the use, manufacture, storage, handling and disposal of medical, radioactive and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical, radioactive or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state, federal authorities or other equivalent national authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical radioactive or hazardous materials. Compliance with applicable environmental laws is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

We may engage third party collaborators to market and commercialize our product candidates, who may fail to effectively commercialize our product candidates.

We may utilize strategic partners or contract sales forces, where appropriate, to assist in the commercialization of our product candidates, if approved. We currently possess limited resources and may not be successful in establishing collaborations or co-promotion arrangements on acceptable terms, if at all. We also face competition in our search for collaborators and co-promoters. By entering into strategic collaborations or similar arrangements, we will rely on third parties for financial resources and for development, commercialization, sales and marketing and regulatory expertise. Any collaborators may fail to develop or effectively commercialize our product candidates because they cannot obtain the necessary regulatory approvals, they lack adequate financial or other resources or they decide to focus on other initiatives. Any failure to enter into collaboration or co-promotion arrangements or the failure of our third party collaborators to successfully market and commercialize our product candidates would diminish our revenues and harm our results of operations. In addition, conflicts may arise with our collaborators, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property. If any conflicts arise with our collaborators, they may act in their self-interest, which may be adverse to our best interest.

We depend on our collaboration with Mitsubishi Tanabe Pharma Corporation, or MTPC, and could be seriously harmed if our license agreement with MTPC was terminated.

We exclusively license roluperidone from MTPC, with the rights to develop, sell and import roluperidone globally, excluding most of Asia.

Substantial potential future milestone payments from Royalty Pharma depend on the development and commercialization of seltorexant. We may be obligated to make payments to Royalty Pharma even if Janssen breaches its obligations to pay us.

On January 19, 2021, we entered into an agreement with Royalty Pharma under which Royalty Pharma acquired our royalty interest in seltorexant for an upfront payment of $60 million and up to $95 million in future milestone payments that are contingent upon the achievement of certain clinical, regulatory and commercial milestones for seltorexant by Janssen or any other party in the event that Janssen sells seltorexant.

Therefore, we will only realize future payments if Janssen achieves certain milestones over which we have no control. Some or all of the milestones may never be achieved, and we may never receive any such future payments.

In addition, if Janssen breaches its contractual obligations to pay royalties, we will be obligated to Royalty Pharma to provide makeup payments to compensate for the loss of those royalties, which payments could be substantial.

We may not be successful in establishing new collaborations which could adversely affect our ability to develop future product candidates and commercialize future products.

We may also seek to enter into product collaborations in the future, including alliances with other biotechnology or pharmaceutical companies, to enhance and accelerate the development of our future product candidates and the commercialization of any resulting products. We face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish collaborations or other alternative arrangements for any future product candidates because our research and development pipeline may be insufficient, our product candidates may be deemed to be at too early of a stage of development for collaboration efforts and/or third parties may view our product candidates as lacking the requisite potential to demonstrate safety and efficacy. As a result, we may have to delay the development of a product candidate and attempt to raise significant additional capital to fund development. Even if we are successful in our efforts to establish collaborations, the terms that we agree upon may not be favorable to us and we may not be able to maintain such collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing.

Risks Related to Intellectual Property

If we are unable to obtain or protect intellectual property rights, we may not be able to compete effectively in our market.

Our success depends in significant part on our and our licensors', licensees' or collaborators' ability to establish, maintain and protect patents and other intellectual property rights and operate without infringing the intellectual property rights of others. We have filed numerous patent applications both in the United States and in foreign jurisdictions to obtain patent rights to inventions we have discovered. We have also licensed from third parties rights to patent portfolios. None of these licenses give us the right to prepare, file and prosecute patent applications and maintain patents we have licensed, although we may provide comments on prosecution matters, which our licensors may or may not choose to follow. If our licensors elect to discontinue prosecution or maintenance of our licensed patents, we have the right, at our expense, to pursue and maintain those patents and applications.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors, licensees or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors, licensees or collaborators. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaborators fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors, licensees or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are highly uncertain. Our and our licensors', licensees' or collaborators' pending and future patent applications may not result in patents being issued that protect our technology or products, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our licensors, licensees or collaborators to narrow the scope of the claims of our or our licensors', licensees' or collaborators' pending and future patent applications, which may limit the scope of patent protection that may be obtained. Our and our licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology.

One or more of our owned or licensed patents directed to our proprietary products or technologies may expire or have limited commercial life before the proprietary product or technology is approved for marketing in a relevant jurisdiction.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after our product candidates obtain regulatory approval, which may subject us to increased competition and reduce or eliminate our ability to recover our development costs. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. For example, our in-licensed U.S. and European patents covering composition of matter and pharmaceutical compositions of roluperidone, respectively, are expected to expire as soon as 2021. Finally, any patent that grants from our U.S. patent applications relating to methods of using MIN-301 to treat neurologic and psychiatric diseases is expected to expire as early as 2028. Although we expect to seek extensions of patent terms where available, including in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, which permits a patent term extension of up to five years beyond the expiration of the patent, we cannot be certain that an extension will be granted, or if granted, what the applicable time period or the scope of patent protection afforded during any extended period will be. The applicable authorities, including the EMA, FDA, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and pre-clinical data and launch their product earlier than might otherwise be the case.

The expiration of composition of matter patent protection with respect to one or more of our product candidates may diminish our ability to maintain a proprietary position for our intended uses of a particular product candidate. Moreover, we cannot be certain that we will be the first applicant to obtain an FDA approval for any indication of one or more of our product candidates and we cannot be certain that it will be entitled to new chemical entity, or NCE, exclusivity. Such diminution of our proprietary position could have a material adverse effect on our business, results of operations and financial condition.

We have in-licensed or acquired a portion of our intellectual property necessary to develop our product candidates, and if we fail to comply with our obligations under any of these arrangements, we could lose such intellectual property rights.

We are a party to and rely on several arrangements with third parties, which give us rights to intellectual property that is necessary for the development of our product candidates. In addition, we may enter into similar arrangements in the future. Our current arrangements impose various development, royalty and other obligations on us. If we materially breach these obligations or if our

counterparts fail to adequately perform their respective obligations, these exclusive arrangements could be terminated, which would result in our inability to develop, manufacture and sell products that are covered by such intellectual property.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our issued patents or other intellectual property. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult. Accordingly, for such undetectable infringement or misappropriation our ability to recover damages will be negligible and we could be at a market disadvantage because we may lack the resources of some of our competitors to monitor for and detect infringement. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in any patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly.

We may need to license or acquire additional patents and intellectual property rights.

One or more third parties may hold intellectual property rights, including patent rights, important or necessary to the development of our products. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties on commercially reasonable terms. If we were not able to obtain a license, or were not able to obtain a license on commercially reasonable terms, our business could be harmed, possibly materially.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our products, and to use our related proprietary technologies. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products, including interference or derivation proceedings before the U.S. Patent and Trademark Office, or the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our products. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Under certain circumstances, we could be forced, including by court order, to cease commercializing our products. In addition, in any such proceeding or litigation, we could be found liable for monetary damages. Regardless of the outcome, such claims or litigation may be time-consuming and costly to defend, divert management resources and have other adverse effects on our business.

Restrictions on our patent rights relating to our product candidates may limit our ability to prevent third parties from competing against us.

Our success will depend, in part, on our ability to obtain and maintain patent protection for our product candidates, preserve our trade secrets, prevent third parties from infringing upon our proprietary rights and operate without infringing upon the proprietary rights of others. Composition-of-matter patents on the biological or chemical active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to any method of use. We have filed and in-licensed composition-of-matter patent applications for all of our product candidates. However, we cannot be certain that the claims in our patent applications to inventions covering our product candidates will be considered patentable by the USPTO and courts in the United States or by the patent offices and courts in foreign countries.

In addition to composition-of-matter patents and patent applications, we also have filed method-of-use patent applications. This type of patent protects the use of the product only for the specified method. However, this type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if these competitors do not actively promote their product for our targeted indication, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

Patent applications in the United States and most other countries are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months or more. As a result, we cannot be certain that we and the inventors of the issued patents and applications that we may in-license were the first to conceive of the inventions covered by such patents and pending patent applications or that we and those inventors were the first to file patent

applications covering such inventions. Also, we have a number of issued patents and numerous patent applications pending before the USPTO and foreign patent offices and the patent protection may lapse before we manage to obtain commercial value from them, which might result in increased competition and materially affect our position in the market.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time-consuming, and inherently uncertain. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' or collaborators' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the United States Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors' or collaborators' ability to obtain new patents or to enforce existing and future patents.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents. For example, the Leahy-Smith America Invents Act, or the America Invents Act, includes provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO developed new regulations and procedures to govern administration of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and in particular, the first to file provisions, are now effective. While it is still not clear what, if any, impact the America Invents Act will have on the operation of our business, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents, all of which could have a material adverse effect on our business and financial condition.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or our licensors or strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed.
- We or our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.

- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- It is possible that our pending patent applications will not lead to issued patents.
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.
- We may not develop additional proprietary technologies that are patentable.
- The patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets of our employees' or consultants' former employers or their clients. These claims may be costly to defend and if we do not successfully do so, we may be required to pay monetary damages and may lose valuable intellectual property rights or personnel.

Many of our employees and contractors were previously employed at universities or biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper our ability to commercialize, or prevent us from commercializing our product candidates, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into invention and patent assignment agreements with our employees and consultants that obligate them to assign their inventions to us. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Ownership of Our Common Stock

We cannot predict what the market price of our common stock will be and, as a result, it may be difficult for you to sell your shares of our common stock.

An inactive market may impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations may be below the expectations of public market analysts and investors and, as a result of these and other factors, the price of our common stock may fall.

The market price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock is likely to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. In addition to the factors discussed in this "Risk Factors" section these factors include:

- the success of competitive products or technologies;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- results of clinical trials of our product candidates or those of our competitors;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;

- the recruitment or departure of key personnel;
- the results of our efforts to in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- changes in the structure of healthcare payment systems, including coverage and reimbursement;
- market conditions in the pharmaceutical and biotechnology sectors; and
- general economic, industry and market conditions.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

To our knowledge, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially own approximately 36% of our voting stock as of December 31, 2020. Accordingly, these stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our existing stockholders sell, or if the market perceives that our existing stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

Our management will continue to have broad discretion over the use of the proceeds we received in our public offerings, private placements, warrant exercises and loans and might not apply the proceeds in ways that increase the value of your investment.

Our management will continue to have broad discretion to use the net proceeds from our public offerings, private placements warrant exercises and loans and you will be relying on the judgment of our management regarding the application of these proceeds. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment. Because of the number and variability of factors that will determine our use of the remaining net proceeds from our initial public offering, follow-on public offering and other financing transactions, their ultimate use may vary substantially from their currently intended use. If we do not invest or apply the net proceeds from our public offerings, private placements, warrant exercises and loans in ways that enhance stockholder value, we may fail to achieve the expected financial results, which could cause our stock price to decline.

Future sales and issuances of equity and debt securities could result in additional dilution to our stockholders and could place restrictions on our operations and assets, and such securities could have rights, preferences and privileges senior to those of our common stock.

We expect that significant additional capital will be needed in the future to fund our planned operations, including to complete clinical trials for our product candidates. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner that we will determine from time to time. If we sell common stock, convertible securities or other equity securities, existing stockholders may be materially diluted by subsequent sales, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

Pursuant to our Amended and Restated 2013 Equity Incentive Plan, our management is authorized to grant up to 11,031,333 stock options or awards to our employees, directors and consultants, and the number of shares of our common stock reserved for future issuance under the plan will be subject to automatic annual increases in accordance with the terms of the plan. To the extent that new options are granted and exercised or we issue additional shares of common stock in the future, our stockholders may experience additional dilution, which could cause our stock price to fall.

We incur increased costs and demands upon management as a result of being a public company.

As a public company listed in the United States, we incur significant additional legal, accounting and other costs. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the Securities and Exchange Commission, or the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and The Nasdaq Stock Market, may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We invest resources to comply with evolving laws, regulations and standards, and this investment results in increased general and administrative expenses and a diversion of management's time and attention. If we do not comply with new laws, regulations and standards, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

Securities litigation could result in substantial damages and may divert management's time and attention from our business.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. We are currently a target of this type of litigation. See Part I, Item 3, "Legal Proceedings" in this Annual Report on Form 10-K for information concerning securities litigation recently initiated against us and certain of our executive officers and directors and certain other defendants. We may become the target of additional securities litigation in the future. The outcome of litigation is necessarily uncertain, and we could be forced to expend significant resources in the defense of such suits, and we may not prevail. Monitoring and defending against legal actions is time-consuming for our management and detracts from management's ability to fully focus our internal resources on our business activities. In addition, we may incur substantial legal fees and costs in connection with any such litigation. We have not established any reserves for any potential liability relating to any such potential lawsuits. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages. We currently maintain insurance coverage for some of these potential liabilities. Other potential liabilities may not be covered by insurance, insurers may dispute coverage or the amount of insurance may not be enough to cover damages awarded. In addition, certain types of damages may not be covered by insurance, and insurance coverage for all or certain forms of liability may become unavailable or prohibitively expensive in the future. A decision adverse to our interests on one or more legal matters or litigation could result in the payment of substantial damages, or possibly fines, and could have a material adverse effect on our reputation, financial condition and results of operations

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change in control was considered favorable by you and other stockholders. For example, our board of directors has the authority to issue up to 100,000,000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change in control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents also contain other provisions that could have an anti-takeover effect, including:

- establishing a classified board of directors such that not all members of the board are elected at one time;
- allowing the authorized number of directors to be changed only by resolution of our board of directors;
- limiting the removal of directors by the stockholders;
- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders;

- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters than can be acted upon at stockholder meetings; and
- requiring the approval of the holders of at least 66 2/3% of the votes that all of our stockholders would be entitled to cast to amend or repeal our bylaws.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

If securities or industry analysts cease publishing research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

We have never paid dividends on our capital stock, and because we do not anticipate paying any cash dividends in the foreseeable future, capital appreciation, if any, of our common stock will be your sole source of gain on an investment in our common stock.

We have paid no cash dividends on any of our classes of capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of our credit facility limit our ability to pay cash dividends on our capital stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which you purchase shares of our common stock.

ITEM 1B. Unresolved Staff Comments

None.

ITEM 2. Properties

Our principal executive offices are located at 1601 Trapelo Road, Suite 286, Waltham, Massachusetts 02451. We lease this facility, which consists of approximately 5,923 square feet of office space, and the term of our Sublease expires on July 27, 2021. We believe that our existing facility is sufficient for our current needs for the foreseeable future.

ITEM 3. Legal Proceedings

On December 8, 2020 and January 11, 2021, purported stockholders of the Company filed two putative securities class action complaints in the United States District Court for the District of Massachusetts, entitled McCoy v. Minerva Neurosciences, Inc., et al., No. 1:20-cv-12176 and Ao v. Minerva Neurosciences, Inc. et al., No. 1:21-cv-10051, respectively, against the Company and the Company's Chairman and Chief Executive Officer (collectively, the "Defendants"). The complaints are nearly identical and allege that the Defendants made material false and/or misleading statements regarding the development of the Company's drug candidate roluperidone purportedly causing losses to investors who acquired the Company's common stock between May 15, 2017 and November 30, 2020. The complaints do not quantify any alleged damages but, in addition to attorneys' fees and costs, plaintiffs seek to recover damages on behalf of themselves and others who acquired the Company's stock during the putative class period at allegedly inflated prices and purportedly suffered financial harm as a result. On February 8, 2021, three putative lead plaintiffs filed motions to consolidate the cases and to appoint a lead plaintiff. Two of the putative lead plaintiffs withdrew their motions on February 22, 2021. The defendants' response to the complaints is stayed pending consolidation and resolution of the lead plaintiff motions. We dispute these claims and intend to defend the matter vigorously. Given the uncertainty of litigation, the preliminary stage of the case, and the legal standards that must be met for, among other things, class certification and success on the merits, we cannot estimate the reasonably possible loss or range of loss that may result from this action.

ITEM 4. Mine Safety Disclosures

Not applicable.

Part II

ITEM 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock has been traded on the Nasdaq Global Market under the symbol "NERV" since our initial public offering on July 1, 2014.

At March 4, 2021, there were approximately 117 holders of record of our common stock. We believe that the number of beneficial owners of our common stock at that date was substantially greater.

Our equity plan information required by this Item is incorporated by reference to the information in Part III, Item 12 of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

During the year ended December 31, 2020, we did not issue or sell any unregistered securities not previously disclosed in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K.

Issuer Purchases of Equity Securities

We did not repurchase any securities during the quarter ended December 31, 2020.

ITEM 6. Selected Financial Data

Not applicable.

ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information in this discussion and analysis contains forward-looking statements reflecting our current expectations and involves risk and uncertainties. For example, statements regarding our expectations as to our plans and strategy for our business, future financial performance, expense levels and liquidity sources are forward-looking statements. Our actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under the "Risk Factors" section and elsewhere in this Annual Report on Form 10-K. Please also see the section entitled "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of proprietary product candidates to treat patients suffering from CNS diseases. Leveraging our scientific insights and clinical experience, we have acquired or in-licensed compounds that we believe have innovative mechanisms of actions and therapeutic profiles that potentially address the unmet needs of patients with these diseases.

We are developing roluperidone (f/k/a MIN-101) for the treatment of negative symptoms in patients with schizophrenia and MIN-301 for the treatment of Parkinson's disease. In addition, we previously co-developed seltorexant (f/k/a MIN-202 or JNJ-42847922) with Janssen for the treatment of insomnia disorder and adjunctive treatment of MDD. During 2020, we exercised our right to opt out of a joint development agreement with Janssen for the future development of seltorexant. As a result, we will be entitled to collect royalties in the mid-single digits on potential future sales of seltorexant worldwide in certain indications, with no further financial obligations to Janssen. In January 2021, we sold our rights to these potential royalties to Royalty Pharma.

Clinical and Regulatory Updates

In May 2020 we announced top level results from our Phase 3 trial of roluperidone to treat negative symptoms in schizophrenia which was conducted in the United States, Europe and Israel. In total, 515 patients were enrolled into the trial and 513 patients received treatment however the trial failed to meet its primary and key secondary endpoints. Patient evaluation in the open-label extension phase of the Phase 3 trial of roluperidone was achieved on February 15, 2021, with a total of 202 patients completing this phase. Data are expected to be available in the first half of 2021.

In November 2020 we met with the FDA regarding the development of roluperidone for the treatment of negative symptoms of schizophrenia. We plan to continue to communicate with FDA regarding their comments and continue to move forward with the clinical pharmacology, non-clinical, and CMC work needed to support an NDA submission. We anticipate requesting a pre-NDA meeting with FDA to discuss our NDA submission plans based on our clinical efficacy and safety data

We have not received regulatory approvals to commercialize any of our product candidates, and we have not generated any revenue from the sales or license of our product candidates. We have incurred significant operating losses every year since inception. We expect to incur net losses and negative cash flow from operating activities for the foreseeable future in connection with the clinical development and the potential regulatory approval, infrastructure development and commercialization of our product candidates.

Financial Overview

Revenue

None of our product candidates have been approved for commercialization and we have not received any revenue in connection with the sale or license of our product candidates.

During 2020 we exercised our right to opt out of the joint development agreement with Janssen for the future development of seltorexant. As a result, we have no future obligations under the agreement and recognized approximately $41.2 million in collaborative revenue, which we had previously included on our balance sheet under deferred revenue.

Research and Development Expenses

Research and development expenses consists of costs incurred in connection with the development of our product candidates, including: fees paid to consultants and clinical research organizations, or CROs, including in connection with our non-clinical and clinical trials, and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis; licensing fees; costs related to acquiring clinical trial materials; costs related to compliance with regulatory requirements; and costs related to salaries, benefits, bonuses and stock-based compensation granted to employees in research and development functions. We expense research and development costs as they are incurred.

The historic direct costs relating to each of our product candidates are summarized as follows (in thousands):

	Year Ended December 31,	
	2020	2019
Roluperidone(1)	$ 17,955	$ 26,353
MIN-117(2)	490	29,007
MIN-301	568	118
Total	$ 19,013	$ 55,478

(1) The $8.4 million decrease in expense for the year ended December 31, 2020 versus 2019 reflects the completion of the Phase 3 core study of roluperidone. Patient evaluation in the open-label extension portion of this study has been completed and data are expected to be available in the first half of 2021.

(2) The $28.5 million decrease in MIN-117 expense for the year ended December 31, 2020 versus 2019 reflects the completion of a Phase 2b study. The study failed to meet its primary endpoints and, as a result, the 2019 expense includes a $19.0 million charge for the impairment of the related in-process research and development.

Completion dates and completion costs can vary significantly for each product candidate and are difficult to predict. We anticipate we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success or failure of each product candidate, the estimated costs to continue the development program relative to our available resources, as well as an ongoing assessment as to each product candidate's commercial potential. We will need to raise additional capital or may seek additional product collaborations in the future in order to complete the development and commercialization of our product candidates.

We test goodwill and in-process research and development for impairment annually on November 30 or more frequently if changes in circumstances or the occurrence of events suggest impairment exists. The test for impairment of in-process research and development requires us to make several estimates about fair value, most of which are based on projected future cash flows. Changes in these estimates may result in the recognition of an impairment loss in our results of operations. An impairment analysis is performed whenever events or changes in circumstances indicate that the carrying amount of any individual asset may not be recoverable. For example, if we or our counterparties fail to perform our respective obligations under an agreement, or if we lack sufficient funding to develop our product candidates, an impairment may result. In addition, any significant change in market conditions, estimates or judgments used to determine expected future cash flows that indicate a reduction in carrying value may give rise to impairment in the period that the change becomes known.

General and Administrative Expenses

General and administrative expenses consist principally of costs for functions in executive, finance, legal, auditing and taxes. Our general and administrative expenses include salaries, bonuses, facility and information system costs and professional fees for auditing, accounting, consulting and legal services. General and administrative costs also include non-cash stock-based compensation expense as part of our compensation strategy to attract and retain qualified staff.

We expect to continue to incur general and administrative expenses related to operating as a publicly-traded company, including increased audit and legal fees, costs of compliance with securities, corporate governance and other regulations, investor relations expenses and higher insurance premiums. In addition, we expect to incur additional costs as we hire personnel and enhance our infrastructure to support the anticipated growth of our business.

Foreign Exchange (Losses) Gains

Foreign exchange (losses) gains are comprised primarily of losses and gains of foreign currency transactions related to clinical trial expenses denominated in Euros. Since our current clinical trials are conducted in Europe, we incur certain expenses in Euros and record these expenses in United States Dollars at the time the liability is incurred. Changes in the applicable foreign currency rate between the date an expense is recorded and the payment date is recorded as a foreign currency loss or gain. We expect to continue to incur future expenses denominated in Euros as certain of our planned clinical trials are expected to be conducted in Europe.

Investment Income

Investment income consists of income earned on our cash equivalents and marketable securities.

Interest Expense

Interest expense consists of interest incurred under our former loan with Oxford Finance LLC ("Oxford"), and Silicon Valley Bank ("SVB"). During the years ended December 31, 2020 and 2019, there was no debt outstanding and no interest expense recorded.

Net Operating Losses and Tax Carryforwards

As of December 31, 2020, we had approximately $102.8 million of federal net operating loss carryforwards. These federal net operating loss carryforwards will begin to expire at various dates beginning in 2030, if not utilized. As of December 31, 2020, we had approximately $98.6 million of state net operating loss carryforwards. During the year ended December 31, 2020, no state operating loss carryforwards had expired.

Results of Operations

Comparison of the Years Ended December 31, 2020 and December 31, 2019 (in thousands):

	Year Ended December 31,	
	2020	2019
Revenues		
Collaborative revenue	$ 41,176	$ —
Total revenues	41,176	—
Expenses		
Research and development	22,040	58,124
General and administrative	17,289	17,741
Total expenses	39,329	75,865
Gain (loss) from operations	1,847	(75,865)
Foreign exchange losses	(67)	(29)
Investment income	161	1,456
Gain (loss) before income taxes	1,941	(74,438)
Benefit for income taxes	—	(2,255)
Net Income (loss)	$ 1,941	$ (72,183)

Collaborative Revenue

Collaborative revenue was $41.2 million and $0.0 for the years ended December 31, 2020 and 2019, respectively. The increase in collaborative revenue was the result of our exercising our right to opt out of the co-development agreement with Janssen during 2020. As a result of the opt out we have no further performance obligations and recognized the $41.2 million, which had been previously included on our balance sheet under deferred revenue.

Research and Development Expenses

Research and development expenses were $22.0 million and $58.1 million for the years ended December 31, 2020 and 2019, respectively, a decrease of $36.1 million. The decrease in research and development expenses was primarily due to (i) a $19.0 million charge for the impairment of the in-process research and development related to MIN-117 in December 2019, (ii) approximately $11.0 million from the

completion of the Phase 2b clinical trial of MIN-117 in December 2019 and (iii) the completion in May 2020 of the core study portion of the Phase 3 clinical trial of roluperidone. Patient evaluation in the open-label extension portion of this study has been completed and data are expected to be available in the first half of 2021. Non-cash stock compensation expense included in research and development expenses was $3.0 million and $2.6 million for the years ended December 31, 2020 and 2019, respectively.

General and Administrative Expenses

General and administrative expenses were $17.3 million and $17.7 million for the years ended December 31, 2020 and 2019, respectively, a decrease of approximately $0.4 million. The decrease in general and administrative expenses was primarily due to approximately $1.1 million in lower pre-commercial expenses in 2020, offset by higher insurance costs of approximately $0.9 million. Non-cash stock compensation expense included in general and administrative expenses was $6.7 million and $6.5 million for the years ended December 31, 2020 and 2019, respectively.

Foreign Exchange Losses

Foreign exchange losses were $67 thousand and $29 thousand for the years ended December 31, 2020 and 2019, respectively, an increase of $38 thousand. The loss was primarily due to a higher level of clinical activities in 2020 denominated in Euros.

Investment Income

Investment income was $0.2 million and $1.5 million for the years ended December 31, 2020 and 2019, respectively, a decrease of $1.3 million. The decrease was primarily due to lower average balances for cash equivalents and marketable securities during 2020.

Benefit for Income Taxes

Benefit for income taxes was zero and $2.3 million for the years ended December 31, 2020 and 2019, respectively, a decrease of $2.3 million. The $2.3 million benefit was a result of lowering the deferred tax liability due to the impairment of the MIN-117 IPR&D asset during 2019.

Liquidity and Capital Resources

As of December 31, 2020, we had an accumulated deficit of approximately $284.8 million. We anticipate that we will continue to incur net losses for the foreseeable future as we continue the development and potential commercialization of our product candidates and to support our operations as a public company. At December 31, 2020, we had approximately $25.5 million in cash, cash equivalents, and restricted cash. In January 2021 Royalty Pharma acquired our royalty interest in seltorexant for an upfront payment of $60 million and up to $95 million in additional milestone payments. The future milestone payments to us will be contingent on the achievement of certain clinical, regulatory and commercialization milestones for seltorexant by Janssen. Seltorexant is currently in Phase 3 development for the treatment of MDD with insomnia symptoms by Janssen. We believe that with the upfront payment of $60 million, our existing cash, cash equivalents, and restricted cash will be sufficient to meet our cash commitments for at least the next 12 months after the date that the financial statements are issued.

The process of drug development can be costly and the timing and outcomes of clinical trials is uncertain. The assumptions upon which we have based our estimates are routinely evaluated and may be subject to change. The actual amount of our expenditures will vary depending upon a number of factors including but not limited to the design, timing and duration of future clinical trials, the progress of our research and development programs, the infrastructure to support a commercial enterprise, the cost of a commercial product launch and the level of financial resources available. We have the ability to adjust our operating plan spending levels based on the timing of future clinical trials which will be predicated upon adequate funding to complete the trials.

Sources of Funds

At-the-Market Equity Offering Program

In August 2018 we entered into the Sales Agreement with Jefferies LLC pursuant to which we may offer and sell, from time to time, through Jefferies, up to $50.0 million in shares of our common stock, by any method permitted by law deemed to be an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. During the year ended December 31, 2020, we issued and sold 3,381,608 shares of our common stock under the Sales Agreement. The shares were sold at an average price of $3.7113 per share for aggregate net proceeds to us of approximately $12.1 million, after deducting sales commissions and offering costs payable by us.

Seltorexant Royalties

We previously co-developed seltorexant with Janssen for the treatment of insomnia disorder and adjunctive treatment of MDD. During 2020, we exercised our right to opt out of a joint development agreement with Janssen for the future development of seltorexant. As a result, we will be entitled to collect royalties in the mid-single digits on potential future sales of seltorexant worldwide in certain indications, with no further financial obligations to Janssen.

On January 19, 2021, we entered into an agreement with Royalty Pharma under which Royalty Pharma has acquired our royalty interest in seltorexant for an upfront payment of $60 million and up to $95 million in future milestone payments, contingent upon the achievement of certain clinical, regulatory and commercial milestones for seltorexant by Janssen or any other party in the event that Janssen sells seltorexant.

Uses of Funds

To date, we have not generated any revenue from sales of products. We have only generated collaborative revenue due to opting out of our license and co-development agreement with Janssen, and have only generated revenue from the one-time sale of our royalty interests in seltorexant to Royalty Pharma. We do not know when, or if, we will generate any revenue from sales of our products, or from the potential future royalty streams associated with the sale of our royalty interests in seltorexant to Royalty Pharma. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize any of our product candidates. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates. We also expect to continue to incur costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or other third party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third party funding, commercialization, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. There can be no assurance that such additional funding, if available, can be obtained on terms acceptable to us, and the uncertainty and volatility in the capital markets caused by the continuing COVID-19 pandemic may negatively impact the availability and cost of capital. If we are unable to obtain additional financing, future operations would need to be scaled back or discontinued. We believe that our existing cash, cash equivalents, and restricted cash will be sufficient to meet our cash commitments for at least the next 12 months after the date that the financial statements are issued. The timing of future capital requirements depends upon many factors including the size and timing of future clinical trials, the timing and scope of any strategic partnering activity and the progress of other research and development activities.

Cash Flows

The tables below set forth our significant sources and uses of cash for the periods set forth below.

	Year Ended December 31,	
	2020	2019
	(dollars in millions)	
Net cash (used in) provided by:		
Operating activities	$ (33.8)	$ (43.4)
Investing activities	24.5	14.1
Financing activities	13.2	0.5
Net increase (decrease) in cash	$ 3.9	$ (28.8)

Net Cash Used in Operating Activities

Net cash used in operating activities of approximately $33.8 million during the year ended December 31, 2020 was primarily due to decreases in deferred revenue of $41.2 million, accrued expenses of $2.1 million and accounts payable of $1.3 million, and an increase of prepaid expense of $0.8 million. The cash used was partially offset by our net income of $1.9 million and stock-based compensation expense of $9.7 million.

Net cash used in operating activities of approximately $43.4 million during the year ended December 31, 2019 was primarily due to our net loss of $72.2 million, a decrease of $2.2 million in deferred taxes, and amortization of investments of $0.8 million, partially offset by an impairment expense of in process research and development assets of $19.0 million, stock-based compensation expense of $9.2 million, an increase in accrued expenses $2.3 million, a decrease in prepaid expenses of $0.7 million, and an increase in accounts payable of $0.6 million.

Net Cash Provided by Investing Activities

Net cash provided by investing activities of approximately $24.5 million during the year ended December 31, 2020 was primarily due to the maturity and redemption of marketable securities of $28.4 million, partially offset by the purchase of marketable securities of $3.9 million.

Net cash provided by investing activities of approximately $14.1 million during the year ended December 31, 2019 was primarily due to the maturity and redemption of marketable securities of $75.2 million, partially offset by the purchase of marketable securities of $61.1 million.

Net Cash Provided by (Used In) Financing Activities

Net cash provided by financing activities of $13.2 million during the year ended December 31, 2020 was due to gross proceeds received from the ‘at the market’ stock offering of $12.6 million less costs of $0.5 million, and proceeds from the exercise of common stock options of $1.1 million.

Net cash provided by financing activities of $0.5 million during the year ended December 31, 2019 was due to the proceeds from the exercise of common stock options of $0.5 million.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements as defined under SEC rules.

Critical Accounting Policies and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our financial statements appearing elsewhere in this Form 10-K, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Research and Development Costs

Costs incurred in connection with research and development activities are expensed as incurred. These costs include licensing fees to use certain technology in our research and development projects as well as fees paid to consultants and various entities that perform certain research and testing on our behalf and costs related to salaries, benefits, bonuses and stock-based compensation granted to employees in research and development functions. We determine our expenses related to clinical studies based on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations

that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual accordingly. The expenses for some trials may be recognized on a straight-line basis if the anticipated costs are expected to be incurred ratably during the period. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the condensed consolidated financial statements as prepaid or accrued expenses.

We make estimates of our accrued research and development expenses as of each balance sheet date in our financial statements based on facts and circumstances known at that time. Although we do not expect that our estimates will be materially different from amounts actually incurred, our understanding of status and timing of services performed relative to the actual status and timing of services performed may vary and may result in our reporting amounts that are too high or too low for any particular period. There had been no material adjustments to our prior period estimates of accrued expenses for clinical trials. However, due to the nature of estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical trials.

In-process Research and Development

In-process research and development, or IPR&D, assets represent capitalized incomplete research projects that we acquired through business combinations. Such assets are initially measured at their acquisition date fair values. The initial fair values of the research projects is recorded as intangible assets on the balance sheet, rather than expensed, regardless of whether these assets have an alternative future use.

The amounts capitalized are being accounted for as indefinite-lived intangible assets, subject to impairment testing, until completion or abandonment of research and development efforts associated with the project. An IPR&D asset is considered abandoned when it ceases to be used (that is, research and development efforts associated with the asset have ceased, and there are no plans to sell or license the asset or derive defensive value from the asset). At that point, the asset is considered to be disposed of and is written off. Upon successful completion of each project, we will make a determination about the then remaining useful life of the intangible asset and begin amortization. We test our indefinite-lived intangibles, IPR&D assets, for impairment annually on November 30 and more frequently if events or changes in circumstances indicate that it is more likely than not that the asset is impaired. In estimating the fair value of IPR&D, an income approach was used with a discounted cash flow analysis. Many assumptions and estimates are included in this analysis including revenue and expense projections, probability of success factors, expected product launch date and a weighted average cost of capital of 19.5%.

Potential triggering events that could indicate whether an impairment to the IPR&D may have occurred include: clinical trial results where the compound under investigation did not meet pre-established criteria or clinical endpoints, failure to obtain regulatory approval, the inability to fund future clinical trials, failure to obtain patent protection, adverse changes in the regulatory environment, the approval of competing therapies or compounds, adverse changes in applicable laws or regulations and a variety of other circumstances. The impairment of IPR&D could have a material adverse impact on our financial condition. In order to determine whether an impairment has occurred, management must evaluate the events and incorporate multiple assumptions including: costs associated with continuing the development program, competing therapies or compounds, potential market size, estimated future cash flows and other factors. When testing indefinite-lived intangibles for impairment, we may assess qualitative factors for our indefinite-lived intangibles to determine whether it is more likely than not (that is, a likelihood of more than 50 percent) that the asset is impaired. Alternatively, we may bypass this qualitative assessment for some or all of our indefinite-lived intangibles and perform the quantitative impairment test that compares the fair value of the indefinite-lived intangible asset with the asset's carrying amount. We test our IPR&D for impairment as of November 30. There was no impairment of the Mind-NRG IPR&D asset for the years ended December 31, 2020 or 2019.

Impairment of MIN-117 In-process Research and Development Asset.

As a result of our Phase 2b trial of MIN-117 in adult patients suffering from moderate to severe MDD not meeting its primary and key secondary endpoints and our decision not to further the clinical development of MIN-117 in MDD, we determined that the MIN-117 IPR&D was fully impaired and recognized a $19.0 million expense, which was included as a component of research and development expense, during the year ended December 31, 2019.

Goodwill

We test our goodwill for impairment annually, or whenever events or changes in circumstances indicate an impairment may have occurred, by comparing our reporting unit's carrying value to its fair value. Impairment may result from, among other things, deterioration in the performance of the acquired business, adverse market conditions, adverse changes in applicable laws or regulations and a variety of other circumstances. If we determine that an impairment has occurred, we are required to record a write-

down of the carrying value and charge the impairment as an operating expense in the period the determination is made. In evaluating the recoverability of the carrying value of goodwill, we must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the acquired assets. Changes in strategy or market conditions could significantly impact those judgments in the future and require an adjustment to the recorded balances. We test our goodwill for impairment as of November 30. There was no impairment of goodwill for the years ended December 31, 2020 or 2019.

Income Taxes

Deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Uncertain tax positions are evaluated and if appropriate, the amount of unrecognized tax benefits are recorded within deferred tax assets. Deferred tax assets are evaluated for realization based on a more-likely-than-not criterion in determining if a valuation allowance should be provided. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

We use a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken, or expected to be taken, in a tax return. We have elected to treat interest and penalties, to the extent they arise, as a component of income taxes. There was no interest or penalties related to income taxes for the years ended December 31, 2020 or 2019. Income tax years beginning in 2012 for federal and state purposes are generally subject to examination by taxing authorities, although net operating losses from all prior years are subject to examinations and adjustments for at least three years following the year in which the tax attributes are utilized.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by Financial Accounting Standards Board (“FASB”) and are adopted by us as of the specified effective date. Unless otherwise disclosed in the notes to the financial statements appearing elsewhere in this Form 10-K, we believe that the impact of other recently issued, but not yet adopted, accounting pronouncements will not have a material impact on the financial position, results of operations or cash flows, or do not apply to our operations.

ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

ITEM 8. Financial Statements and Supplementary Data

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Minerva Neurosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Minerva Neurosciences, Inc. and subsidiaries (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations, stockholders' equity, and cash flows, for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

In-Process Research and Development — Refer to Note 2 to the financial statements

Critical Audit Matter Description

The Company has in-process research and development assets (“IPR&D”) that are indefinite-lived intangible assets. As of December 31, 2020, the carrying value of the Company’s IPR&D was $15 million and has not changed since 2019. To assess the IPR&D carrying value for impairment, management estimates the fair value of IPR&D annually on its elected assessment date of November 30, 2020, using a multi-period excess earnings method, which is a specific discounted cash flow method. The determination of the fair value requires management to make significant estimates related to the discount rate used in the model and for the estimated timing of commercialization of the drugs. Changes in these assumptions could have a significant impact on the fair value of the IPR&D and a significant change in fair value could cause a significant impairment.

We identified IPR&D as a critical audit matter because of the significant estimates and assumptions management makes related to the commercialization dates of the drugs and selection of the discount rates to determine the fair value of the IPR&D. This required a high degree of auditor judgment and an increased extent of effort, including the need to involve our fair value specialists, when performing audit procedures to evaluate the selection of the discount rates and the reasonableness of management’s forecast of the commercialization dates for IPR&D.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the selection of the discount rates and forecast of the commercialization dates for IPR&D included the following, among others:

- We evaluated the reasonableness and consistency of management's selection and application of the models used to perform the annual impairment evaluation.
- With the assistance of our fair value specialists, we:
  - Evaluated the valuation model to ensure it is consistent with the selected valuation methodologies and assumptions.
  - Tested the mathematical accuracy of the models used by management.
  - Evaluated the reasonableness of the discount rates by:
    - Testing the source information underlying the determination of the discount rates and the mathematical accuracy of the calculation.
    - Developing a range of independent estimates and comparing those to the discount rates selected by management.
- We evaluated the reasonableness of management's forecasts of commercialization dates by:
  - Comparing management's forecasts with internal communications to management and the Board of Directors.
  - Considering the impact of changes in the regulatory environment on management's forecasts.
  - Comparing management's forecasts with industry data.

/s/ DELOITTE & TOUCHE LLP

Boston, Massachusetts
March 8, 2021

We have served as the Company's auditor since 2013.

MINERVA NEUROSCIENCES, INC.
Consolidated Balance Sheets

	December 31, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 25,356,952	$ 21,412,623
Marketable securities	—	24,441,520
Restricted cash	100,000	100,000
Prepaid expenses and other current assets	1,983,264	1,182,483
Total current assets	27,440,216	47,136,626
Equipment, net	—	16,011
Other noncurrent assets	14,808	14,808
Operating lease right-of-use assets	101,786	261,952
In-process research and development	15,200,000	15,200,000
Goodwill	14,869,399	14,869,399
Total assets	**$ 57,626,209**	**$ 77,498,796**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 995,614	$ 2,317,004
Accrued expenses and other current liabilities	2,053,409	4,139,163
Operating leases	111,229	172,901
Total current liabilities	3,160,252	6,629,068
Deferred taxes	1,803,356	1,803,356
Deferred revenue	—	41,175,600
Noncurrent operating leases	—	111,229
Total liabilities	4,963,608	49,719,253
Commitments and contingencies (Note 9)		
Stockholders' equity		
Preferred stock; $.0001 par value; 100,000,000 shares authorized; none issued or outstanding as of December 31, 2020 and 2019, respectively	—	—
Common stock; $.0001 par value; 125,000,000 shares authorized; 42,721,566 and 39,084,121 shares issued and outstanding as of December 31, 2020 and 2019, respectively	4,272	3,908
Additional paid-in capital	337,453,776	314,511,853
Accumulated deficit	(284,795,447)	(286,736,218)
Total stockholders' equity	52,662,601	27,779,543
Total liabilities and stockholders' equity	**$ 57,626,209**	**$ 77,498,796**

See accompanying notes to the consolidated financial statements.

MINERVA NEUROSCIENCES, INC.
Consolidated Statements of Operations

	Year Ended December 31,	
	2020	**2019**
Revenues		
Collaborative revenue	$ 41,175,600	$ —
Total revenues	41,175,600	—
Expenses		
Research and development	22,039,440	58,124,354
General and administrative	17,289,413	17,740,742
Total expenses	39,328,853	75,865,096
Gain (loss) from operations	1,846,747	(75,865,096)
Foreign exchange losses	(67,183)	(28,545)
Investment income	161,207	1,456,019
Gain (loss) before income taxes	1,940,771	(74,437,622)
Benefit for income taxes	—	(2,254,132)
Net Income (loss)	$ 1,940,771	$ (72,183,490)
Net income (loss) per share, basic	$ 0.05	$ (1.85)
Weighted average shares outstanding, basic	40,823,717	39,014,302
Net income (loss) per share, diluted	$ 0.05	$ (1.85)
Weighted average shares outstanding, diluted	40,916,871	39,014,302

See accompanying notes to the consolidated financial statements.

MINERVA NEUROSCIENCES, INC.
Consolidated Statements of Stockholders' Equity

	Common Stock		Additional	Accumulated	
	Shares	Amount	Paid-In Capital	Deficit	Total
Balances at January 1, 2019	**38,937,971**	**$ 3,894**	**$ 304,813,603**	**$ (214,552,728)**	**$ 90,264,769**
Exercise of stock options	87,500	8	524,991	—	524,999
Vesting of restricted stock units	58,650	6	(6)	—	—
Stock-based compensation	—	—	9,173,265	—	9,173,265
Net loss	—	—	—	(72,183,490)	(72,183,490)
Balances at December 31, 2019	**39,084,121**	**$ 3,908**	**$ 314,511,853**	**$ (286,736,218)**	**$ 27,779,543**
Issuance of common stock in a public offering	3,381,608	338	12,549,731	—	12,550,069
Costs related to issuance of common stock	—	—	(455,666)	—	(455,666)
Exercise of stock options	198,762	20	1,143,635	—	1,143,655
Vesting of restricted stock units	57,075	6	(6)	—	—
Stock-based compensation	—	—	9,704,229	—	9,704,229
Net income	—	—	—	1,940,771	1,940,771
Balances at December 31, 2020	**42,721,566**	**$ 4,272**	**$ 337,453,776**	**$ (284,795,447)**	**$ 52,662,601**

See accompanying notes to the consolidated financial statements.

MINERVA NEUROSCIENCES, INC.
Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2020	**2019**
Cash flows from operating activities:		
Net income (loss)	$ 1,940,771	$ (72,183,490)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Impairment of in-process research and development	—	19,000,000
Depreciation and amortization	16,011	17,467
Accretion of marketable securities premium	(86,774)	(764,057)
Amortization of right-of-use assets	160,166	144,040
Stock-based compensation expense	9,704,229	9,173,265
Deferred taxes	—	(2,254,132)
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	(800,781)	723,266
Accounts payable	(1,321,390)	517,338
Accrued expenses and other current liabilities	(2,085,754)	2,329,631
Operating lease liabilities, current	(61,672)	37,351
Deferred revenue	(41,175,600)	—
Operating lease liabilities, noncurrent	(111,229)	(172,902)
Net cash used in operating activities	(33,822,023)	(43,432,223)
Cash flows from investing activities:		
Purchases of marketable securities	(3,871,706)	(61,094,024)
Proceeds from the maturity and redemption of marketable securities	28,400,000	75,179,000
Net cash provided by investing activities	24,528,294	14,084,976
Cash flows from financing activities:		
Proceeds from sales of common stock in public offering	12,550,069	—
Fees paid in connection with public offering	(455,666)	—
Proceeds from exercise of stock options	1,143,655	524,999
Net cash provided by financing activities	13,238,058	524,999
Net increase (decrease) in cash, cash equivalents, and restricted cash	3,944,329	(28,822,248)
Cash, cash equivalents, and restricted cash		
Beginning of period	21,512,623	50,334,871
End of period	$ 25,456,952	$ 21,512,623
Supplemental disclosure of cash flow information		
Cash paid for interest	$ —	$ —
Reconciliation of the Condensed Consolidated Statements of Cash Flows to the Condensed Consolidated Balance Sheets		
Cash and cash equivalents	$ 25,356,952	$ 21,412,623
Restricted cash	$ 100,000	$ 100,000
Total cash, cash equivalents, and restricted cash	$ 25,456,952	$ 21,512,623

See accompanying notes to the consolidated financial statements.

NOTE 1 — NATURE OF OPERATIONS AND LIQUIDITY

Nature of Operations

Minerva Neurosciences, Inc. ("Minerva" or the "Company") is a clinical-stage biopharmaceutical company focused on the development and commercialization of product candidates to treat patients suffering from central nervous system diseases ("CNS"). The Company's lead product candidate is roluperidone (f/k/a MIN-101), a compound the Company is developing for the treatment of negative symptoms in patients with schizophrenia, and MIN-301, a compound the Company is developing for the treatment of Parkinson's disease. In addition, Minerva has been co-developing seltorexant (f/k/a MIN-202 or JNJ-42847922) with Janssen Pharmaceutica NV ("Janssen") for the treatment of insomnia disorder and adjunctive treatment of Major Depressive Disorder ("MDD"). During 2020 Minerva exercised its right to opt out of the joint development agreement with Janssen for the future development of seltorexant. As a result, the Company will be entitled to collect a royalty on worldwide sales of seltorexant in certain indications in the mid-single digits, with no further financial obligations to Janssen. In January 2021, the Company sold its rights to these potential royalties to Royalty Pharma.

The Company holds the license to roluperidone from Mitsubishi Tanabe Pharma Corporation ("MTPC") with the rights to develop, sell and import roluperidone globally, excluding most of Asia. The Company also has exclusive rights to develop and commercialize MIN-301.

Liquidity

The accompanying financial statements have been prepared as though the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has limited capital resources and has incurred recurring operating losses and negative cash flows from operations since inception. As of December 31, 2020, the Company has an accumulated deficit of approximately $284.8 million and net cash used in operating activities was approximately $33.8 million during the year ended December 31, 2020. Management expects to continue to incur operating losses and negative cash flows from operations. The Company has financed its operations to date from proceeds from the sale of common stock, warrants, loans and convertible promissory notes.

As of December 31, 2020, the Company had cash, cash equivalents, and restricted cash of $25.5 million. In January 2021, Royalty Pharma acquired Minerva's royalty interest in seltorexant for an upfront payment of $60 million and up to $95 million in additional milestone payments. The future milestone payments to Minerva will be contingent on the achievement of certain clinical, regulatory and commercialization milestones for seltorexant by Janssen. Seltorexant is currently in Phase 3 development for the treatment of major depressive disorder (MDD) with insomnia symptoms by Janssen. The Company believes that with the upfront payment of $60 million, its existing cash, cash equivalents, and restricted cash will be sufficient to meet its cash commitments for at least the next 12 months after the date that the financial statements are issued. The process of drug development can be costly and the timing and outcomes of clinical trials is uncertain. The assumptions upon which the Company has based its estimates are routinely evaluated and may be subject to change. The actual amount of the Company's expenditures will vary depending upon a number of factors including but not limited to the design, timing and duration of future clinical trials, the progress of the Company's research and development programs, the infrastructure to support a commercial enterprise, the cost of a commercial product launch, and the level of financial resources available. The Company has the ability to adjust its operating plan spending levels based on the timing of future clinical trials, which will be predicated upon adequate funding to complete the trials.

During the 12 months ended December 31, 2020, the Company issued and sold 3,381,608 shares of the Company's common stock under the Open Market Sale Agreement (the "Sales Agreement") with Jefferies, LLC ("Jefferies"). The shares were sold at an average price of $3.7113 per share for aggregate net proceeds to the Company of approximately $12.1 million, after deducting sales commissions and offering costs payable by the Company.

The Company will need to raise additional capital in order to continue to fund operations and fully fund later stage clinical development programs. The Company believes that it will be able to obtain additional working capital through equity financings or other arrangements to fund future operations; however, there can be no assurance that such additional financing, if available, can be obtained on terms acceptable to the Company. If the Company is unable to obtain such additional financing, future operations would need to be scaled back or discontinued.

Significant Risks and Uncertainties

Litigation

On December 8, 2020 and January 11, 2021, purported stockholders of the Company filed two putative securities class action complaints in the United States District Court for the District of Massachusetts, entitled McCoy v. Minerva Neurosciences, Inc., et al., No. 1:20-cv-12176 and Ao v. Minerva Neurosciences, Inc. et al., No. 1:21-cv-10051, respectively, against the Company and the Company's Chairman and Chief Executive Officer (collectively, the "Defendants"). The complaints are nearly identical and allege that the Defendants made material false and/or misleading statements regarding the development of the Company's drug candidate roluperidone purportedly causing losses to investors who acquired the Company's common stock between May 15, 2017 and November 30, 2020. The complaints do not quantify any alleged damages but, in addition to attorneys' fees and costs, plaintiffs seek to recover damages on behalf of themselves and others who acquired the Company's stock during the putative class period at allegedly inflated prices and purportedly suffered financial harm as a result. On February 8, 2021, three putative lead plaintiffs filed motions to consolidate the cases and to appoint a lead plaintiff. Two of the putative lead plaintiffs withdrew their motions on February 22, 2021. The defendants' response to the complaints is stayed pending consolidation and resolution of the lead plaintiff motions. We dispute these claims and intend to defend the matter vigorously. Given the uncertainty of litigation, the preliminary stage of the case, and the legal standards that must be met for, among other things, class certification and success on the merits, we cannot estimate the reasonably possible loss or range of loss that may result from this action.

COVID-19 Pandemic

The Company's business could be adversely affected by the effects of the ongoing COVID-19 pandemic, which continues to have a negative impact on the local, regional, national and global scale. In response to the pandemic, a number of jurisdictions in which the Company or its service providers operate implemented shelter-in-place or similar type restrictions, which limited on-site activity to certain service providers. Additionally, the Company's headquarters are located in Massachusetts, which implemented such restrictions. In response, the Company implemented work-from-home policies for its employees, which continue to be in effect. While certain jurisdictions, including Massachusetts, have begun a phased re-opening of businesses and governmental agencies, there remain limitations on the physical operations of businesses and prohibitions on certain non-essential gatherings, and it is unclear if such phased re-openings will continue or be rolled back, and there is uncertainty about when, if, or how the Company's workforce may return. The effects of the state executive order, local shelter-in-place orders, government-imposed quarantines and the Company's work-from-home policies, including the uncertainty about their duration, may negatively impact productivity, disrupt our business and delay the clinical programs and timelines.

While the COVID-19 pandemic has not had a material adverse impact on the Company's operations to date, this disruption, if sustained or recurrent, could have a material adverse effect on the Company's operating results, its ability to raise capital needed to develop and commercialize products and the Company's overall financial condition. In addition, a recession or market correction resulting from the spread of the coronavirus could materially affect the value of the Company's common stock. The impact of the COVID-19 pandemic may also exacerbate other risks discussed in this Annual Report on Form 10-K. Refer to Item 1A. "Risk Factors" in this Annual Report on Form 10-K for a complete description of the material risks that the Company currently faces.

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

The financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"), and include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented. From its inception, the Company has devoted substantially all of its efforts to business planning, engaging regulatory, manufacturing and other technical consultants, planning and executing clinical trials and raising capital.

Consolidation

The accompanying consolidated financial statements include the results of the Company and its wholly-owned subsidiaries, Mind-NRG Sarl and Minerva Neurosciences Securities Corporation. Intercompany transactions have been eliminated.

Significant risks and uncertainties

The Company's operations are subject to a number of factors that can affect its operating results and financial condition. Such factors include, but are not limited to: the results of clinical testing and trial activities of the Company's products, the Company's ability to obtain regulatory approval to market its products, competition from products manufactured and sold or being developed by other

companies, the price of, and demand for, Company products, the Company's ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products, and the Company's ability to raise capital.

The Company currently has no commercially approved products and there can be no assurance that the Company's research and development will be successfully commercialized. Developing and commercializing a product requires significant time and capital and is subject to regulatory review and approval as well as competition from other biotechnology and pharmaceutical companies. The Company operates in an environment of rapid change and is dependent upon the continued services of its employees and consultants and obtaining and protecting intellectual property.

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Cash and cash equivalents

Cash equivalents include short-term, highly-liquid instruments, consisting of money market accounts and short-term investments with maturities from the date of purchase of 90 days or less. The majority of cash and cash equivalents are maintained with major financial institutions in North America. Deposits with these financial institutions may exceed the amount of insurance provided on such deposits. These deposits may be redeemed upon demand which reduces counterparty performance risk.

Restricted cash

Cash accounts with any type of restriction are classified as restricted. The Company maintained restricted cash balances as collateral for corporate credit cards in the amount of $0.1 million at December 31, 2020 and 2019.

Marketable securities

Marketable securities consisted of corporate and U.S. government debt securities. Based on the Company's intentions regarding its marketable securities, all marketable securities were classified as held-to-maturity and were carried under the amortized cost approach. The Company's investments in marketable securities were classified as Level 2 within the fair value hierarchy. As of December 31, 2020, all marketable securities have matured or been redeemed. The following table provides the amortized cost basis, aggregate fair value, unrealized gains/losses, and the net carrying value of investments in held-to-maturity securities as of December 31, 2019:

	December 31, 2019				
	Amortized Cost	Aggregate Fair Value	Unrealized Gains	Unrealized Losses	Net Carrying Value
Marketable securities:					
Corporate bonds/notes	$ 2,701,114	$ 2,700,678	$ 436	$ —	$ 2,701,114
Commercial paper	19,245,921	19,245,921	—	—	19,245,921
U.S. government agency securities	2,494,485	2,495,675	—	(1,190)	2,494,485
Marketable securities total	$ 24,441,520	$ 24,442,274	$ 436	$ (1,190)	$ 24,441,520

Research and development costs

Costs incurred in connection with research and development activities are expensed as incurred. These costs include licensing fees to use certain technology in the Company's research and development projects as well as fees paid to consultants and various entities that perform certain research and testing on behalf of the Company and costs related to salaries, benefits, bonuses and stock-based compensation granted to employees in research and development functions. The Company determines expenses related to clinical studies based on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations ("CROs") that conduct and manage clinical studies on its behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the accrual is adjusted accordingly. The expenses for some trials may be recognized on a straight-line basis if the anticipated costs are expected to

be incurred ratably during the period. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued expenses.

In-process research and development

In-process research and development ("IPR&D") assets represent capitalized incomplete research projects that the Company acquired through business combinations. Such assets are initially measured at their acquisition date fair values. The initial fair values of the research projects are recorded as intangible assets on the balance sheet, rather than expensed, regardless of whether these assets have an alternative future use.

The amounts capitalized are being accounted for as indefinite-lived intangible assets, subject to impairment testing, until completion or abandonment of research and development efforts associated with the project. An IPR&D asset is considered abandoned when it ceases to be used (that is, research and development efforts associated with the asset have ceased, and there are no plans to sell or license the asset or derive defensive value from the asset). At that point, the asset is considered to be disposed of and is written off. Upon successful completion of each project, the Company will make a determination about the then remaining useful life of the intangible asset and begin amortization. The Company tests its indefinite-lived intangibles, IPR&D assets, for impairment annually on November 30 and more frequently if events or changes in circumstances indicate that it is more likely than not that the asset is impaired. When testing indefinite-lived intangibles for impairment, the Company may assess qualitative factors for its indefinite-lived intangibles to determine whether it is more likely than not (that is, a likelihood of more than 50 percent) that the asset is impaired. Alternatively, the Company may bypass this qualitative assessment for some or all of its indefinite-lived intangibles and perform the quantitative impairment test that compares the fair value of the indefinite-lived intangible asset with the asset's carrying amount. There was no impairment of the Mind-NRG IPR&D asset for the years ended December 31, 2020 or 2019.

Impairment of MIN-117 In-process Research and Development Asset.

As a result of the Company's Phase 2b trial of MIN-117 in adult patients suffering from moderate to severe MDD not meeting its primary and key secondary endpoints and the Company's decision not to further the clinical development of MIN-117 in MDD, the Company determined that the MIN-117 IPR&D was fully impaired and recognized a $19.0 million expense, which was included as a component of research and development expense, during the year ended December 31, 2019.

Stock-based compensation

The Company recognizes compensation cost relating to stock-based payment transactions using a fair-value measurement method, which requires all stock-based payments to employees, including grants of employee stock options, to be recognized in operating results as compensation expense based on fair value over the requisite service period of the awards. The Company determines the fair value of stock-based awards using the Black-Scholes option-pricing model which uses both historical and current market data to estimate fair value. The method incorporates various assumptions such as the risk-free interest rate, expected volatility, expected dividend yield, and expected life of the options. Forfeitures are recorded as they occur instead of estimating forfeitures that are expected to occur. The fair value of restricted stock units ("RSUs") is equal to the closing price of the Company's common stock on the date of grant.

An accounting policy change was made by the Company related to the accounting for non-employee awards on January 1, 2019 as a result of the adoption of ASU No. 2018-07, *Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* for which the Company now accounts for non-employee awards in the same manner as employee awards.

The date of expense recognition for grants to non-employees is the earlier of the date at which a commitment for performance by the counterparty to earn the equity instrument is reached or the date at which the counterparty's performance is complete. The Company determines the fair value of stock-based awards granted to non-employees similar to the way fair value of awards are determined for employees except that certain assumptions used in the Black-Scholes option-pricing model, such as expected life of the option, may be different.

Foreign currency transactions

The Company's functional currency is the U.S. Dollar. The Company pays certain vendor invoices in the respective foreign currency. The Company records an expense in U.S. Dollars at the time the liability is incurred. Changes in the applicable foreign currency rate between the date an expense is recorded and the payment date is recorded as a foreign currency gain or loss.

Income (loss) per share

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding for the period. Diluted net income (loss) per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that shared in the earnings of the entity. The treasury stock method is used to determine the dilutive effect of the Company's stock options and warrants.

Income taxes

Deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Uncertain tax positions are evaluated and if appropriate, the amount of unrecognized tax benefits are recorded within deferred tax assets. Deferred tax assets are evaluated for realization based on a more-likely-than-not criterion in determining if a valuation allowance should be provided. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company uses a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken, or expected to be taken, in a tax return. The Company has elected to treat interest and penalties, to the extent they arise, as a component of income tax expense. There was no interest or penalties related to income taxes for the years ended December 31, 2020 or 2019. Income tax years beginning in 2012 for federal and state purposes are generally subject to examination by taxing authorities, although net operating losses from all prior years are subject to examinations and adjustments for at least three years following the year in which the tax attributes are utilized.

Concentration of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash, cash equivalents and marketable securities. The Company maintains its cash and cash equivalent balances in the form of business checking accounts and money market accounts, the balances of which, at times, may exceed federally insured limits. Exposure to cash and cash equivalents credit risk is reduced by placing such deposits with major financial institutions and monitoring their credit ratings. Marketable securities consist primarily of corporate bonds, with fixed interest rates. Exposure to credit risk of marketable securities is reduced by maintaining a diverse portfolio and monitoring their credit ratings.

Equipment

Equipment is stated at cost less accumulated depreciation. Equipment is depreciated on the straight-line basis over their estimated useful lives of three years. Expenditures for maintenance and repairs are charged to expense as incurred.

Leases

Effective January 1, 2019, the Company adopted Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 842, *Leases* ("ASC 842"), using the required modified retrospective approach and utilizing the effective date as its date of initial application, for which prior periods are presented in accordance with the previous guidance in ASC 840, *Leases* ("ASC 840").

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Most leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and short-term and long-term lease liabilities, as applicable. The Company has elected not to recognize on the balance sheet leases with terms of 12 months or less. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew. The Company monitors its plans to renew its material leases on a quarterly basis.

Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The interest rate implicit in the Company's leases is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term and in a similar economic environment. In transition to ASC 842, the Company utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rates.

In accordance with ASC 842, components of a lease should be allocated between lease components (e.g., land, building, etc.) and non-lease components (e.g., common area maintenance, consumables, etc.). The fixed and in-substance fixed contract consideration (including any consideration related to non-components) must be allocated based on the respective relative fair values to the lease components and non-lease components.

Although separation of lease and non-lease components is required, certain expedients are available. Entities may elect the practical expedient to not separate lease and non-lease components by class of underlying asset where entities would account for each lease component and the related non-lease component together as a single component. For new and amended leases beginning in 2019 and after, the Company has elected to account for the lease and non-lease components for leases for classes of all underlying assets and allocate all of the contract consideration to the lease component only.

Long-lived assets

The Company reviews the recoverability of all long-lived assets, including the related useful lives, whenever events or changes in circumstances indicate that the carrying amount of a long-lived asset might not be recoverable. If required, the Company compares the estimated undiscounted future net cash flows to the related asset's carrying value to determine whether there has been an impairment. If an asset is considered impaired, the asset is written down to fair value, which is based either on discounted cash flows or appraised values in the period the impairment becomes known. The Company believes that all long-lived assets are recoverable, and no impairment was deemed necessary at December 31, 2020 and 2019.

Goodwill

The Company tests its goodwill for impairment annually, or whenever events or changes in circumstances indicate an impairment may have occurred, by comparing its reporting unit's carrying value to its fair value. Impairment may result from, among other things, deterioration in the performance of the acquired business, adverse market conditions, adverse changes in applicable laws or regulations and a variety of other circumstances. If the Company determines that an impairment has occurred, it is required to record a write-down of the carrying value and charge the impairment as an operating expense in the period the determination is made. In evaluating the recoverability of the carrying value of goodwill, the Company must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the acquired assets. Changes in strategy or market conditions could significantly impact those judgments in the future and require an adjustment to the recorded balances. The Company tested its goodwill for impairment as of November 30. There was no impairment of goodwill for the years ended December 31, 2020 or 2019.

Fair value of financial instruments

The Company provides disclosure of financial assets and financial liabilities that are carried at fair value based on the price that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value measurements may be classified based on the amount of subjectivity associated with the inputs to fair valuation of these assets and liabilities using the following three levels:

Level 1 — Inputs are unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2 — Inputs include quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (i.e., interest rates, yield curves, etc.) and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).

Level 3 — Unobservable inputs that reflect the Company's estimates of the assumptions that market participants would use in pricing the asset or liability. The Company develops these inputs based on the best information available, including its own data.

The following tables present information about the Company's cash equivalents and marketable securities as of December 31, 2020 and 2019, measured at fair value on a recurring basis and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

	December 31, 2020			
	Total	Level 1	Level 2	Level 3
Cash equivalents	$ 21,992,701	$ 21,992,701	$ —	$ —
Total fair value	$ 21,992,701	$ 21,992,701	$ —	$ —

	December 31, 2019			
	Total	Level 1	Level 2	Level 3
Cash equivalents	$ 17,385,141	$ 16,187,361	$ 1,197,780	$ —
Marketable securities	24,442,274	—	24,442,274	—
Total fair value	$ 41,827,415	$ 16,187,361	$ 25,640,054	$ —

Cash equivalents include short-term, highly-liquid instruments, consisting of money market accounts and short-term investments with maturities from the date of purchase of 90 days or less. The majority of cash and cash equivalents are maintained with major financial institutions in North America. Deposits with these financial institutions may exceed the amount of insurance provided on such deposits. These deposits may be redeemed upon demand which reduces counterparty performance risk.

Marketable securities consists of corporate and U.S. government debt securities maturing in four months or less. Based on the Company's intentions regarding its marketable securities, all marketable securities are classified as held-to-maturity and are carried under the amortized cost approach. Marketable securities are valued using models or other valuation methodologies that use Level 2 inputs. These models are primarily industry-standard models that consider various assumptions, including time value, yield curve, volatility factors, default rates, current market and contractual prices for the underlying financial instruments, as well as other relevant economic measures. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace.

The carrying amounts of cash, restricted cash, accounts payable, and accrued liabilities approximate fair value because of their short-term nature.

Revenue recognition

The Company applies the revenue recognition guidance in accordance with ASC 606, *Revenue from Contracts with Customers*. Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred and title has passed, the price is fixed or determinable, and collectability is reasonably assured. The Company is a development stage company and has had no revenues from product sales to date.

When the Company enters into an arrangement that meets the definition of a collaboration under ASC 808, *Collaborative Arrangements*, the Company recognizes revenue as research and development is performed and its respective share of the expenses are incurred. The Company assesses whether the arrangement contains

multiple elements or deliverables, which may include (1) licenses to the Company's technology, (2) research and development activities performed for the collaboration partner, and (3) participation on Joint Steering Committees. Payments may include non-refundable, upfront payments, milestone payments upon achieving significant development events, and royalties on future sales. Each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting based on whether the deliverable has “stand-alone value” to the customer. The arrangement’s consideration is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The estimated selling price of each deliverable is determined using the following hierarchy of values: (i) vendor-specific objective evidence of fair value, (ii) third-party evidence of selling price, and (iii) best estimate of selling price. The best estimate of selling price reflects the Company’s best estimate of what the selling price would be if the deliverable was regularly sold by the Company on a stand-alone basis. The consideration allocated to each unit of accounting is then recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. Supply or service transactions may involve the charge of a nonrefundable initial fee with subsequent periodic payments for future products or services. The up-front fees, even if nonrefundable, are recognized as revenue as the products and/or services are delivered and performed over the term of the arrangement. During the year ended December 31, 2020, the Company recognized $41.2 million in collaborative revenue as a result of opting out of its agreement with Janssen (see Note 5).

Deferred revenue

The Company applies the revenue recognition guidance in accordance with ASC 606. Using ASC 606, revenue that is unearned is deferred. Deferred revenue that is expected to be recognized as revenue more than one year subsequent to the balance sheet date is classified as long-term deferred revenue.

Segment information

Operating segments are defined as components of an enterprise (business activity from which it earns revenue and incurs expenses) about which discrete financial information is available and regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company’s chief decision maker, who is the Chief Executive Officer, reviews operating results to make decisions about allocating resources and assessing performance for the entire Company. The Company views its operations and manages its business as one operating segment.

Comprehensive loss

The Company had no items of comprehensive loss other than its net loss for each period presented.

Recent accounting pronouncements

From time to time, new accounting pronouncements are issued by the FASB and are adopted by the Company as of the specified effective date.

Recently adopted accounting pronouncements

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*. This update is intended to clarify that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606. The Company adopted the new standard on January 1, 2020.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles — Goodwill and Other (Topic 350).* The new standard simplifies the test for goodwill impairment. The Company adopted the new standard on January 1, 2020.

NOTE 3 — ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities consist of the following:

	Year Ended December 31,	
	2020	2019
Research and development costs and other accrued expenses	$ 1,880,552	$ 3,824,950
Accrued Severance	31,876	—
Professional fees	140,981	314,213
	$ 2,053,409	$ 4,139,163

NOTE 4 — NET INCOME (LOSS) PER SHARE OF COMMON STOCK

Basic income (loss) per share is calculated by dividing the net income (loss) by the weighted average number of shares of common stock outstanding. Diluted income per share is computed by dividing the net income by the weighted average number of shares of common stock outstanding, plus potential outstanding common stock for the period. Potential outstanding common stock includes stock options and shares underlying RSUs, but only to the extent that their inclusion is dilutive. The following table sets forth the computation of basic and diluted income (loss) per share for common stockholders:

	Year Ended December 31,	
	2020	2019
Net income (loss)	$ 1,940,771	$ (72,183,490)
Weighted average shares of common stock outstanding - basic	40,823,717	39,014,302
Dilutive effect	93,154	—
Weighted average shares of common stock outstanding - diluted	40,916,871	39,014,302
Net income (loss) per ordinary share:		
Basic	$ 0.05	$ (1.85)
Diluted	$ 0.05	$ (1.85)

The following securities outstanding at December 31, 2020 and 2019 have been excluded from the calculation of weighted average shares outstanding as their effect on the calculation of loss per share is antidilutive:

	Year Ended December 31,	
	2020	2019
Common stock options	8,602,722	9,040,328
Restricted stock units	—	68,650
Common stock warrants	40,790	40,790

NOTE 5 — CO-DEVELOPMENT AND LICENSE AGREEMENT

On February 13, 2014, the Company signed a co-development and license agreement (the “Agreement”) with Janssen, which became effective upon completion of the Company’s initial public offering and provided for the payment of a $22.0 million license fee by the Company. Under the Agreement, Janssen, the licensor, granted the Company an exclusive license, with the right to sublicense, in the Minerva Territory, under (i) certain patent and patent applications to sell products containing any orexin 2 compound, controlled by the licensor and claimed in a licensor patent right as an active ingredient, and (ii) seltorexant for any use in humans.

The Company has accounted for the Agreement as a joint risk-sharing collaboration in accordance with ASC 808, *Collaborative Arrangements*.

In June 2017, the Company entered into an amendment (“the Amendment”) to the Agreement, which became effective on August 29, 2017. Under the Amendment, Janssen waived its right to royalties on seltorexant insomnia sales in the Minerva Territory and made an upfront payment to the Company of $30 million and agreed to waive development payments from the Company until completion of the Phase 2b development milestone, referred to as “Decision Point 4”.

Top-line results have been reported from three Phase 2b trials and one Phase 1b trial with seltorexant.

On June 30, 2020, the Company exercised its right to opt out of the Agreement with Janssen pursuant to a Settlement Agreement with Janssen dated June 24, 2020 (the “Settlement Agreement”), which became effective upon exercise of the opt out, pursuant to which the Company and Janssen resolved certain disputes under the Agreement. Under the Settlement Agreement, the Company agreed not to assert that Decision Point 4 has not been reached, Janssen waived the requirement that opt-out occur after Decision Point 4 in order for the Company to receive a royalty on sales of seltorexant after opt-out, and the Company and Janssen agreed to waive any payments to the other with respect to development costs for seltorexant. As a result of the exercise of its right to opt out of the Agreement with Janssen, the Agreement is deemed to have been terminated effective as of October 2, 2019. The Company will be entitled to collect a royalty on worldwide sales of seltorexant in certain indications in the mid-single digits, with no further financial obligations to Janssen.

As a result of opting out of the Agreement with Janssen, the Company recognized $41.2 million in collaborative revenue during the second quarter of 2020 which had previously been included on the balance sheet under deferred revenue. The $41.2 million in collaborative revenue represents the $30 million payment made by Janssen and $11.2 million in previously accrued collaborative

expenses forgiven by Janssen upon the effective date of the Amendment. The Company does not have any future performance obligations under the agreement and would recognize any future royalty revenues in the periods of the sale of the related products.

On January 19, 2021, The Company announced an agreement with Royalty Pharma under which Royalty Pharma acquired Minerva's royalty interest in seltorexant for an upfront payment of $60 million and up to an additional $95 million in additional milestone payments. These milestone payments are contingent upon the achievement of certain clinical, regulatory and commercial milestones for seltorexant by Janssen or any other party in the event that Janssen sells seltorexant.

NOTE 6 — STOCKHOLDERS' EQUITY

At-the-Market Equity Offering Program

On August 10, 2018, the Company entered into the Sales Agreement with Jefferies pursuant to which the Company may offer and sell, from time to time, through Jefferies, up to $50.0 million in shares of the Company's common stock, by any method permitted by law deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. During the year ended December 31, 2020, the Company issued and sold 3,381,608 shares of the Company's common stock under the Sales Agreement. The shares were sold at an average price of $3.7113 per share for aggregate net proceeds to the Company of approximately $12.1 million, after deducting sales commissions and offering costs payable by the Company.

Term Loan Warrants

In connection with the Company's former Loan and Security Agreement with Oxford Finance LLC and Silicon Valley Bank (the "Lenders"), which provided for term loans to the Company in an aggregate principal amount of up to $15 million in two tranches on January 15, 2016, the Company issued the Lenders warrants to purchase 40,790 shares of common stock at a per share exercise price of $5.516. The warrants are immediately exercisable upon issuance, and other than in connection with certain mergers or acquisitions, will expire on the ten-year anniversary of the date of issuance. The fair value of the warrants was estimated at $0.2 million using a Black-Scholes model and assuming: (i) expected volatility of 100.8%, (ii) risk free interest rate of 1.83%, (iii) an expected life of 10 years and (iv) no dividend payments. The fair value of the warrants was included as a discount to the term loans drawn at such time and also as a component of additional paid-in capital and were amortized to interest expense over the term of the loan. Although the term loans were repaid in August 2018, all related warrants were outstanding and exercisable as of December 31, 2020.

NOTE 7 — STOCK AWARD PLAN AND STOCK-BASED COMPENSATION

In December 2013, the Company adopted the 2013 Equity Incentive Plan (as subsequently amended and restated, the "Plan"), which provides for the issuance of options, stock appreciation rights, stock awards and stock units. Pursuant to Nasdaq listing rules, the Company issued inducement awards in December 2017 to the Company's President outside of the Plan in the form of an option to purchase 775,000 shares of the Company's common stock and a RSU award to purchase 40,000 shares of the Company's common stock. As of September 30, 2020, all remaining inducement awards have been canceled or expired. In June 2020, the Company increased the aggregate number of shares of common stock authorized for issuance under the Plan by 2,000,000 shares. Stock option activity for employees and non-employees for the year ended December 31, 2020 is as follows:

	Shares Issuable Pursuant to Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Terms (years)	Total Intrinsic Value (in thousands)
Outstanding January 1, 2020	9,040,328	$ 6.98	7.3	$ 7,420
Granted	3,003,344	$ 5.86		
Exercised	(198,762)	$ 5.75		
Forfeited	(1,689,031)	$ 7.20		
Expired	(105,356)	$ 9.63		
Outstanding December 31, 2020	10,050,523	$ 6.60	7.0	$ —
Exercisable December 31, 2020	6,341,404	$ 6.80	6.0	$ —
Available for future grant	157,616			

The weighted average grant-date fair value of stock options outstanding on December 31, 2020 was $4.15 per share. Total unrecognized compensation costs related to non-vested stock options at December 31, 2020 were approximately $11.3 million and are expected to be recognized within future operating results over a weighted-average period of 2.01 years. The total intrinsic value of the options exercised during the years ended December 31, 2020 and 2019 was approximately $0.9 million and $0.2 million, respectively.

The expected term of the employee-related options was estimated using the "simplified" method as defined by the SEC's Staff Accounting Bulletin No. 107, *Share-Based Payment*. The volatility assumption was determined by examining the historical volatilities for industry peer companies, as the Company did not have sufficient trading history for its common stock. The risk-free interest rate assumption is based on the U.S. Treasury instruments, the term of which was consistent with the expected term of the options. The dividend assumption is based on the Company's history and expectation of dividend payouts. The Company has never paid dividends on its common stock and does not anticipate paying dividends on its common stock in the foreseeable future. Accordingly, the Company has assumed no dividend yield for purposes of estimating the fair value of the options

The Company uses the Black-Scholes model to estimate the fair value of stock options granted. For stock options granted during the years ended December 31, 2020 and 2019, the Company utilized the following assumptions:

	Year Ended December 31,	
	2020	2019
Expected term (years)	5.5-6.25	5.5-6.25
Risk free interest rate	0.37%-0.54%	1.78%-1.96%
Volatility	68%-72%	69%-78%
Dividend yield	0%	0%
Weighted average grant date fair value per share of common stock	$ 1.78	$ 4.21

RSU activity under the Plan for the year ended December 31, 2020 is as follows:

	RSUs	Weighted-Average Grant Date Fair Value
Unvested January 1, 2020	68,650	$ 11.29
Granted	—	$ —
Vested	(57,075)	$ 12.15
Forfeited	(11,575)	$ 7.06
Unvested December 31, 2020	—	$ —

RSUs awarded to employees generally vest one-fourth per year over four years from the anniversary of the date of grant, provided the employee remains continuously employed with the Company. Shares of the Company's stock are delivered to the employee upon vesting, subject to payment of applicable withholding taxes. The fair value of RSUs is equal to the closing price of the Company's common stock on the date of grant. Total unrecognized compensation costs related to non-vested RSUs at December 31, 2020 was zero. The total fair value of RSUs vested, as of their respective vesting dates, during the years ended December 31, 2020 and 2019 was approximately $0.2 million and $0.4 million, respectively.

The following table presents stock-based compensation expense included in the Company's consolidated statements of operations:

	Year Ended December 31,	
	2020	2019
Research and development	$ 3,026,056	$ 2,646,210
General and administrative	6,678,173	6,527,055
Total	$ 9,704,229	$ 9,173,265

NOTE 8 — INCOME TAXES

The provision for federal, foreign and state income taxes for the years ended December 31, 2020 and 2019 are as follows:

	Year Ended December 31,	
	2020	2019
Current income tax provision (benefit)		
Federal	$ —	$ —
Foreign	—	—
State	—	—
Deferred income tax provision (benefit)		
Federal	—	(2,119,709)
Foreign	—	—
State	—	(134,423)
Total income tax provision (benefit)	$ —	$ (2,254,132)

Net deferred tax assets (liabilities) as of December 31, 2020 and 2019 consist of the following:

	Year Ended December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 27,962,495	$ 20,988,129
Research and development tax credits	145,115	145,115
Capitalized research and development costs	31,036,403	29,446,106
Stock-based compensation	9,507,000	7,518,780
Deferred start-up and license costs	4,724,696	5,327,213
Deferred revenue	—	11,249,174
Other	2,938	2,319
Total deferred tax assets	73,378,647	74,676,836
Deferred tax asset valuation allowance	(71,028,174)	(72,324,255)
Net deferred tax assets	2,350,473	2,352,581
Deferred tax liabilities:		
In-process research and development	(4,152,640)	(4,152,640)
Other	(1,189)	(3,297)
Total deferred tax liabilities	(4,153,829)	(4,155,937)
Total	$ (1,803,356)	$ (1,803,356)

A reconciliation between the Company’s effective tax rate and the federal statutory rate for the years ended December 31, 2020 and 2019 are as follows:

	Year Ended December 31,	
	2020	2019
Federal statutory rate	21.00%	(21.00%)
Permanent differences	4.38%	(0.37%)
State income taxes	0.00%	0.00%
Valuation allowance	(25.38%)	24.39%
Effective tax rate	0.00%	3.03%

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of the deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based upon the level of historical losses and the uncertainty of future taxable income over the periods which the Company will realize the benefits of its net deferred tax assets, management believes it is more likely than not that the Company will not realize the benefits on the balance of its net deferred tax asset and, accordingly, the Company has established a full valuation allowance on its net deferred tax assets. The valuation allowance decreased by approximately $1.3 million and increased by approximately $17.6 million during the years ended December 31, 2020 and 2019, respectively.

As of December 31, 2020, the Company had approximately $102.8 million of federal net operating losses that will begin to expire in 2030. Of the total federal net operating loss, approximately $48.9 million has an unlimited carryforward and therefore will not expire. As of December 31, 2020, the Company had approximately $7.7 million of New Jersey and approximately $90.9 million of Massachusetts operating losses that will begin to expire in 2029 and 2034, respectively. As of December 31, 2020, the Company had approximately $0.2 million of federal research and development credits that will begin to expire in 2027.

The Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") was enacted in the United States on March 27, 2020. The CARES act is a $2 trillion relief package comprising a combination of tax provisions and other stimulus measures, including provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carry back periods, alternative minimum tax credit refunds, modifications to the interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. For the year ended December 31, 2020, the company did not require application or modification of its tax positions in relation to the tax provisions of the CARES Act.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending income tax examinations. The Company’s tax years are still open under statute from 2017 to present.

As of December 31, 2020 and 2019, the Company had no liability recorded for unrecognized tax benefit. The Company classifies penalties and interest expense related to income tax liabilities as an income tax expense. There were no interest and penalties recognized in the statements of operations for the years ended December 31, 2020 and 2019, or accrued on the balance sheets as of December 31, 2020 and 2019.

NOTE 9 — COMMITMENTS AND CONTINGENCIES

Legal Proceedings

On December 8, 2020 and January 11, 2021, purported stockholders of the Company filed two putative securities class action complaints in the United States District Court for the District of Massachusetts, entitled McCoy v. Minerva Neurosciences, Inc., et al., No. 1:20-cv-12176 and Ao v. Minerva Neurosciences, Inc. et al., No. 1:21-cv-10051, respectively, against the Company and the Company’s Chairman and Chief Executive Officer (collectively, the “Defendants"). The complaints are nearly identical and allege that the Defendants made material false and/or misleading statements regarding the development of the Company’s drug candidate roluperidone purportedly causing losses to investors who acquired the Company’s common stock between May 15, 2017 and November 30, 2020. The complaints do not quantify any alleged damages but, in addition to attorneys' fees and costs, plaintiffs seek to recover damages on behalf of themselves and others who acquired the Company’s stock during the putative class period at allegedly inflated prices and purportedly suffered financial harm as a result. On February 8, 2021, three putative lead plaintiffs filed motions to consolidate the cases and to appoint a lead plaintiff. Two of the putative lead plaintiffs withdrew their motions on February 22, 2021. The defendants’ response to the complaints is stayed pending consolidation and resolution of the lead plaintiff motions. We dispute these claims and intend to defend the matter vigorously. Given the uncertainty of litigation, the preliminary stage of the case, and the legal standards that must be met for, among other things, class certification and success on the merits, we cannot estimate the reasonably possible loss or range of loss that may result from this action.

Leases

Please refer to Note 10, for the Company’s current lease commitments.

NOTE 10 — LEASES

Operating leases

On October 2, 2017, the Company entered into an office sublease agreement (the "Sublease") with Profitect, Inc. (the "Sublandlord") to sublease approximately 5,923 rentable square feet of office space located at 1601 Trapelo Road, Waltham, MA 02451 (the "Premises"). The term of the Sublease began on November 1, 2017 and will expire on July 31, 2021 (the "Term"), with a monthly rental rate starting at $14,808 and escalating to a maximum monthly rental rate of $16,288 in the final 12 months of the Term. The Sublandlord provided the Premises to the Company free of charge for the first two months of the Term. The Company will recognize the remaining expense in accordance with ASC 842.

Throughout the Term, the Company is responsible for paying certain costs and expenses, in addition to the rent, as specified in the Sublease, including a proportionate share of applicable taxes, operating expenses and utilities. In applying the ASC 842 transition guidance, the Company retained the classification of this Sublease as operating and recorded a lease liability and a right-of-use asset on the ASC 842 effective date.

The following table contains a summary of the Sublease costs recognized under ASC 842 and other information pertaining to the Company's operating Sublease for the years ended December 31, 2020:

	Year Ended December 31, 2020
Sublease cost	
Operating Sublease cost	$ 179,269
Total Sublease cost	$ 179,269
Other information	
Operating cash flows used for operating Sublease	$ 192,004
Weighted average remaining Sublease term	0.6 years
Weighted average discount rate	10%

Future minimum Sublease payments under the Company's non-cancelable operating Sublease as of December 31, 2020 and December 31, 2019, are as follows:

Future Operating Sublease Payments	Year Ended December 31, 2020
2021	$ 114,018
Thereafter	—
Total Sublease payments	114,018
Less: imputed interest	(2,789)
Total operating Sublease liabilities at December 31, 2020	$ 111,229

Future Operating Sublease Payments	Year Ended December 31, 2019
2020	$ 192,004
2021	114,018
Thereafter	—
Total Sublease payments	306,022
Less: imputed interest	(21,892)
Total operating Sublease liabilities at December 31, 2019	$ 284,130

NOTE 11 — RELATED PARTY TRANSACTIONS

None.

NOTE 12 — QUARTERLY RESULTS (Unaudited)

	Three Months Ended			
	March 31, 2020	June 30, 2020	September 30, 2020	December 31, 2020
	(in thousands, except per share data)			
Total revenues	$ —	$ 41,176	$ —	$ —
Operating (loss) gain	$ (12,272)	$ 29,508	$ (8,090)	$ (7,299)
Net (loss) income	$ (12,151)	$ 29,529	$ (8,113)	$ (7,324)
Net (loss) income in per share, basic	$ (0.31)	$ 0.75	$ (0.19)	$ (0.17)
Net (loss) income in per share, diluted	$ (0.31)	$ 0.73	$ (0.19)	$ (0.17)

	Three Months Ended			
	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019
	(in thousands, except per share data)			
Total revenues	$ —	$ —	$ —	$ —
Operating loss	$ (16,312)	$ (12,904)	$ (14,282)	$ (32,367)
Net loss	$ (15,827)	$ (12,476)	$ (13,962)	$ (29,918)
Net (loss) income in per share, basic	$ (0.41)	$ (0.32)	$ (0.36)	$ (0.77)
Net (loss) income in per share, diluted	$ (0.41)	$ (0.32)	$ (0.36)	$ (0.77)

NOTE 13 — SUBSEQUENT EVENTS

On January 19, 2021, The Company announced an agreement with Royalty Pharma under which Royalty Pharma acquired Minerva’s royalty interest in seltorexant for an upfront payment of $60 million and up to an additional $95 million in additional milestone payments. These milestone payments are contingent upon the achievement of certain clinical, regulatory and commercial milestones for seltorexant by Janssen or any other party in the event that Janssen sells seltorexant.

ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

ITEM 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act, that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2020. Based on the evaluation of our disclosure controls and procedures as of December 31, 2020, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

As of December 31, 2020, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013 Framework). Based on this assessment, our management concluded that, as of December 31, 2020, our internal control over financial reporting was effective based on those criteria. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

This annual report does not include an attestation report of our registered public accounting firm due to the Securities and Exchange Commission adopted amendments to the accelerated filer and large accelerated filer definitions on March 12, 2020. Following the adoption of the amendments, smaller reporting companies with less than $100 million in revenues will continue to be required to establish and maintain effective internal control over financial reporting ("ICFR") but, will no longer be required to obtain a separate attestation of their ICFR from an outside auditor.

Changes in Internal Control over Financial Reporting

There were no changes in internal control over financial reporting during the fourth quarter that would have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. Other Information

None.

Part III

ITEM 10. Directors, Executive Officers and Corporate Governance

The information required by this Item 10 will be contained in the sections entitled “Election of Directors,” “Corporate Governance” and “Section 16(a) Beneficial Ownership Reporting Compliance” appearing in the definitive proxy statement we will file in connection with our 2020 Annual Meeting of Stockholders and is incorporated by reference herein. The information required by this item relating to executive officers may be found in Part I, Item 1 of this report under the heading “Business—Executive Officers” and is incorporated herein by reference.

ITEM 11. Executive Compensation

The information required by this Item 11 will be contained in the sections entitled “Executive and Director Compensation,” “Executive and Director Compensation—Compensation Committee Interlocks and Insider Participation” and “Executive and Director Compensation—Compensation Committee Report” appearing in the definitive proxy statement we will file in connection with our 2020 Annual Meeting of Stockholders and is incorporated by reference herein.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item 12 will be contained in the sections entitled “Ownership of Our Common Stock” and “Executive and Director Compensation—Equity Compensation Plan Information” appearing in the definitive proxy statement we will file in connection with our 2020 Annual Meeting of Stockholders and is incorporated by reference herein.

ITEM 13. Certain Relationships and Related Person Transactions, and Director Independence

The information required by this Item 13 will be contained in the sections entitled “Certain Relationships and Related Person Transactions” appearing in the definitive proxy statement we will file in connection with our 2021 Annual Meeting of Stockholders and is incorporated by reference herein.

ITEM 14. Principal Accounting Fees and Services

The information required by this Item 14 will be contained in the section entitled “Corporate Governance—Principal Accountant Fees and Services” appearing in the definitive proxy statement we will file in connection with our 2020 Annual Meeting of Stockholders and is incorporated by reference herein.

Part IV

ITEM 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of Form 10-K.

(1) Financial Statements

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2020 and 2019

Consolidated Statements of Operations for the Years Ended December 31, 2020 and 2019

Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2020 and 2019

Consolidated Statements of Cash Flows for the Years Ended December 31, 2020 and 2019

Notes to Consolidated Financial Statements

(2) Schedules

Schedules have been omitted as all required information has been disclosed in the financial statements and related footnotes.

(3) Exhibits

The following exhibits are filed as part of this Annual Report on Form 10-K or are incorporated herein by reference.

Exhibit No.	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith
2.1	Agreement and Plan of Merger of Sonkei Pharmaceuticals, Inc. with and into Cyrenaic Pharmaceuticals, Inc., dated as of November 12, 2013	S-1	333-195169	10.11	April 9, 2014	
2.2	Certificate of Merger Merging Sonkei Pharmaceuticals, Inc. with and into Cyrenaic Pharmaceuticals, Inc., dated as of November 12, 2013	S-1/A	333-195169	3.3	June 10, 2014	
3.1	Amended and Restated Certificate of Incorporation of the Registrant	S-1/A	333-195169	3.1	June 10, 2014	
3.2	Amended and Restated Bylaws of the Registrant	10-Q	001-36517	3.2	November 4, 2019	
4.1	Form of Common Stock Certificate	S-1/A	333-195169	4.1	June 10, 2014	
4.2	Investor Rights Agreement among the Registrant f/k/a Cyrenaic Pharmaceuticals, Inc. and certain of its security holders, dated as of August 29, 2007	S-1/A	333-195169	4.2	June 10, 2014	
4.3	Amendment No. 1 to Investor Rights Agreement among the Registrant and certain of its security holders, dated as of December 20, 2013	S-1/A	333-195169	4.3	June 10, 2014	
4.4	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.					X
10.1	Share Purchase Agreement between the Registrant, Mind-NRG SA and Various Shareholders dated as of February 11, 2014	S-1	333-195169	10.13	April 9, 2014	
10.2	Common Stock Purchase Agreement between Johnson & Johnson Development Corporation and the Registrant, dated as of February 13, 2014	S-1	333-195169	10.14	April 9, 2014	
10.3	Loan Agreement by and among certain stockholders and their affiliates and the Registrant, dated as of April 30, 2014	S-1/A	333-195169	10.26	June 10, 2014	
10.4	Loan Agreement by and among certain stockholders and their affiliates and the Registrant, dated as of May 23, 2014	S-1/A	333-195169	10.27	June 10, 2014	
10.5	Stock Purchase Agreement between Care Capital Investments III LP, Index Ventures III L.P. and the Registrant f/k/a Cyrenaic Pharmaceuticals, Inc., dated as of August 29, 2007	S-1	333-195169	10.19	April 9, 2014	
10.6	Amendment No. 1 to Stock Purchase Agreement between Care Capital Investments III LP, Index Ventures III L.P. and the Registrant and various Shareholders, dated as of March 28, 2014	S-1	333-195169	10.20	April 9, 2014	
10.7†	Employment Agreement between Remy Luthringer and Mind-NRG SA, the Registrant's subsidiary, dated as of April 8, 2014	S-1	333-195169	10.22	April 9, 2014	
10.8†	Employment Agreement between Geoff Race and Mind-NRG SA, the Registrant's subsidiary, dated as of April 8, 2014	S-1	333-195169	10.23	April 9, 2014	
10.9†	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers	S-1/A	333-195169	10.1	June 10, 2014	

Exhibit No.	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith
10.10*	License Agreement between Mitsubishi Pharma Corporation and the Registrant f/k/a Cyrenaic Pharmaceuticals, Inc., dated as of August 30, 2007	S-1/A	333-195169	10.2	June 10, 2014	
10.11*	Amendment to License Agreement between Mitsubishi Tanabe Pharma Corporation and the Registrant f/k/a Cyrenaic Pharmaceuticals, Inc., dated as of June 16, 2011	S-1/A	333-195169	10.3	June 10, 2014	
10.12*	Second Amendment to License Agreement between Mitsubishi Tanabe Pharma Corporation and the Registrant, dated as of January 20, 2014	S-1/A	333-195169	10.4	June 10, 2014	
10.13*	License Agreement between Mitsubishi Tanabe Pharma Corporation and the Registrant as successor in interest to Sonkei Pharmaceuticals, Inc., dated as of September 1, 2008	S-1/A	333-195169	10.5	June 10, 2014	
10.14*	Amendment to License Agreement between Mitsubishi Tanabe Pharma Corporation and the Registrant, dated as of January 20, 2014	S-1/A	333-195169	10.6	June 10, 2014	
10.15*	Co-Development and License Agreement between Janssen Pharmaceutica, N.V. and the Registrant, dated as of February 13, 2014	S-1/A	333-195169	10.7	June 10, 2014	
10.16†	Employment Agreement between Joseph Reilly and the Registrant, dated as of December 23, 2013	S-1/A	333-195169	10.9	June 10, 2014	
10.17†	Amended and Restated 2013 Equity Incentive Plan of the Registrant	8-K	001-36517	99.1	June 11, 2018	
10.18	Form of Securities Purchase Agreement between certain investors referenced therein and the Registrant, dated as of March 13, 2015	8-K	001-36517	10.1	March 18, 2015	
10.19	Form of Registration Rights Agreement between certain investors referenced therein and the Registrant, dated as of March 13, 2015	8-K	001-36517	10.3	March 18, 2015	
10.20	Second Amendment to License Agreement between Mitsubishi Tanabe Pharma Corporation and the Registrant, dated as of April 21, 2015	10-Q	001-36517	10.5	May 7, 2015	
10.21†	Amended and Restated Non-Employee Director Compensation Plan	10-Q	001-36517	10.2	August 2, 2018	
10.22†	Employment Agreement between Fred Ahlholm and the Registrant, dated as of May 30, 2014	10-Q	001-36517	10.2	November 5, 2015	
10.23	Common Stock Purchase Agreement, dated March 17, 2016, by and between David Kupfer and the Registrant	8-K	001-36517	10.1	March 18, 2016	
10.24†	Employment Agreement, dated as of August 1, 2016, by and between Mind-NRG SARL and Dr. Remy Luthringer	10-Q	001-36517	10.1	August 4, 2016	
10.25†	Employment Agreement, dated as of August 1, 2016, by and between Mind-NRG SARL and Geoffrey Race	10-Q	001-36517	10.2	August 4, 2016	
10.26†	Employment Agreement, dated as of August 1, 2016, by and between the Registrant and Frederick Ahlholm	10-Q	001-36517	10.3	August 4, 2016	
10.27†	Employment Agreement, dated as of August 1, 2016, by and between the Registrant and Mark S. Levine	10-Q	001-36517	10.4	August 4, 2016	

Exhibit No.	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith
10.28†	Employment Agreement, dated as of August 1, 2016, by and between the Registrant and Joseph Reilly	10-Q	001-36517	10.5	August 4, 2016	
10.29†	Form of Restricted Stock Unit Agreement under the Amended and Restated 2013 Equity Incentive Plan of the Registrant	8-K	001-36517	10.1	December 16, 2016	
10.30†	Form of Option Grant Agreement under the Amended and Restated 2013 Equity Incentive Plan	10-K	001-36517	10.36	March 13, 2017	
10.31	Sublease Agreement dated October 2, 2017 by and between the Registrant and Profitect, Inc. NV	10-Q	001-36517	10.1	November 6, 2017	
10.32	Amendment No. 1 to Co-Development and License Agreement dated June 13, 2017, by and between the Registrant and Janssen Pharmaceutica NV	8-K	001-36517	10.1	June 14, 2017	
10.33	Stock Repurchase Agreement dated June 13, 2017 by and between the Registrant and Johnson & Johnson Innovation-JJDC Inc.	8-K	001-36517	10.2	June 14, 2017	
10.34†	Offer Letter by and between the Registrant and Rick Russell, dated December 11, 2017.	8-K	001-36517	10.1	December 11, 2017	
10.35†	New Hire Inducement Stock Option Grant by and between the Registrant and Rick Russell, dated December 11, 2017.	8-K	001-36517	10.2	December 11, 2017	
10.36†	New Hire Inducement Restricted Stock Unit Grant by and between the Registrant and Rick Russell, dated December 11, 2017.	8-K	001-36517	10.3	December 11, 2017	
10.37*	Commercial Supply Agreement by and between the Registrant and Catalent Germany Schorndorf GmbH, dated September 18, 2019	10-Q	001-36517	10.1	November 4, 2019	
10.38	Open Market Sale Agreement, dated as of August 10, 2018, by and between the Registrant and Jefferies LLC	S-3	333-226783	1.2	August 10, 2018	
10.39	Settlement Agreement, dated as of June 24, 2020, by and between the Registrant and Janssen Pharmaceutica, N.V.	10-Q	001-36517	10.2	August 3, 2020	
10.40†	Amended and Restated 2013 Equity Incentive Plan	10-Q	001-36517	10.3	August 3, 2020	
10.41*	Remy Luthringer Retention Benefits Letter Agreement (redacted)	10-Q	001-36517	10.1	November 2, 2020	
10.42*	Geoff Race Retention Benefits Letter Agreement (redacted)	10-Q	001-36517	10.2	November 2, 2020	
10.43*	Jay Saoud Retention Benefits Letter Agreement (redacted)	10-Q	001-36517	10.3	November 2, 2020	
10.44*	Devin Smith Retention Benefits Letter Agreement (redacted)	10-Q	001-36517	10.4	November 2, 2020	
10.45*	Frederick Ahlholm Retention Benefits Letter Agreement (redacted)	10-Q	001-36517	10.5	November 2, 2020	
10.46*	Joseph Reilly Retention Benefits Letter Agreement (redacted)	10-Q	001-36517	10.6	November 2, 2020	
10.47*	Michael Davidson Retention Benefits Letter Agreement (redacted)	10-Q	001-36517	10.7	November 2, 2020	

Exhibit No.	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith
10.48*	Royalty Purchase Agreement, dated as of January 15, 2021, by and between the Registrant and RPI 2019 Intermediate Finance Trust (redacted)					X
21.1	List of Subsidiaries					X
23.1	Consent of Deloitte & Touche, LLP, independent registered public accounting firm					X
24.1	Power of Attorney (included on the Signature page of this Annual Report on Form 10-K)					X
31.1	Certification of Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002					X
31.2	Certification of Chief Financial Officer (Principal Financial Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002					X
32.1**	Certification of Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer) pursuant to Section 906 of Sarbanes-Oxley Act of 2002					X
101.INS	Inline XBRL Instance Document					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X

† Indicates management contract or compensatory plan or arrangement.

* Confidential treatment has been granted by the Securities and Exchange Commission as to certain portions of this document.

** These certifications are being furnished solely to accompany this annual report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

ITEM 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MINERVA NEUROSCIENCES, INC.

By:

/s/ Remy Luthringer, Ph.D.
Remy Luthringer, Ph.D.
Executive Chairman and
Chief Executive Officer
(Principal Executive Officer)

Date: March 8, 2021

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Remy Luthringer, Ph.D. and Geoffrey Race, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Remy Luthringer, Ph.D. Remy Luthringer, Ph.D.	Executive Chairman and Chief Executive Officer *(Principal Executive Officer)*	March 8, 2021
/s/ Geoffrey Race Geoffrey Race	Chief Financial Officer *(Principal Financial Officer)*	March 8, 2021
/s/ Frederick Ahlholm Frederick Ahlholm	Chief Accounting Officer *(Principal Accounting Officer)*	March 8, 2021
/s/ William F. Doyle William F. Doyle	Member of the Board of Directors	March 8, 2021
/s/ Hans Peter Hasler Hans Peter Hasler	Member of the Board of Directors	March 8, 2021
/s/ Jeryl Hilleman Jeryl Hilleman	Member of the Board of Directors	March 8, 2021
/s/ David Kupfer, MD David Kupfer, MD	Member of the Board of Directors	March 8, 2021
/s/ Fouzia Laghrissi-Thode, MD Fouzia Laghrissi-Thode, MD	Member of the Board of Directors	March 8, 2021
/s/ Jan van Heek Jan van Heek	Member of the Board of Directors	March 8, 2021

Exhibit 4.4

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of March 4, 2021, Minerva Neurosciences, Inc. (the "Company") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): our common stock.

The following description of our common stock is a summary, does not purport to be complete and is subject to, and is qualified in its entirety by reference to, the applicable provisions of Delaware law and our amended and restated certificate of incorporation and our amended and restated bylaws, copies of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.4 is a part. We encourage you to read our certificate of incorporation, our bylaws and the applicable provisions of Delaware law for additional information.

Authorized Capital Stock

Our authorized capital stock consists of 125,000,000 shares of common stock, $0.0001 par value per share, and 100,000,000 shares of preferred stock, $0.0001 par value per share.

Common stock

Voting rights. Each holder of our common stock is entitled to one vote for each share of common stock on all matters submitted to a vote of the stockholders, including the election of directors. The holders of our common stock do not have cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividend rights. Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation. In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

Rights and Preferences. Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The outstanding shares of our common stock are fully paid and nonassessable.

Preferred stock

Under our amended and restated certificate of incorporation, our board of directors has the authority, without further action by our stockholders, to issue up to 100,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change of control of our company or other corporate action.

Anti-takeover Provisions

Certificate of Incorporation and Bylaws. Our amended and restated certificate of incorporation provides for our board of directors to be divided into three classes, with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors. Our amended and restated certificate of incorporation and amended and restated bylaws provide that all stockholder action must be effected at a duly called meeting of stockholders and not by a consent in writing, and that only our board of directors or chairman of the board may call a special meeting of stockholders.

Our amended and restated certificate of incorporation requires a 66$^{2}/_{3}$% stockholder vote for the amendment, repeal or modification of certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws relating to the classification of our board of directors, the requirement that stockholder actions be effected at a duly called meeting, and the designated parties entitled to call a special meeting of the stockholders. The combination of the classification of our board of directors, the lack of cumulative voting and the 66$^{2}/_{3}$% stockholder voting requirements will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of our company.

These provisions may have the effect of deterring hostile takeovers or delaying changes in control of our company or management. These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of us. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal. The provisions also are intended to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they also may inhibit fluctuations in the market price of our shares that could result from actual or rumored takeover attempts. Such provisions may also have the effect of preventing changes in our management.

Forum. Our amended and restated certificate of incorporation and our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer or other employee or stockholder of the Company to us or our stockholders, any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws or as to which the Delaware General Corporation Law confers jurisdiction on the Court of Chancery of the State of Delaware, or any action asserting a claim governed by the internal affairs doctrine. Our amended and restated certificate of incorporation and our amended and restated bylaws further provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the foregoing provision. Although our amended and restated certificate of incorporation and our amended and restated bylaws include these provisions, it is possible that a court could rule that such provisions are inapplicable or unenforceable.

Delaware Anti-takeover Law

The Company is subject to Section 203 of the Delaware General Corporation Law (“Section 203”), an anti-takeover law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date such person became an interested stockholder, unless the business combination or the transaction in which such person became an interested stockholder is approved in a prescribed manner. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. Generally, an “interested stockholder” is a person that, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the Board, including discouraging attempts that might result in a premium over the market price for the shares of common stock.

Listing on the Nasdaq Global Market

Our common stock is listed on the Nasdaq Global Market under the symbol “NERV”.

Exhibit 10.48

Certain identified information identified with brackets ("[•••]") has been excluded from this exhibit because it both (i) is not material and (ii) would be competitively harmful if publicly disclosed.

EXHIBIT 10.48 Royalty Purchase Agreement (redacted)

Execution Copy

Royalty Purchase Agreement

By and Between

Minerva Neurosciences, Inc.

and

RPI 2019 Intermediate Finance Trust

Dated as of January 15, 2021

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Index of Exhibits

ROYALTY PURCHASE AGREEMENT

This ROYALTY PURCHASE AGREEMENT, dated as of January 15, 2021 (this "Agreement"), is made and entered into by and between Minerva Neurosciences, Inc., a Delaware corporation (the "Seller"), on the one hand, and RPI 2019 Intermediate Finance Trust, a Delaware statutory trust (the "Buyer"), on the other hand.

W I T N E S S E T H:

WHEREAS, pursuant to the License Agreement, Janssen granted to the Seller certain license rights with respect to the Compound and the Seller and Janssen agreed to collaborate regarding the development and commercialization of the Licensed Products in their respective territories;

WHEREAS, notwithstanding the termination of the License Agreement via the Settlement Agreement, Janssen is obligated to pay specified royalties to the Seller with respect to Licensed Products sold anywhere in the world by Janssen, its Affiliates and its Sublicensees; and

WHEREAS, the Buyer desires to purchase the Royalty from the Seller, and the Seller desires to sell, transfer and assign the Royalty to the Buyer.

NOW THEREFORE, in consideration of the representations, warranties, covenants and agreements set forth herein and for good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Seller and the Buyer hereby agree as follows:

ARTICLE 1
DEFINED TERMS AND RULES OF CONSTRUCTION

Section 1.1 Definitions. As used in this Agreement, the following terms shall have the following meanings:

"Additional Purchase Price Payment" is defined in Section 2.2(b).

"Affiliate" means, with respect to any particular Person, any other Person directly or indirectly, and whether by contract or otherwise, controlling, controlled by or under common control with such Person. For purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of at least fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.

"Agreement" is defined in the preamble.

"Bankruptcy Laws" means, collectively, bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance, fraudulent transfer or other similar laws affecting the enforcement of creditors' rights generally.

"Bill of Sale" is defined in Section 3.3.

"Business Day" means any day other than (i) a Saturday or Sunday or (ii) a day on which banking institutions located in New York are permitted or required by applicable law or regulation to remain closed.

"Buyer" is defined in the preamble.

"Buyer Indemnified Parties" is defined in Section 6.2(a).

"Closing" means the closing of the transactions contemplated hereby.

"Closing Date" means the date on which the Closing occurs.

"Code" means the U.S. Internal Revenue Code of 1986, as amended.

"Compound" has the meaning ascribed thereto in Section 1.19 of the License Agreement.

"Confidential Information" is defined in Section 5.1(b).

"Cover" has the meaning ascribed thereto in Section 1.22 of the License Agreement.

"Data Site" is defined in Section 3.7.

"Disclosing Party" is defined in Section 5.1(b).

"Disclosure Schedule" means the Disclosure Schedule, dated as of the date hereof, delivered to the Buyer by the Seller concurrently with the execution of this Agreement.

"EMA" means the European Medicines Agency or any successor agency thereof.

"[•••]" is defined in Section 6.6.

"FDA" means the United States Food and Drug Administration, or a successor federal agency thereto in the United States.

"Field" means all therapeutic, prophylactic and diagnostic uses for humans.

"First Commercial Sale" has the meaning ascribed thereto in Section 1.36 of the License Agreement.

"Governmental Entity" means any: (a) nation, principality, republic, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or other entity and any court, arbitrator or other tribunal); (d) multi-national organization or body; or (e) individual, body or other entity exercising, or

entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

"Indemnified Party" is defined in Section 6.3.

"Indemnifying Party" is defined in Section 6.3.

"Indemnity Event" is defined [•••].

"Indication" is defined in Section 2.2(b).

"Initial Formulation" has the meaning ascribed thereto in Section 1.44 of the License Agreement.

"Initial Indication" has the meaning ascribed thereto in Section 1.45 of the License Agreement.

"Initial Purchase Price" is defined in Section 2.2(a).

"Instruction Letter" is defined in Section 3.4.

"Janssen" means Janssen Pharmaceutica, N.V., a corporation organized and existing under the laws of Belgium.

"Janssen Patents" has the meaning ascribed thereto in Section 1.48 of the License Agreement.

"Joint Steering Committee" shall have the same meaning ascribed to the term "JSC" in Section 3.1(a) of the License Agreement.

"Judgment" means any judgment, order, writ, injunction, citation, award or decree of any nature entered by or with any Governmental Entity.

"Knowledge of the Seller" means the actual knowledge of Remy Luthringer, Geoff Race, Michael Davidson, Jay Saoud, and Devin Smith.

"License Agreement" means that certain Co-Development and License Agreement, dated February 13, 2014, by and between the Seller and Janssen, as amended by that certain Amendment No. 1, dated June 13, 2017.

"Licensed Patents" is defined in Section 4.1(k)(i).

"Licensed Product" has the meaning ascribed thereto in Section 1.52 of the License Agreement.

"Lien" means any mortgage, lien, pledge, hypothecation, charge, adverse claim, security interest, encumbrance or restriction of any kind, including any restriction on use, transfer or exercise of any other attribute of ownership of any kind.

"Loss" means any and all Judgments, damages, losses, claims, costs, liabilities and expenses, including reasonable fees and out-of-pocket expenses of counsel.

"Marketing Approval" means an NDA approved by the FDA, a marketing authorization application approved by the EMA under the centralized European procedure, or any corresponding non-U.S. or non-EMA application, registration or certification, necessary or reasonably useful to market a Licensed Product approved by the corresponding Regulatory Authority, including pricing and reimbursement approvals where required.

"Material Adverse Effect" shall mean (i) a material adverse effect on the legality, validity or enforceability of any provision of this Agreement, (ii) a material adverse effect on the ability of the Seller to perform any of its obligations hereunder, (iii) a material adverse effect on the rights or remedies of the Buyer hereunder, (iv) a material adverse effect on the rights of the Seller under the License Agreement, (v) a material adverse effect on the validity or enforceability of any of the Licensed Patents, or (vi) an adverse effect in any material respect on the timing, amount or duration of the payments to be made to the Buyer following the Closing in respect of any portion of the Royalty or the right of the Buyer to receive such payments.

"Minerva Patent" has the meaning ascribed thereto in Section 1.58 of the License Agreement.

"NDA" means a New Drug Application submitted to the FDA in the United States in accordance with the Federal Food, Drug, and Cosmetic Act with respect to a pharmaceutical product or any analogous application or submission with any Regulatory Authority outside of the United States.

"Net Sales" has the meaning ascribed thereto in Section 1.63 of the License Agreement.

"Patent Office" means the United States Patent and Trademark Office or any successor agency thereto.

"Payment Triggering Event" is defined in Section 2.2(b).

"Permitted Liens" means any (i) mechanic's, materialmen's, and similar liens for amounts not yet due and payable, (ii) statutory liens for taxes not yet due and payable or for taxes that the taxpayer is contesting in good faith and (iii) other liens and encumbrances not incurred in connection with the borrowing of money that do not materially and adversely affect the use or value of the affected assets (it being understood that any obligations secured by such "Permitted Liens" shall remain the sole and exclusive obligations of the Seller).

"Permitted Reduction" means any Royalty Reduction pursuant to Section 6.3(b) or Section 6.3(c) of the License Agreement, but excluding any Royalty Reduction pursuant to Section 3.10(c)(ii) or any other provision of the License Agreement.

"Person" means any individual, firm, corporation, company, partnership, limited liability company, trust, joint venture, association, estate, trust, Governmental Entity or other entity, enterprise, association or organization.

"Prime Rate" means the prime rate published by the Wall Street Journal, from time to time, as the prime rate.

"Procedures" is defined in Section 4.1(k)(ii).

"Proceeds" means any amounts recovered by the Seller (or its designee) as a result of any settlement or resolution of any actions, suits, proceedings, claims or disputes related to the License Agreement or the Settlement Agreement in respect of unpaid Royalties (or any interest payable on such unpaid amounts) (including, for clarity, payments in lieu of any amounts payable by Janssen to the Seller pursuant to Section 6.3(a) and Section 11.6(b)(iii) of the License Agreement).

"Product Information" means all notices or other communications to or from the Seller and Janssen under the License Agreement or the Settlement Agreement that (i) Janssen provides to the Seller or (ii) that the Seller otherwise receives or furnishes (a) to the extent related to any Licensed Product, Payment Triggering Event or the Royalty or (b) that would reasonably be expected to have a Material Adverse Effect.

"Program Invention" has the meaning ascribed thereto in Section 1.78 of the License Agreement.

"Program Patent" has the meaning ascribed thereto in Section 1.79 of the License Agreement.

"Purchase Price" is defined in Section 2.2(b).

"Receiving Party" is defined in Section 5.1(b).

"Regulatory Authority" means any national or supranational governmental authority, including the FDA, the EMA or such equivalent regulatory authority, or any successor agency thereto, that has responsibility in granting a Marketing Approval.

"Regulatory Exclusivity" has the meaning ascribed thereto in Section 1.85 of the License Agreement.

"Remedied" is defined [•••].

"Remedy Payment" is defined [•••].

"Representative" means, with respect to any Person, (i) any direct or indirect stockholder, member or partner of such Person and (ii) any manager, director, officer, employee, agent, advisor or other representative (including attorneys, accountants, consultants, bankers, financial advisors and actual and potential lenders and investors) of such Person.

"Royalty" means all amounts payable by Janssen to the Seller under the License Agreement and the Settlement Agreement pursuant to Section 6.3(a) and Section 11.6(b)(iii) of the License Agreement with respect to worldwide Net Sales of the Licensed Products sold by Janssen and its Affiliates and Sublicensees, and any amounts payable by Janssen under the License Agreement or the Settlement Agreement in lieu of such payments.

"Royalty Reduction" is defined in Section 4.1(i)(iv)(C).

"Royalty Reports" means the quarterly reports deliverable by Janssen pursuant to Section 7.1(c) of the License Agreement.

"Royalty Report Certification" is defined in Section 5.4.

"Seller" is defined in the preamble.

"Seller Indemnified Parties" is defined in Section 6.2(b).

"Seltorexant" means the selective, small-molecule antagonist of the OX_2 receptor that is under investigation by or on behalf of Janssen for diseases, disorders and conditions of the central nervous system, including pursuant to the phase III study for the treatment of major depressive disorder with insomnia symptoms.

"Settlement Agreement" means that certain Confidential Settlement Agreement, dated June 24, 2020, by and between Janssen and the Seller.

"[•••]" is defined in Section 6.6.

"Special Representations" means those representations and warranties set forth in Sections 4.1(i)(iv)(B) and (C).

"Sublicensee" has the meaning ascribed thereto in Section 2.7(a) of the License Agreement.

"Tax" or "Taxes" means all income, gross receipts, franchise, profits, estimated, alternative minimum, add-on minimum, sales, use, transfer, registration, value added, ad valorem, excise, export, natural resources, severance, margin, stamp, withholding, occupation, premium, windfall profit, environmental, customs, duties, real property, personal property, capital stock, capital gains, net worth, intangibles, social security, pension insurance contributions, employment, unemployment, disability, payroll, license, employee or other tax or similar levy, of any kind whatsoever, including any interest, penalties, or additions to tax in respect of the foregoing, whether disputed or not.

"Tax Return" means any return, declaration, report, claim for refund, information return, or other document (including any related or supporting estimates, elections, schedules, statements information, attachments thereto, or amendments thereof) filed or required to be filed in connection with the determination, assessment, or collection of any Tax or the administration of any laws, regulations, or administrative requirements relating to any Tax.

"UCC" means Article 9 of the Uniform Commercial Code of the State of New York, as in effect from time to time.

Section 1.2 Certain Interpretations. Except where expressly stated otherwise in this Agreement, the following rules of interpretation apply to this Agreement:

(a) "either" and "or" are not exclusive and "include," "includes" and "including" are not limiting and shall be deemed to be followed by the words "without limitation;"

(b) "extent" in the phrase "to the extent" means the degree to which a subject or other thing extends, and such phrase does not mean simply "if;"

(c) "hereof," "hereto," "herein" and "hereunder" and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement;

(d) references to a Person are also to its permitted successors and assigns;

(e) definitions are applicable to the singular as well as the plural forms of such terms;

(f) unless otherwise indicated, references to an "Article", "Section" or "Exhibit" refer to an Article or Section of, or an Exhibit to, this Agreement, and references to a "Schedule" refer to the corresponding part of the Disclosure Schedule;

(g) references to "$" or otherwise to dollar amounts refer to the lawful currency of the United States; and

(h) references to a law include any amendment or modification to such law and any rules and regulations issued thereunder, whether such amendment or modification is made, or issuance of such rules and regulations occurs, before or after the date of this Agreement.

Section 1.3 Headings. The table of contents and the descriptive headings of the several Articles and Sections of this Agreement and the Exhibits and Schedules are for convenience only, do not constitute a part of this Agreement and shall not control or affect, in any way, the meaning or interpretation of this Agreement.

ARTICLE 2
PURCHASE, SALE AND ASSIGNMENT

Section 2.1 Purchase, Sale and Assignment. Upon the terms and subject to the conditions of this Agreement, at the Closing, the Seller shall sell, transfer, assign and convey to the Buyer, and the Buyer shall purchase, acquire and accept from the Seller, free and clear of all Liens, all of the Seller's right, title and interest in and to the Royalty.

Section 2.2 Purchase Price.

(a) In consideration for the sale, transfer, assignment and conveyance (inclusive of any value added or similar tax) of the Seller's right, title and interest in and to the Royalty, the Buyer shall pay (or cause to be paid) to the Seller $60,000,000 (the "Initial Purchase Price") at the Closing.

(b) Following the Closing, following the occurrence of each of the following events (each, a "Payment Triggering Event"), but subject to [•••], the Buyer shall make a cash payment (each, an "Additional Purchase Price Payment" and, collectively, with the Initial Purchase Price, the "Purchase Price") to the Seller in the amount corresponding to such Payment Triggering Event:

#	PAYMENT TRIGGERING EVENT	ADDITIONAL PURCHASE PRICE PAYMENT AMOUNT
1	The earlier to occur of: (A) public disclosure by Janssen of Studies 3001 and 3002 both meeting their primary endpoint of change from baseline to Day 43 in MADRS Total Score and the secondary endpoint of change from baseline to Day 43 in MADRS-WOSI (Without Sleep Item) Total Score and (B) Marketing Approval from the FDA for Seltorexant for the adjunctive treatment of major depressive disorder in patients with insomnia symptoms, or an equivalent or broader indication (the "Indication").	$10,000,000
2	Marketing Approval from the FDA of Seltorexant for the Indication.	$30,000,000
3	Marketing Approval from the EMA of Seltorexant for the Indication.	$15,000,000
4	The earlier to occur of the first Marketing Approval in China and Japan of Seltorexant for the Indication.	$10,000,000
5	The first occurrence of the Buyer receiving $60,000,000 in Royalty payments with respect to worldwide Net Sales of Seltorexant during any calendar year.	$10,000,000
6	The first occurrence of the Buyer receiving $120,000,000 in Royalty payments with respect to worldwide Net Sales of Seltorexant during any calendar year.	$20,000,000
	TOTAL	**$95,000,000**

(c) The Seller hereby agrees and acknowledges that: (i) the Additional Purchase Price Payments are contingent payment obligations of the Buyer and there can be no assurance regarding the occurrence of any of the Payment Triggering Events corresponding to each Additional Purchase Price Payment and (ii) the Buyer shall have no obligation or liability with respect to any Additional Purchase Price Payment unless and until the corresponding Payment Triggering Event has occurred. Any Additional Purchase Price Payment owed to the Seller by the Buyer in accordance with this Section 2.2 shall be paid to the Seller by wire transfer of immediately available funds to the account specified by the Seller on Exhibit A (or such other account as

specified by the Seller in a writing delivered to the Buyer in accordance with Section 8.1 of this Agreement) within ten (10) Business Days following the occurrence of a Payment Triggering Event. For clarity, only one Additional Purchase Price Payment shall be due hereunder with respect to each Payment Triggering Event; no Additional Purchase Price Payment shall be payable for subsequent or repeated achievements of any applicable Payment Triggering Events. Each party hereto further agrees and acknowledges that the other party shall have the right to offset any amounts owed by such party to the other party hereunder.

(d) The parties hereto agree that: (i) the aggregate Additional Purchase Price Payments payable by the Buyer hereunder shall not exceed $95,000,000 and (ii) the total Purchase Price payable to the Seller by the Buyer hereunder (inclusive of the Initial Purchase Price and the Additional Purchase Price Payments) shall not exceed $155,000,000 in the aggregate.

Section 2.3 No Assumed Obligations; Excluded Assets. Notwithstanding any provision in this Agreement to the contrary, the Buyer is purchasing, acquiring and accepting only the Royalty, and is not assuming any liability or obligation of the Seller of whatever nature (including any Liens), whether presently in existence or arising or asserted hereafter, under the License Agreement, the Settlement Agreement or otherwise. Except as specifically set forth herein in respect of the Royalty purchased, acquired and accepted hereunder, the Buyer does not, by such purchase, acquisition and acceptance, acquire any other contract rights of the Seller under the License Agreement, the Settlement Agreement or any other assets of the Seller.

Section 2.4 True Sale. It is the intention of the parties hereto that the sale, transfer, assignment and conveyance contemplated by this Agreement constitute a sale of the Royalty from the Seller to the Buyer and not a financing transaction, borrowing or loan. In connection therewith, the Seller shall treat the sale, transfer, assignment and conveyance of the Royalty as a sale of an “account” or a “payment intangible” (as appropriate) in accordance with the UCC, and the Seller hereby authorizes the Buyer to file financing statements (and continuation statements with respect to such financing statements when applicable) naming the Seller as the debtor and the Buyer as the secured party in respect of the Royalty. If, notwithstanding the foregoing, the sale, transfer, assignment and conveyance contemplated hereby is hereafter held not to be a sale, the Seller does hereby grant to the Buyer, as security for the obligations of the Seller hereunder, a first priority security interest in and to all right, title and interest of the Seller, in, to and under the Royalty and any “proceeds” (as such term is defined in the UCC) thereof, and the Seller does hereby authorize the Buyer, from and after the Closing, to file such financing statements (and continuation statements with respect to such financing statements when applicable) as may be necessary to perfect such security interest.

ARTICLE 3
CLOSING

Section 3.1 Closing. The Closing shall take place remotely via the exchange of documents and signatures on the date hereof or at such other place, time and date as the parties hereto may mutually agree.

Section 3.2 Payment of Initial Purchase Price. At the Closing, the Buyer shall deliver (or cause to be delivered) payment of the Initial Purchase Price to the Seller by wire transfer of immediately available funds to one or more accounts specified by the Seller on Exhibit A.

Section 3.3 Bill of Sale. At the Closing, upon confirmation of the receipt of the Initial Purchase Price, the Seller shall deliver to the Buyer a duly executed bill of sale evidencing the sale, transfer, assignment and conveyance of the Royalty substantially in the form attached hereto as Exhibit B (the "Bill of Sale").

Section 3.4 Janssen Instruction. Promptly following the Closing, the Seller and the Buyer shall deliver to Janssen an instruction letter, in the form attached hereto as Exhibit C (the "Instruction Letter"), duly executed by the Seller and the Buyer, notifying Janssen that the Royalty has been sold to the Buyer and instructing Janssen to pay the Royalty and deliver the Royalty Reports and any other Product Information to the Buyer.

Section 3.5 Form W-9. At the Closing, the Seller shall deliver to the Buyer a valid, properly executed IRS Form W-9 certifying the Seller's U.S. tax identification number and that the Seller is exempt from U.S. federal "backup" withholding tax. The Seller acknowledges that the Buyer may provide or disclose such documentation to the U.S. Internal Revenue Service or other governmental authorities or agencies.

Section 3.6 Form W-8 BEN-E. At the Closing, the Buyer shall deliver to the Seller a valid, properly executed IRS Form W-8 BEN-E certifying that the Buyer is exempt from U.S. federal withholding tax.

Section 3.7 Copy of Data Site. Prior to the Closing, the Seller shall have delivered to the Buyer a secure share-file link or a USB thumb drive containing copies of all documents uploaded to any data site maintained by or on behalf of the Seller and made available to the Buyer related to the Royalty and the transactions contemplated by this Agreement (the "Data Site").

ARTICLE 4
REPRESENTATIONS AND WARRANTIES

Section 4.1 Seller's Representations and Warranties. The Seller represents and warrants to the Buyer that as of the date hereof:

(a) Existence; Good Standing. The Seller is a corporation duly incorporated, validly existing and in good standing under the laws of the State of Delaware. The Seller is duly licensed or qualified to do business and is in corporate good standing in each jurisdiction in which the nature of the business conducted by it or the character or location of the properties and assets owned, leased or operated by it makes such licensing or qualification necessary, except where the failure to be so licensed or qualified and in corporate good standing has not and would not reasonably be expected to have, either individually or in the aggregate, a Material Adverse Effect.

(b) Authorization. The Seller has all requisite corporate power and authority to execute, deliver and perform its obligations under this Agreement. The execution, delivery and

performance of this Agreement, and the consummation of the transactions contemplated hereby, have been duly authorized by all necessary corporate action on the part of the Seller.

(c) Enforceability. This Agreement has been duly executed and delivered by an authorized officer of the Seller and constitutes the valid and binding obligation of the Seller, enforceable against the Seller in accordance with its terms, except as may be limited by applicable Bankruptcy Laws or by general principles of equity (whether considered in a proceeding in equity or at law).

(d) No Conflicts. The execution, delivery and performance by the Seller of this Agreement and the consummation of the transactions contemplated hereby do not and shall not (i) contravene or conflict with the certificate of incorporation or bylaws of the Seller, (ii) materially contravene or conflict with or constitute a material default under any law or Judgment binding upon or applicable to the Seller, any of the Seller's subsidiaries or the Royalty, (iii) contravene or conflict with or constitute a default under the License Agreement or the Settlement Agreement or (iv) materially contravene or conflict with or constitute a material default under any other material contract or material agreement binding upon or applicable to the Seller or any of the Seller's subsidiaries or related to the Royalty.

(e) Consents. Except for the consents that have been obtained on or prior to the Closing or filings required by the federal securities laws or stock exchange rules, no consent, approval, license, order, authorization, registration, declaration or filing with or of any Governmental Entity or other Person is required to be done or obtained by the Seller in connection with (i) the execution and delivery by the Seller of this Agreement, (ii) the performance by the Seller of its obligations under this Agreement or (iii) the consummation by the Seller of any of the transactions contemplated by this Agreement (including the sale, transfer and assignment of the Royalty from the Seller to the Buyer).

(f) No Litigation. There is no action, suit, investigation or proceeding pending before any Governmental Entity (x) to which the Seller or any of the Seller's subsidiaries is a party or the Royalty is subject, or (y) to the Knowledge of the Seller, which is threatened against the Seller or any of its subsidiaries, and, in each case of (x) and (y), that, has had or would reasonably be expected to have, either individually or in the aggregate a Material Adverse Effect.

(g) Compliance.

(i) Neither the Seller nor any of its subsidiaries is in violation of, and to the Knowledge of the Seller, is under investigation with respect to or has been threatened to be charged with or given notice of any violation of, any law or Judgment applicable to the Seller or any of its subsidiaries, which violation has had or would reasonably be expected to have, either individually or in the aggregate, a Material Adverse Effect.

(ii) The Seller has provided to the Buyer prior to the date hereof in a Data Site true, correct and complete copies of all material written communications with any Regulatory Authority that relate to the Compounds or the Licensed Products, in each case, in the possession of the Seller or any of its

Affiliates. To the Knowledge of the Seller, no written communications with any Regulatory Authority exist which: (A) have not been provided to the Buyer and (B) would, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect.

(h) No Undisclosed Events or Circumstances. Except for the transactions contemplated hereby, no event or circumstance has occurred or exists with respect to the Seller, its Affiliates, or their respective businesses, properties, operations or financial condition, which, under applicable law, rule, regulation or Judgment, requires public disclosure or announcement by the Seller but which has not been so publicly announced or disclosed and which individually or in the aggregate, would reasonably be expected to result in a Material Adverse Effect.

(i) License Agreement; Settlement Agreement. Attached hereto as Exhibit D and Exhibit E are true, correct and complete copies of the License Agreement and the Settlement Agreement with a fully executed Annex A to the Settlement Agreement, respectively, in each case, as amended to date. The Seller has delivered to the Buyer true, correct and complete copies of (a) all minutes and records from, and meeting materials of, the Joint Steering Committee or any other committee or subcommittee under the License Agreement and relating to any Compound or Licensed Product that are within the possession or control of the Seller, (b) the License Agreement, (c) the Settlement Agreement, (d) all other agreements referenced in the License Agreement or the Settlement Agreement, and (e) all material reports, written communications and notices to or from the Seller and Janssen or, to the extent in the Seller's possession or control, any of their agents or designees, including any notices or written communications with any Governmental Entity, institutional review board or other ethics committee.

(i) No Other Agreements. The License Agreement and the Settlement Agreement, together with the agreements, instruments, arrangements, waivers or understandings set forth on Schedule 4.1(i)(i) of the Disclosure Schedule (copies of which have been made available in a Data Site prior to the date hereof), are the only agreements, instruments, arrangements, waivers or understandings between the Seller (or any predecessor or Affiliate thereof), on the one hand, and Janssen (or any predecessor or Affiliate thereof), on the other hand, relating to the subject matter thereof, and there are no other agreements, instruments, arrangements, waivers or understandings between the Seller (or any predecessor or any Affiliate thereof), on the one hand, and Janssen (or any predecessor or Affiliate thereof), on the other hand, that relate to any of the Royalty, the Compound or the Licensed Products (including the development or commercialization thereof).

(ii) Licenses/Sublicenses. Except for the License Agreement, the Settlement Agreement or as set forth on Schedule 4.1(i)(ii) of the Disclosure Schedule, there are no licenses or sublicenses entered into by the Seller (or any predecessor or Affiliate thereof) or, to the Knowledge of the Seller, any other Person in respect of the Seller's rights and obligations under either the License Agreement or the Settlement Agreement, and to the Knowledge of the Seller, there are no licenses or sublicenses entered into by Janssen or any other Person (or any predecessor or Affiliate thereof) in respect of Janssen's rights and obligations under the License Agreement or the Settlement Agreement.

(iii) Validity and Enforceability of Agreements. The Settlement Agreement and the surviving provisions of the License Agreement are valid, binding and in full force and effect and are enforceable against each of the parties thereto in accordance with their terms. No party to the License Agreement or the Settlement Agreement has repudiated any provision of the Settlement Agreement or any of the surviving provisions of the License Agreement and the Seller has not received any written notice in connection with the License Agreement or the Settlement Agreement challenging the validity, enforceability or interpretation of any provision of such agreement, including the obligation to pay any portion of the Royalty without any Royalty Reduction of any kind.

(iv) Licensed Product; Royalty Rate; Royalty Reductions.

(A) Seltorexant is a Licensed Product under the License Agreement and, to the Knowledge of the Seller, there are no other Licensed Products being developed or commercialized by Janssen under the License Agreement. The Seller has made available to the Buyer true, correct and complete copies of any material written communication regarding the Licensed Patents covering any Licensed Product (including Seltorexant) and any Regulatory Exclusivity of any Licensed Product (including Seltorexant), including paragraph IV certification letters under the Hatch-Waxman Act, received by the Seller prior to the date hereof (including any communication from Janssen in accordance with Section 8.2(b) of the License Agreement and Section 8.2(d) of the License Agreement), if and as applicable.

(B) The Seller has the right, subject to reduction only for Permitted Reductions, under and in accordance with Section 11.6(b)(iii) of the License Agreement, to receive the Royalty on Net Sales of Licensed Products in any Initial Formulation sold by Janssen or its Affiliates or Sublicensees in each country in the world for any Initial Indication in the Field at the rate of [•••], which right shall commence, on a Licensed Product-by-Licensed Product and country-by-country basis, upon the First Commercial Sale of a given Licensed Product in a particular country and shall continue with respect to such Licensed Product and country until the latest of (i) the ten (10) year anniversary of the First Commercial Sale of such Licensed Product in such country, (ii) the expiration of the last to expire Program Patent or Minerva Patent Covering the Compound of such Licensed Product as a composition of matter or labeled use of such Licensed Product in such country, and (iii) the end of the period during which such Licensed Product is subject to Regulatory Exclusivity in such country.

(C) The Royalty payable to the Seller under the License Agreement and the Settlement Agreement is not, to the Knowledge of the Seller and as of the date hereof, subject to any claim against the Seller pursuant to any right of set-off, offset, counterclaim, credit, reduction or deduction by contract or otherwise (a "Royalty Reduction"), including any

Permitted Reduction. To the Knowledge of the Seller, no event or condition exists that, upon notice or passage of time or both, would reasonably be expected to permit Janssen to claim, or have the right to claim, any Permitted Reduction prior to the latest of (i) the ten (10) year anniversary of the First Commercial Sale of such Licensed Product in a country, (ii) the expiration of the last to expire Program Patent or Minerva Patent Covering the Compound of such Licensed Product as a composition of matter or labeled use of such Licensed Product in such country, and (iii) the statutory period of Regulatory Exclusivity for such Licensed Product in such country. [•••]

(v) [•••]

(vi) No Liens or Assignments by the Seller. The Seller has not, except as contemplated hereby, conveyed, assigned or in any other way transferred or granted any Liens with respect to all or any portion of its right, title and interest in and to the Royalty.

(vii) No Waivers, Releases or Amendments. Other than the waivers and releases explicitly provided for in the Settlement Agreement: (A) the Seller has not granted any material waiver under the License Agreement or the Settlement Agreement and has not released Janssen, in whole or in part, from any of its respective material obligations under either of the License Agreement or the Settlement Agreement; and (B) the Seller has not received from Janssen any written proposal, and has not made any proposal to Janssen, to amend or waive any provision of either of the License Agreement or the Settlement Agreement.

(viii) No Termination. Except as provided in the Settlement Agreement (including the Opt-Out Notice (as defined therein)), the Seller has not (A) given any notice of termination of either of the License Agreement or the Settlement Agreement (whether in whole or in part) or any notice expressing any intention or desire to terminate either of the License Agreement or the Settlement Agreement or (B) received any notice of termination of either of the License Agreement or the Settlement Agreement (whether in whole or in part) or any notice expressing any intention or desire to terminate the License Agreement or the Settlement Agreement. To the Knowledge of the Seller, no event has occurred that would give rise to the expiration or termination of the Settlement Agreement or, except as provided in the Settlement Agreement, the License Agreement (whether in whole or in part).

(ix) No Breaches or Defaults. There is and has been no material breach or default under any provision of either of the License Agreement or the Settlement Agreement, either by the Seller (or any predecessor thereof) or, to the Knowledge of the Seller, by Janssen (or any predecessor thereof), except for any purported or actual breaches or defaults that were the subject of the Dispute, as defined in and subject to the waivers provided for in the Settlement Agreement. There is no event that upon notice or the passage of time, or both, would reasonably

be expected to give rise to any breach or default either by the Seller or, to the Knowledge of the Seller, by Janssen, or otherwise permit termination, modification, or acceleration, under the Settlement Agreement or the surviving provisions of the License Agreement.

(x) Payments Made. The Seller has timely received from Janssen the full amount of the payments due and payable under the License Agreement and the Settlement Agreement as of the Closing Date.

(xi) No Assignments. The Seller has not consented to any assignment or other transfer by Janssen or any of its predecessors of any of their rights or obligations under the License Agreement or the Settlement Agreement, and Janssen has not assigned or otherwise transferred any of its rights or obligations under the License Agreement or the Settlement Agreement to any Person.

(xii) No Indemnification Claims. The Seller has not notified Janssen or any other Person of, or otherwise made, any claims for indemnification under the License Agreement nor has the Seller received any claims for indemnification under the License Agreement, whether pursuant to Article 12 thereof or otherwise.

(xiii) No Notice of Infringement. The Seller has not received any written notice from, or given any written notice to, Janssen pursuant to Section 8.3(a) of the License Agreement or otherwise regarding any claim of infringement.

(xiv) Inspections. The Seller has not initiated, pursuant to Section 7.5 of the License Agreement or otherwise, any inspection or audit of books of accounts or other records pertaining to Net Sales, the calculation of royalties or other amounts payable to the Seller under the License Agreement.

(xv) No Remaining Obligations. The Seller has fully complied with, satisfied and performed its obligations under the Settlement Agreement, and the only remaining performance obligations of the Seller under the License Agreement and the Settlement Agreement are as provided in Section 11.6 and Section 11.8 of the License Agreement.

(j) Title to Royalty. The Seller has good and marketable title to the Royalty free and clear of all Liens (other than Permitted Liens). Upon payment of the Initial Purchase Price by the Buyer, the Buyer shall have acquired, subject to the terms and conditions set forth in this Agreement, good and marketable title to all of the Royalty, free and clear of all Liens (other than Liens created by the Buyer).

(k) Intellectual Property.

(i) Schedule 4.1(k)(i) of the Disclosure Schedule sets forth a complete and accurate list of all issued patents and patent applications included in the Program Patents, the Minerva Patents and, to the Knowledge of the Seller, the Janssen Patents (collectively, the "Licensed Patents"). Schedule 4.1(k)(i) of the

Disclosure Schedule specifies as to each of the Licensed Patents: (i) the jurisdictions in which such Licensed Patent is pending, allowed, granted or issued, (ii) the patent number or patent serial number, (iii) the owner of such Licensed Patent, and (iv) the expected expiration date of such Licensed Patent.

(ii) Janssen has not provided the Seller with written notice of any pending or threatened litigations, interferences, reexamination, oppositions or the like procedures ("Procedures") involving any Janssen Patents that have not been publicly disclosed, which publicly disclosed Procedures include those listed in Schedule 4.1(k)(ii) of the Disclosure Schedule.

(iii) The Program Patents, the Minerva Patents, and to the Knowledge of the Seller, the Janssen Patents, are in full force and effect and have not lapsed, expired or otherwise terminated, and, to the Knowledge of the Seller, the Licensed Patents are valid and enforceable. The Seller has not received any written notice relating to the lapse, expiration or other termination of any of the Licensed Patents, or any written legal opinion that alleges that any of the issued Licensed Patents is invalid or unenforceable.

(iv) To the Knowledge of the Seller, each individual associated with the prosecution of the Licensed Patents, including the named inventors, has complied in all material respects with all applicable duties of candor and good faith in dealing with any Patent Office, including any duty to disclose to any Patent Office all information known by such inventors to be material to the patentability of each of the Licensed Patents (including any relevant prior art), in each case, in those jurisdictions where such duties exist. To the Knowledge of the Seller, there is no Person who is or claims to be an inventor under any of the Licensed Patents who is not a named inventor thereof.

(v) The Seller has not, and, to the Knowledge of the Seller, Janssen has not, received any written notice of any claim by any Person challenging the inventorship or ownership of, the rights of the Seller or Janssen, as applicable, in and to, or the patentability, validity or enforceability of, any Licensed Patent, or asserting that the development, manufacture, importation, sale, offer for sale or use of any Licensed Product infringes any patents or other intellectual property rights of such Person.

(vi) Neither the Seller nor, to the Knowledge of the Seller, Janssen, has in-licensed any patent or other intellectual property rights covering the manufacture, use, sale, offer for sale or import of any Compound or Licensed Product.

(vii) To the Knowledge of the Seller, the research, discovery, development, manufacture, use, marketing, sale, offer for sale, importation or distribution of any Compound or Licensed Product has not and will not, infringe, misappropriate or otherwise violate any patents or other intellectual property rights owned by any other Person.

(viii) To the Knowledge of the Seller, no third party has infringed, misappropriated or otherwise violated, or is infringing, misappropriating or otherwise violating, any of the Licensed Patents or any other patent right claiming the composition of matter of, or the method of making or using, any Licensed Products.

(ix) To the Knowledge of the Seller, all required maintenance fees, annuities and like payments with respect to the Licensed Patents have been timely paid.

(l) UCC Representation and Warranties. The Seller's exact legal name is, and for the immediately preceding five years has been, "Minerva Neurosciences, Inc." Seller is, and for the prior ten years has been, incorporated in the State of Delaware.

(m) Brokers' Fees. There is no investment banker, broker, finder, financial advisor or other intermediary who has been retained by or is authorized to act on behalf of the Seller who might be entitled to any fee or commission in connection with the transactions contemplated by this Agreement.

(n) Tax Matters. To the Knowledge of the Seller, no deduction or withholding for or on account of any material Tax has been made, or was required under applicable law to be made, from any payment made to the Seller under the License Agreement in the past three (3) taxable years. The Seller has not received written notice from Janssen of any intention to withhold or deduct any material Tax from future payments to the Seller under the License Agreement in the past three (3) taxable years. There are no existing Liens for Taxes on the Royalty (or any portion thereof). The Seller has filed (or caused to be filed) all material Tax Returns required to be filed by it under applicable law with respect to the Royalty and has paid all material Taxes required to be paid by it with respect to the Royalty, except for any such Taxes that are being contested in good faith by appropriate proceedings and for which adequate reserves have been provided in accordance with generally accepted accounting principles applicable to the Seller, as in effect from time to time. The Seller has not in the past three (3) taxable years taken the position on a Tax Return that the License Agreement is treated as a partnership for U.S. federal income tax purposes. The Seller has not in the past three (3) taxable years received a K-1 or other similar U.S. tax form furnished to it as a partner in a partnership as a result of being a party to the License Agreement.

Section 4.2 The Buyer's Representations and Warranties. The Buyer represents and warrants to the Seller that as of the date hereof:

(a) Existence; Good Standing. The Buyer is a statutory trust duly organized, validly existing and in good standing under the laws of the State of Delaware. The Buyer is duly licensed or qualified to do business and is in corporate good standing in each jurisdiction in which the nature of the business conducted by it or the character or location of the properties and assets owned, leased or operated by it makes such licensing or qualification necessary, except where the failure to be so licensed or qualified and in corporate good standing has not and would not reasonably be expected to have, either individually or in the aggregate, a material adverse effect upon the Buyer's ability to enter into and to perform its obligations under this Agreement.

(b) Authorization. The Buyer has the requisite trust right, power and authority to execute, deliver and perform its obligations under this Agreement. The execution, delivery and performance of this Agreement, and the consummation of the transactions contemplated hereby, have been duly authorized by all necessary action on the part of the Buyer.

(c) Enforceability. This Agreement has been duly executed and delivered by an authorized person of the owner trustee of the Buyer and constitutes the valid and binding obligation of the Buyer, enforceable against the Buyer in accordance with its terms, except as may be limited by applicable Bankruptcy Laws or by general principles of equity (whether considered in a proceeding in equity or at law).

(d) No Conflicts. The execution, delivery and performance by the Buyer of this Agreement and the consummation of the transactions contemplated hereby do not and shall not (i) contravene or conflict with the organizational documents of the Buyer, (ii) contravene or conflict with or constitute a default under any material provision of any law or Judgment binding upon or applicable to the Buyer or (iii) contravene or conflict with or constitute a default under any material contract or other material agreement or Judgment binding upon or applicable to the Buyer.

(e) Consents. Except for any filings required by the federal securities laws or stock exchange rules and the filing of the financing statement(s) in accordance with Section 2.4, no consent, approval, license, order, authorization, registration, declaration or filing with or of any Governmental Entity or other Person is required to be done or obtained by the Buyer in connection with (i) the execution and delivery by the Buyer of this Agreement, (ii) the performance by the Buyer of its obligations under this Agreement or (iii) the consummation by the Buyer of any of the transactions contemplated by this Agreement.

(f) No Litigation. There is no action, suit, investigation or proceeding pending before any Governmental Entity or, to the knowledge of the Buyer, threatened to which the Buyer is a party that has had or would reasonably be expected to have, either individually or in the aggregate, a material adverse effect on the ability of the Buyer to enter into and to perform its obligations under this Agreement.

(g) Compliance with Laws. The Buyer is not in violation of, and to the knowledge of the Buyer, the Buyer is not under investigation with respect to, nor has the Buyer been threatened to be charged with or given notice of, any violation of, any law or Judgment applicable to the Buyer, which violation has had or would reasonably be expected to have, either individually or in the aggregate, a material adverse effect on the Buyer’s ability to enter into and to perform any of its obligations under this Agreement.

(h) Financing. The Buyer has sufficient cash on hand to pay the entire Initial Purchase Price and any Additional Purchase Price Payments. Neither the execution and delivery by the Buyer of this Agreement, nor the consummation by the Buyer of any of the transactions contemplated hereby will render the Buyer insolvent or unable to pay its debts as they become due.

(i) Brokers' Fees. There is no investment banker, broker, finder, financial advisor or other intermediary who has been retained by or is authorized to act on behalf of the Buyer who might be entitled to any fee or commission in connection with the transactions contemplated by this Agreement.

Section 4.3 No Implied Representations and Warranties. EXCEPT AS EXPRESSLY SET FORTH IN SECTION 4.1, THE SELLER MAKES NO REPRESENTATION OR WARRANTY, EXPRESSED OR IMPLIED, AT LAW OR IN EQUITY IN RESPECT OF THE ROYALTY OR THE TRANSACTIONS CONTEMPLATED HEREBY, INCLUDING WITH RESPECT TO MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE, AND ANY SUCH OTHER REPRESENTATIONS OR WARRANTIES ARE HEREBY EXPRESSLY DISCLAIMED.

ARTICLE 5
COVENANTS

Section 5.1 Confidentiality; Press Release.

(a) Except for a press release and a Current Report on Form 8-K previously approved in form and substance by the Seller and the Buyer or any other public announcement using substantially the same text as such press release or Form 8-K, neither the Buyer nor the Seller shall, and each party hereto shall cause its respective Representatives, Affiliates and Affiliates' Representatives not to, issue a press release or other public announcement or otherwise make any public disclosure with respect to this Agreement or the subject matter hereof without the prior written consent of the other party hereto (which consent shall not be unreasonably withheld or delayed), except as may be required by applicable law or stock exchange rule; provided that the Seller and the Buyer shall be entitled to describe the transactions contemplated hereby in their financial statements and footnotes thereto and respond to analysts' and investors' questions in the ordinary course and in a manner substantially consistent with any previous disclosure made in accordance with this Section 5.1.

(b) Except as provided in this Section 5.1 or otherwise agreed in writing by the parties, the parties hereto agree that each party (the "Receiving Party") shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any information furnished to it by or on behalf of the other party (the "Disclosing Party") pursuant to this Agreement (such information, "Confidential Information" of the Disclosing Party), except for that portion of such information that

(i) was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the Disclosing Party;

(ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(iii) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party in breach of this Agreement;

(iv) is independently developed by the Receiving Party or any of its Affiliates, as evidenced by written records, without the use of or reference of the Confidential Information; or

(v) is subsequently disclosed to the Receiving Party on a non-confidential basis by a third party without obligations of confidentiality with respect thereto.

(c) Either party as the Receiving Party may disclose Confidential Information of the Disclosing Party with the prior written consent of the Disclosing Party or to the extent such disclosure is otherwise reasonably necessary in the following situations:

(i) prosecuting or defending litigation;

(ii) complying with applicable laws and regulations, including regulations promulgated by securities exchanges;

(iii) complying with a valid order of a court of competent jurisdiction or other Governmental Entity;

(iv) for regulatory, tax or customs purposes;

(v) for audit purposes, provided that each recipient of Confidential Information must be bound by customary obligations of confidentiality and nonuse prior to any such disclosure (which obligations must be consistent with the obligations of confidentiality set forth in the License Agreement and no less protective than those in this Agreement);

(vi) disclosure to its Affiliates and its and its Affiliates' Representatives on a need-to-know basis, provided that each recipient of Confidential Information must be bound by customary obligations of confidentiality and non-use prior to any such disclosure (which obligations must be consistent with the obligations of confidentiality set forth in the License Agreement and no less protective than those in this Agreement); or

(vii) disclosure to its actual or potential investors and co-investors, and other sources of funding, including debt financing, or potential partners, collaborators or acquirers, and their respective accountants, financial advisors and other professional representatives, provided, that such disclosure shall be made only to the extent customarily required to consummate such investment, financing transaction partnership, collaboration or acquisition and that each recipient of Confidential Information must be bound by customary obligations of confidentiality and non-use prior to any such disclosure (which obligations must be consistent with the obligations of confidentiality set forth in the License Agreement and no less protective than those in this Agreement).

(d) Notwithstanding the foregoing, in the event the Receiving Party is required to make a disclosure of the Disclosing Party's Confidential Information pursuant to Sections

5.1(c)(i), (ii), (iii) or (iv), it will, except where impracticable, give reasonable advance notice to the Disclosing Party of such disclosure and use reasonable efforts to secure confidential treatment of such information. In any event, the Buyer shall not file any patent application based upon or using the Confidential Information of the Seller provided hereunder and the parties hereto expressly agree that neither party will make any disclosure of any Confidential Information that has been disclosed under this Agreement that is also the "Confidential Information" (as defined in the License Agreement) of Janssen under the License Agreement other than to the extent that such disclosure would be permitted by the terms of the License Agreement.

Section 5.2 Payments Received by the Seller. If, notwithstanding the terms of this Agreement and the Instruction Letter, Janssen, or any other Person, makes any payment in respect of the Royalty to the Seller (or to any of the Seller's Affiliates or designees) instead of to the Buyer, the Seller shall pay such amount to the Buyer, promptly (and in any event within five (5) Business Days) after the receipt thereof, by wire transfer of immediately available funds to an account designated in writing by the Buyer. The Seller shall notify the Buyer of such wire transfer and provide reasonable details regarding the Royalty payment so received by the Seller. The Seller agrees that, in the event any such payment of the Royalty is paid to the Seller, the Seller shall (i) until paid to the Buyer, hold such payment received in trust for the benefit of the Buyer and (ii) have no right, title or interest in such payment and that it shall not pledge or otherwise grant any security interest therein. A late fee of 4% over the Prime Rate shall accrue on all unpaid amounts with respect to any sum payable under this Section 5.2 beginning five (5) Business Days after receipt by the Seller of such payment received in error.

Section 5.3 Set-Off; Off-Set. If Janssen exercises any Royalty Reduction against any payment of the Royalty, other than for a Permitted Reduction, and other than as a result of any actual, purported or alleged liability or obligation of the Buyer or its Affiliates to Janssen, and [•••], then the Buyer shall promptly notify the Seller of such Royalty Reduction (and provide the Seller with any documentation reasonably related thereto) and the Seller shall promptly (and in any event within five (5) Business Days following notice of such Royalty Reduction, as the case may be) make a true-up payment to the Buyer such that the Buyer receives the full amount of any such payment that would have been payable to the Buyer had such Royalty Reduction not occurred.

Section 5.4 Royalty Reports; Correspondence.

(a) Until such time as Janssen has agreed to provide copies of Royalty Reports directly to the Buyer pursuant to the Instruction Letter, as promptly as possible (and in any event within five (5) Business Days) following the receipt by the Seller of any Royalty Report, the Seller shall deliver to the Buyer a report in the form attached hereto as Exhibit F prepared by the Seller and certified by a duly authorized official of the Seller as to the authenticity of such Royalty Report (a "Royalty Report Certification"). From and after such time as Janssen has agreed to provide copies of Royalty Reports directly to the Buyer pursuant to the Instruction Letter, the Seller shall as promptly as possible (and in any event within two (2) Business Days following awareness thereof) deliver to the Buyer copies of any Royalty Reports received by the Seller from Janssen that are not provided to the Buyer directly.

(b) Until such time as Janssen has agreed to provide Product Information directly to the Buyer pursuant to the Instruction Letter, as promptly as possible (and in any event

within five (5) Business Days) following the receipt by the Seller of any Product Information, the Seller shall deliver to the Buyer a copy of such Product Information, subject to Section 5.4(c). From and after such time as Janssen has agreed to provide copies of Product Information directly to the Buyer pursuant to the Instruction Letter, the Seller shall as promptly as possible (and in any event within two (2) Business Days following awareness thereof) deliver to the Buyer copies of any Product Information received by the Seller from Janssen that are not provided to the Buyer directly.

(c) Notwithstanding the foregoing, until such time as Janssen has agreed to deliver the Royalty Reports and/or other Product Information directly to the Buyer, if the Seller is advised by its counsel that providing the Buyer with a true, correct and complete copy of the Royalty Reports or other Product Information pursuant to this Agreement (whether pursuant to this Section 5.4 or otherwise) would be reasonably expected to constitute a breach by the Seller of its confidentiality obligations under the License Agreement (a "Confidentiality Breach"), then the Seller shall, in lieu of any required delivery of such Royalty Reports or Product Information, provide a written summary thereof to the Buyer describing in as much detail as would not result in a Confidentiality Breach, the substance of such Royalty Reports or other Product Information.

(d) The Seller shall not send (and shall refrain from sending), except as reasonably instructed in writing by the Buyer, any material written notice or correspondence to Janssen to the extent relating to the License Agreement, the Settlement Agreement, the Licensed Products, the Royalty or the parties' other rights or obligations under this Agreement.

(e) The Seller shall, as promptly as practicable after the Closing: (i) request Janssen's agreement to provide Royalty Reports and other Confidential Information under (and as defined in) the License Agreement, including Product Information, directly to the Buyer, (ii) use commercially reasonable efforts to obtain such agreement from Janssen (without obligation to make any payment for such agreement) and (iii) upon receipt of such agreement, deliver to the Buyer the Instruction Letter duly acknowledged and executed by Janssen. Until such time as the Seller delivers to the Buyer the Instruction Letter duly acknowledged and executed by Janssen pursuant to the foregoing Section 5.4(e)(iii), the Seller shall keep the Buyer reasonably apprised of the status of the execution and delivery of the Instruction Letter. In furtherance of the foregoing, at the Buyer's request, the Seller and the Buyer shall participate in scheduled telephone calls, which shall include Devin Smith, the Seller's Senior Vice President and General Counsel, at least once every two (2) weeks until the executed Instruction Letter is delivered to the Buyer, during which the Seller shall update the Buyer and answer the Buyer's questions regarding the execution and delivery of the Instruction Letter.

(f) Following the date that Janssen has agreed to deliver the Royalty Reports and/or other Product Information directly to the Buyer, as applicable, upon Seller's reasonable request, the Buyer shall as promptly as practicable deliver to the Seller copies of any Royalty Reports and/or Product Information received by the Buyer from Janssen directly that are not provided to the Seller.

Section 5.5 Amendment, Waiver, etc. of License Agreement and Settlement Agreement. The Seller shall not (without the Buyer's written consent), and shall (if reasonably instructed in writing by the Buyer), amend, modify, waive, supplement or restate (or consent to

any amendment, modification, waiver, supplement or restatement of) the Settlement Agreement, the Instruction Letter or any surviving provision of the License Agreement; provided that (i) the Buyer shall indemnify the Seller from and against any and all Losses resulting from any such amendment, modification, waiver, supplement or restatement undertaken at the Buyer's written instruction and (ii) Seller's obligation to amend, modify, waive, supplement or restate the Settlement Agreement, the Instruction Letter or any surviving provision of the License Agreement shall only apply the extent that such request from the Buyer for any such action is (a) related, directly or indirectly, to the Royalty, any Product Information, any Licensed Product or the Buyer's rights or obligations under this Agreement and (b) accepted by Janssen (other than in the case of any waiver that Seller may provide unilaterally). Subject to the foregoing, promptly, and in any event within five (5) Business Days, following receipt by the Seller of any final amendment, modification, waiver, supplement or restatement of the provisions of the Settlement Agreement, the Instruction Letter or the surviving provisions of the License Agreement, the Seller shall furnish a copy of the same to the Buyer. The Seller shall deliver further directions to Janssen regarding the payment of the Royalty if (and only if) instructed to do so in writing by the Buyer.

Section 5.6 Maintenance of License Agreement and Settlement Agreement.

(a) The Seller shall comply in all material respects with its obligations under (i) the surviving provisions of the License Agreement and (ii) the Settlement Agreement, and shall not take any action or forego any action that would reasonably be expected to constitute a material breach thereof or default thereunder. Promptly, and in any event within five (5) Business Days, after receipt of any (written or oral) notice from Janssen of an alleged breach or default by the Seller under any of the provisions of the Settlement Agreement or the surviving provisions of the License Agreement, the Seller shall give notice thereof to the Buyer, including delivering to the Buyer a copy of such written notice (or a written summary of any oral notice) and supporting documentation. The Seller shall consult with the Buyer regarding such alleged breach or default and shall act as reasonably instructed in writing by the Buyer to cure any breaches or defaults by it and shall give written notice to the Buyer upon curing any such breach or default. In connection with any dispute regarding any such alleged breach or default, the Seller shall employ such counsel, reasonably acceptable to the Seller, as the Buyer may select.

(b) If (and only if) reasonably instructed by the Buyer in writing, the Seller shall forgive, release or compromise any amount owed to or becoming owed to the Seller under the License Agreement (as amended by way of the Settlement Agreement) in respect of the Royalty; provided that the Seller shall not have any liability with respect to any amounts so forgiven, released or compromised.

(c) The Seller shall not enter into any new agreement or legally binding arrangement in respect of the Licensed Products or the Licensed Patents without the prior written consent of the Buyer (not to be unreasonably withheld, conditioned or delayed).

Section 5.7 Enforcement of License Agreement and Settlement Agreement.

(a) Notice of Breaches or Royalty Reduction by Janssen. Promptly (and in any event within five (5) Business Days) after either party becomes aware of, or comes to believe in good faith that there has been or could be a Royalty Reduction or a breach or default of the

Settlement Agreement or the License Agreement by Janssen, such party shall provide written notice of such potential Royalty Reduction, breach or default to the other party.

(b) Enforcement of Settlement Agreement and License Agreement.

(i) Except as set forth in Section 5.7(b)(ii) below, in the event of any actual, threatened or potential (x) breach or default of the Settlement Agreement or the License Agreement by Janssen, or (y) dispute or disagreement related to any Royalty Reduction (including any Indemnity Event that has not yet been Remedied in full), the Seller shall consult with the Buyer regarding the timing, manner and conduct of any enforcement of Janssen's obligations under the Settlement Agreement or any surviving obligations under the License Agreement or any dispute in connection with the purported Royalty Reduction. Following such consultation, the Seller shall exercise such rights and remedies relating to any such breach, default, dispute or disagreement as reasonably instructed by the Buyer and at the Buyer's expense, whether under the Settlement Agreement, the License Agreement or by operation of law. In connection with any dispute regarding any such alleged breach, default, dispute or disagreement, the Seller shall employ such counsel, reasonably acceptable to the Seller, as the Buyer may select. The Proceeds resulting from any enforcement of Janssen's obligations under the Settlement Agreement or the License Agreement undertaken at the Buyer's request pursuant to this Section 5.7(b)(i) shall be distributed to the Buyer. The Seller hereby assigns and, if not presently assignable, agrees to assign to the Buyer the amount of Proceeds due to the Buyer in accordance with this Section 5.7(b)(i).

(ii) If, and only if, (A) an Indemnity Event occurs and such Indemnity Event is then Remedied in full, or (B) any Royalty Reduction that is not a Permitted Reduction occurs or there is any breach or alleged breach of any Special Representation hereunder and, in any such case, the Buyer has been fully and completely indemnified pursuant to, and in accordance with, Sections 6.2(a) and 6.6, then the Seller shall have the right, in its discretion and at its sole expense, to enforce Janssen's obligations under the Settlement Agreement, or any of Janssen's surviving obligations under the License Agreement and exercise any of the Seller's rights and remedies thereunder with respect to any such Indemnity Event, Royalty Reduction or circumstances causing any alleged breach of any Special Representation, [•••]. The Seller agrees to provide written updates from time to time with respect to the status of any such enforcement actions to the Buyer upon the Buyer's reasonable request. The Proceeds resulting from any enforcement of Janssen's obligations under the Settlement Agreement or the License Agreement undertaken by the Seller pursuant to this Section 5.7(b)(ii) shall be allocated [•••], with all other recoveries of such Proceeds to be retained by the Seller.

Section 5.8 Inspections of Janssen. If (and only if) requested in writing by the Buyer, the Seller shall cause an inspection or audit to be made by an independent public accounting firm under Section 7.5 of the License Agreement, as permitted thereunder. With respect to any such inspection or audit requested by the Buyer, the Seller shall, for purposes of Section 7.5 of the License Agreement, select such independent public accounting firm as the Buyer shall recommend for such purpose (as long as such independent certified public accounting firm is reasonably acceptable to Janssen as required by Section 7.5 of the License Agreement). The Buyer shall pay the Seller the expenses of any inspection or audit requested by the Buyer (including the fees and expenses of such independent public accounting firm designated for such purpose) that would

otherwise be borne by the Seller pursuant to the License Agreement (if and as such expenses are actually incurred by the Seller). Notwithstanding the foregoing, the Seller shall have the right, at its own cost and expense, to conduct any inspection or audit under Section 7.5 of the License Agreement for a particular calendar year, if the Buyer has received Royalty payments under this Agreement in excess of $55 million in such calendar year or to the extent undertaken in respect of any Royalty Reduction for which Seller has any payment obligation to the Buyer pursuant to Section 5.3, Section 6.2 or Section 6.6 of this Agreement; provided that the Seller shall provide prior written notice to the Buyer of the Seller's intent to exercise such right.

Section 5.9 Termination of Settlement Agreement. The Seller shall not (without the Buyer's written consent), and shall (if reasonably instructed in writing by the Buyer) (i) exercise any right, or take any action, to terminate the Settlement Agreement, in whole or in part, or any of the surviving provisions of the License Agreement, (ii) agree with Janssen to terminate the Settlement Agreement, in whole or in part, or any of the surviving provisions of the License Agreement and (iii) take, or permit any Person to take, any action, or fail to take an action, that would reasonably be expected to give Janssen the right to terminate the Settlement Agreement, in whole or in part, or any of the surviving provisions of the License Agreement, in whole or in part; provided that the Buyer shall indemnify the Seller from and against any and all Losses resulting from any exercise of such right, action or termination undertaken at the instruction of the Buyer.

Section 5.10 Preservation of Rights. The Seller shall not, without the prior written consent of the Buyer, subject to a Lien (other than a Permitted Lien) any of its interest in any portion of the Licensed Products, the Licensed Patents, the Settlement Agreement or any surviving provision of the License Agreement. The Seller agrees that upon the Closing, the Seller shall not have the right to, and shall not, impose a Lien upon, or otherwise propose to sell, transfer, hypothecate, assign, convey title (in whole or in part), grant any right to, or otherwise dispose of any portion of the Royalty. Unless otherwise permitted by Section 8.3, the Seller shall not sell, transfer, hypothecate, assign, convey title (in whole or in part), grant any right to, or otherwise dispose of any of its interest in any portion of the Licensed Products, the Licensed Patents, the Settlement Agreement or any surviving provision of the License Agreement without the Buyer's prior written consent.

Section 5.11 Further Assurances. After the Closing, the Seller and the Buyer agree to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be reasonably necessary in order to give effect to the transactions contemplated by this Agreement.

Section 5.12 Continuing Obligations. Notwithstanding the sale, transfer, assignment and conveyance to the Buyer of the Royalty, the Seller shall continue to honor and satisfy its obligations and liabilities under the Settlement Agreement and the surviving provisions of the License Agreement.

ARTICLE 6
INDEMNIFICATION

Section 6.1 Survival of Representations and Warranties. The representations and warranties contained in Section 4.1 and Section 4.2 shall survive the Closing and shall remain

in full force and effect until the date that is eighteen (18) months following the Closing Date, except that: (x) the Special Representations shall remain in full force and effect until the expiration or termination of this Agreement; (y) the representations and warranties contained in Section 4.1(a) (Existence; Good Standing), Section 4.1(b) (Authorization), Section 4.1(c) (Enforceability), Section 4.1(d) (No Conflicts), Section 4.1(i)(ii) (Licenses/Sublicenses), Section 4.1(i)(iii) (Validity and Enforceability of Agreements), Section 4.1(i)(iv)(A) (Licensed Product), Section 4.1(i)(vi) (No Liens or Assignments by the Seller), Section 4.1(i)(xi) (No Assignments), Section 4.1(i)(xv) (No Remaining Obligations), Section 4.1(j) (Title; Sufficiency) and Section 4.1(m) (Brokers' Fees) shall remain in full force and effect until the date that is five (5) years following the Closing Date and (z) the representations and warranties contained in Section 4.1(n) (Tax Matters) shall remain in full force and effect until the date that is six (6) years following the Closing Date. Subject to Section 7.1, all of the covenants and agreements contained in this Agreement that by their nature are required to be performed after the Closing shall survive the Closing until fully performed or fulfilled.

Section 6.2 General Indemnity. Subject to Section 6.4 and Section 6.6, from and after the Closing:

(a) Without limiting any indemnification set forth in Section 6.6, the Seller hereby agrees to indemnify, defend and hold harmless the Buyer and its Affiliates and its and their directors, managers, trustees, officers, agents and employees (the "Buyer Indemnified Parties") from, against and in respect of all Losses suffered or incurred by the Buyer Indemnified Parties to the extent arising out of or resulting from (i) any inaccuracy in or breach of any of the representations or warranties of the Seller in this Agreement or contained in any certificate delivered in connection with this Agreement or (ii) any breach of any of the covenants or agreements of the Seller in this Agreement or contained in the Bill of Sale; and

(b) the Buyer hereby agrees to indemnify, defend and hold harmless the Seller and its Affiliates and its and their directors, officers, agents and employees ("Seller Indemnified Parties") from, against and in respect of all Losses suffered or incurred by the Seller Indemnified Parties to the extent arising out of or resulting from (i) any inaccuracy in or breach of any of the representations or warranties of the Buyer in this Agreement or contained in the Bill of Sale or (ii) any breach of any of the covenants or agreements of the Buyer in this Agreement or contained in any certificate delivered in connection with this Agreement.

Section 6.3 Notice of Claims. If either a Buyer Indemnified Party, on the one hand, or a Seller Indemnified Party, on the other hand (such Buyer Indemnified Party on the one hand and such Seller Indemnified Party on the other hand being hereinafter referred to as an "Indemnified Party"), has suffered or incurred any Losses for which indemnification may be sought under this Article 6, the Indemnified Party shall so notify the other party from whom indemnification is sought under this Article 6 (the "Indemnifying Party") promptly in writing describing such Loss, the amount or estimated amount thereof, if known or reasonably capable of estimation, and the method of computation of such Loss, all with reasonable particularity and containing a reference to the provisions of this Agreement in respect of which such Loss shall have occurred. If any claim, action, suit or proceeding is asserted or instituted by or against a third party with respect to which an Indemnified Party intends to claim any Loss under this Article 6, such Indemnified Party shall promptly notify the Indemnifying Party of such claim, action, suit or

proceeding and tender to the Indemnifying Party the defense of such claim, action, suit or proceeding. A failure by an Indemnified Party to give notice and to tender the defense of such claim, action, suit or proceeding in a timely manner pursuant to this Section 6.3 shall not limit the obligation of the Indemnifying Party under this Article 6, except to the extent such Indemnifying Party is actually prejudiced thereby.

Section 6.4 Limitations on Liability. No party hereto shall be liable for any consequential, punitive, special or incidental damages under this Article 6 (and no claim for indemnification hereunder shall be asserted) as a result of any breach or violation of any covenant or agreement of such party (including under this Article 6) in or pursuant to this Agreement. Notwithstanding the foregoing, other than with respect to any fraud, willful misconduct, or intentional misrepresentation, (i) in no event shall an Indemnifying Party's aggregate liability for Losses under Section 6.2(a) or Section 6.2(b) exceed the Purchase Price less the Royalty payments actually received by Buyer following the fourth (4th) anniversary of the date hereof and (ii) no Indemnifying Party shall have any liability for Losses under Section 6.2(a) or Section 6.2(b) except to the extent the aggregate amount of all Losses incurred by the Indemnified Party equals or exceeds $195,000, at which point the full amount of the Losses shall be recoverable. For the sake of clarity, (i) and (ii) shall not apply to [•••] as set forth in Section 6.6.

Section 6.5 Third Party Claims. Upon providing notice to an Indemnifying Party by an Indemnified Party pursuant to Section 6.3 of the commencement of any action, suit or proceeding against such Indemnified Party by a third party with respect to which such Indemnified Party intends to claim any Loss under this Article 6, such Indemnifying Party shall have the right to defend such claim, at such Indemnifying Party's expense and with counsel of its choice reasonably satisfactory to the Indemnified Party. If the Indemnifying Party assumes the defense of such claim, the Indemnified Party shall, at the request of the Indemnifying Party, use commercially reasonable efforts to cooperate in such defense; provided that the Indemnifying Party shall bear the Indemnified Party's reasonable out-of-pocket costs and expenses incurred in connection with such cooperation. So long as the Indemnifying Party is conducting the defense of such claim as provided in this Section 6.5, the Indemnified Party may retain separate co-counsel at its expense and may participate in the defense of such claim, and the Indemnifying Party shall not consent to the entry of any Judgment or enter into any settlement with respect to such claim without the prior written consent of the Indemnified Party unless such Judgment or settlement (A) provides for the payment by the Indemnifying Party of money as sole relief (if any) for the claimant (other than customary and reasonable confidentiality obligations relating to such claim, Judgment or settlement), (B) results in the full and general release of the Indemnified Party from all liabilities arising out of, relating to or in connection with such claim and (C) does not involve a finding or admission of any violation of any law, rule, regulation or Judgment, or the rights of any Person, and has no effect on any other claims that may be made against the Indemnified Party. In the event the Indemnifying Party does not or ceases to conduct the defense of such claim as so provided, (i) the Indemnified Party may defend against such claim in any manner it may reasonably deem to be appropriate and may consent to the entry of any Judgment or enter into any settlement with respect to such claim without the prior written consent of the Indemnifying Party; (ii) subject to the limitations set forth in Section 6.4, the Indemnifying Party shall reimburse the Indemnified Party promptly and periodically for the reasonable out-of-pocket costs of defending against such claim, including reasonable attorneys' fees and expenses against reasonably detailed invoices; and (iii) the Indemnifying Party shall remain responsible for any Losses the Indemnified

Party may suffer as a result of such claim to the full extent provided in this Article 6; provided, however, in the event that the Indemnified Party assumes the defense of any such claim, the Indemnified Party will keep the Indemnifying Party reasonably informed of the progress of any such defense, including with respect to any Judgment or settlement.

Section 6.6 [•••]

Section 6.7 Exclusive Remedy. Except as set forth in Section 8.11, from and after Closing, the rights of the parties hereto pursuant to (and subject to the conditions of) this Article 6 shall be the sole and exclusive remedy of the parties hereto and their respective Affiliates with respect to any claims (whether based in contract, tort or otherwise) resulting from or relating to any breach of the representations, warranties covenants and agreements made under this Agreement or any certificate, document or instrument delivered hereunder, and each party hereto hereby waives, to the fullest extent permitted under applicable law, and agrees not to assert after Closing, any other claim or action in respect of any such breach. Notwithstanding the foregoing, claims for fraud shall not be waived or limited in any way by this Article 6.

Section 6.8 Tax Treatment of Indemnification Payments. For all purposes hereunder, any indemnification payments made pursuant to this Article 6 will be treated as an adjustment to the consideration paid, or treated as paid, for U.S. federal income tax purposes with respect to the Royalty to the fullest extent permitted by applicable law.

ARTICLE 7
TERMINATION AND SURVIVAL

Section 7.1 Termination; Survival. This Agreement shall continue in full force and effect until sixty (60) days after such time as Janssen is no longer obligated to make any payments of the Royalty, at which point this Agreement shall automatically terminate, except with respect to any rights and obligations that shall have accrued prior to such termination. Notwithstanding anything to the contrary in this Section 7.1, this sentence and the following provisions shall survive termination of this Agreement: Section 5.1 (Confidentiality), Article 6 (Indemnification) and Article 8 (Miscellaneous). Termination of the Agreement shall not relieve any party of liability in respect of breaches under this Agreement by any party on or prior to termination.

ARTICLE 8
MISCELLANEOUS

Section 8.1 Notices. All notices and other communications under this Agreement shall be in writing and shall be by email with PDF attachment, courier service or personal delivery to the following addresses, or to such other addresses as shall be designated from time to time by a party hereto in accordance with this Section 8.1:

If to the Seller, to it at:
Minerva Neurosciences, Inc.
1601 Trapelo Road, Suite 286
Waltham, MA 02451
Attention: Dr. Remy Luthringer, Geoff Race, Devin Smith
Email: rluthringer@minervaneurosciences.com, grace@minervaneurosciences.com, dsmith@minervaneurosciences.com

With a copy to:
Cooley LLP
500 Boylston Street
Boston, MA 02116-3736
Attention: Marc Recht
Email: mrecht@cooley.com

If to the Buyer, to it at:
RPI 2019 Intermediate Finance Trust
110 E. 59th Street, Suite 3300
New York, New York 10022
Attention: George Lloyd
Email: glloyd@royaltypharma.com

With a copy to:
Goodwin Procter LLP
100 Northern Avenue
Boston, Massachusetts 02210
Attention: Arthur R. McGivern, Robert J. Crawford
and Jacqueline Mercier
Email: amcgivern@goodwinlaw.com
rcrawford@goodwinlaw.com
jmercier@goodwinlaw.com

All notices and communications under this Agreement shall be deemed to have been duly given (i) when delivered by hand, if personally delivered, (ii) when received by a recipient, if sent by email, or (iii) one Business Day following sending within the United States by overnight delivery via commercial one-day overnight courier service.

Section 8.2 Expenses. Except as otherwise provided herein, all fees, costs and expenses (including any legal, accounting and banking fees) incurred in connection with the

preparation, negotiation, execution and delivery of this Agreement and to consummate the transactions contemplated hereby shall be paid by the party hereto incurring such fees, costs and expenses.

Section 8.3 Assignment. The Seller may not assign this Agreement or any of its rights and obligations hereunder, in whole or in part, without the Buyer's prior written consent, except to a third party in connection with the sale or transfer of all or substantially all of the Seller's business or assets, whether by merger, sale of assets or otherwise and only if upon closing any such transaction, the Seller causes such third party to deliver a writing to the Buyer in which such third party assumes all of the obligations of the Seller to the Buyer under this Agreement. The Buyer may assign this Agreement in whole or in part. This Agreement shall be binding upon, inure to the benefit of and be enforceable by, the parties hereto and their respective permitted successors and assigns. Any purported assignment in violation of this Section 8.3 shall be null and void.

Section 8.4 Amendment and Waiver.

(a) This Agreement may be amended, modified or supplemented only in a writing signed by each of the parties hereto. Any provision of this Agreement may be waived only in a writing signed by the parties hereto granting such waiver.

(b) No failure or delay on the part of any party hereto in exercising any right, power or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power or remedy preclude any other or further exercise thereof or the exercise of any other right, power or remedy. No course of dealing between the parties hereto shall be effective to amend, modify, supplement or waive any provision of this Agreement.

Section 8.5 Entire Agreement. This Agreement, the Exhibits annexed hereto, and the Disclosure Schedule constitute the entire understanding between the parties hereto with respect to the subject matter hereof and supersede all other understandings and negotiations with respect thereto.

Section 8.6 Independent Nature of Relationship. The relationship between the Seller and the Buyer is solely that of seller and buyer, and neither the Seller nor the Buyer has any fiduciary or other special relationship with the other party hereto or any of its Affiliates. Nothing in this Agreement shall be deemed in any way or for any purpose as constituting or creating any partnership or joint venture between the Seller and the Buyer or any other party (neither for general legal purposes nor for tax purposes). Further, this Agreement is not intended to create any relationship in the nature of an employer/employee, a franchisor/franchisee, a supplier/customer, a principal/agent, or any other legal relationship or duties beyond the contractual obligations specifically provided for herein. Except to the limited extent expressly provided in this Agreement, neither party shall have the authority to bind, obligate or represent the other party. The Seller and the Buyer agree that, except as required by applicable law, they shall not take any inconsistent position with respect to such treatment in any filing with any Governmental Entity.

Section 8.7 No Third-Party Beneficiaries. This Agreement is for the sole benefit of the Seller and the Buyer and their permitted successors and assigns and nothing herein expressed

or implied shall give or be construed to give to any Person, including Janssen, other than the parties hereto and such successors and assigns, any legal or equitable rights hereunder, except that the Indemnified Parties shall be third party beneficiaries of the benefits provided for in Article 6.

Section 8.8 Governing Law. This Agreement shall be governed by, and construed in accordance with, the laws of the State of New York without giving effect to any choice or conflict of law provision or rule that would cause the application of the laws of any other jurisdiction.

Section 8.9 JURISDICTION; VENUE.

(a) EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY AND UNCONDITIONALLY SUBMITS, FOR ITSELF AND ITS RESPECTIVE PROPERTY AND ASSETS, TO THE EXCLUSIVE JURISDICTION OF ANY NEW YORK STATE COURT OR FEDERAL COURT OF THE UNITED STATES OF AMERICA SITTING IN NEW YORK COUNTY, NEW YORK, AND ANY APPELLATE COURT THEREOF, IN ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT, OR FOR RECOGNITION OR ENFORCEMENT OF ANY JUDGMENT IN RESPECT THEREOF, AND THE BUYER AND THE SELLER HEREBY IRREVOCABLY AND UNCONDITIONALLY AGREE THAT ALL CLAIMS IN RESPECT OF ANY SUCH ACTION OR PROCEEDING MAY BE HEARD AND DETERMINED IN ANY SUCH NEW YORK STATE COURT OR, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, IN SUCH FEDERAL COURT. THE BUYER AND THE SELLER HEREBY AGREE THAT A FINAL JUDGMENT IN ANY SUCH ACTION OR PROCEEDING SHALL BE CONCLUSIVE AND MAY BE ENFORCED IN OTHER JURISDICTIONS BY SUIT ON THE JUDGMENT OR IN ANY OTHER MANNER PROVIDED BY APPLICABLE LAW. EACH OF THE BUYER AND THE SELLER HEREBY SUBMITS TO THE EXCLUSIVE PERSONAL JURISDICTION AND VENUE OF SUCH NEW YORK STATE AND FEDERAL COURTS. THE BUYER AND THE SELLER AGREE, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, THAT PROCESS MAY BE SERVED ON THE BUYER OR THE SELLER IN THE SAME MANNER THAT NOTICES MAY BE GIVEN PURSUANT TO SECTION 8.1 HEREOF.

(b) EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES, TO THE FULLEST EXTENT IT MAY LEGALLY AND EFFECTIVELY DO SO, ANY OBJECTION THAT IT MAY NOW OR HEREAFTER HAVE TO THE LAYING OF VENUE OF ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT IN ANY NEW YORK STATE OR FEDERAL COURT. EACH OF THE BUYER AND THE SELLER HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, THE DEFENSE OF AN INCONVENIENT FORUM TO THE MAINTENANCE OF SUCH ACTION OR PROCEEDING IN ANY SUCH COURT.

(c) EACH PARTY HEREBY JOINTLY AND SEVERALLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY ACTION OR PROCEEDING RELATING TO THIS AGREEMENT OR ANY OTHER DOCUMENT DELIVERED HEREUNDER OR IN CONNECTION HEREWITH, OR ANY TRANSACTION ARISING FROM OR CONNECTED

TO ANY OF THE FOREGOING. EACH OF THE PARTIES REPRESENTS THAT THIS WAIVER IS KNOWINGLY, WILLINGLY, AND VOLUNTARILY GIVEN.

Section 8.10 Severability. If any term or provision of this Agreement shall for any reason be held to be invalid, illegal or unenforceable in any situation in any jurisdiction, then, to the extent that the economic and legal substance of the transactions contemplated hereby is not affected in a manner that is materially adverse to either party hereto, all other terms and provisions of this Agreement shall nevertheless remain in full force and effect and the enforceability and validity of the offending term or provision shall not be affected in any other situation or jurisdiction.

Section 8.11 Specific Performance. Each of the parties acknowledges and agrees that the other parties would be damaged irreparably in the event any of the provisions of this Agreement are not performed in accordance with their specific terms or otherwise are breached or violated. Accordingly, notwithstanding Section 6.7, each of the parties agrees that, without posting bond or other undertaking, the other parties shall be entitled to an injunction or injunctions to prevent breaches or violations of the provisions of this Agreement and to enforce specifically this Agreement and the terms and provisions hereof in any action, suit or other proceeding instituted in any court of the United States or any state thereof having jurisdiction over the parties and the matter in addition to any other remedy to which it may be entitled, at law or in equity. Each party further agrees that, in the event of any action for specific performance in respect of such breach or violation, it shall not assert that the defense that a remedy at law would be adequate.

Section 8.12 Trustee Capacity of Wilmington Trust, National Association. Notwithstanding anything contained herein to the contrary, it is expressly understood and agreed by the parties hereto that (i) this Agreement is executed and delivered by Wilmington Trust, National Association, not individually or personally but solely in its trustee capacity, in the exercise of the powers and authority conferred and vested in it under the trust agreement of the Buyer, (ii) each of the representations, undertakings and agreements herein made on the part of the Buyer is made and intended not as a personal representation, undertaking and agreement by Wilmington Trust, National Association, but is made and intended for the purpose of binding only the Buyer and, (iii) nothing herein contained shall be construed as creating any liability on Wilmington Trust, National Association, individually or personally, to perform any covenant either expressed or implied contained herein, all such liability, if any, being expressly waived by the parties hereto and by any Person claiming by, through or under the parties hereto, (iv) Wilmington Trust, National Association has made no investigation as to the accuracy or completeness of any representations and warranties made by the Buyer in this Agreement, and (v) under no circumstances shall Wilmington Trust, National Association be personally liable for the payment of any indebtedness or expenses of the Buyer or be liable for the breach or failure of any obligation, representation, warranty or covenant made or undertaken by the Buyer under this Agreement or any related documents.

Section 8.13 Counterparts. This Agreement may be executed in any number of counterparts and by the parties hereto in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement. Copies of executed counterparts transmitted by telecopy, facsimile or other similar

means of electronic transmission, including “PDF,” shall be considered original executed counterparts, provided receipt of such counterparts is confirmed.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed and delivered by their respective representatives thereunto duly authorized as of the date first above written.

MINERVA NEUROSCIENCES, INC.

By: /Remy Luthringer/
Name: Remy Luthringer
Title: Chairman and CEO

RPI 2019 INTERMEDIATE FINANCE TRUST

By: Wilmington Trust, National Association, not in its individual capacity but solely in its capacity as owner trustee

By: /Cynthia L Major/
Name: Cynthia L Major
Title: Banking Officer

Exhibit A

Seller's Wire Transfer Instructions

[•••]

Exhibit B

Form of Bill of Sale

BILL OF SALE

This **BILL OF SALE** (this "**Bill of Sale**") is dated as of January [_], 2021 by Minerva Neurosciences, Inc., a Delaware corporation (the "**Seller**"), in favor of RPI 2019 Intermediate Finance Trust, a Delaware statutory trust (the "**Buyer**"). Unless otherwise specifically defined herein, each capitalized term used herein shall have the meaning assigned to such term in the Purchase Agreement (as defined below). References to the Seller herein shall be deemed to include any assignee of the Seller pursuant to Section 8.3 of the Purchase Agreement.

RECITALS

WHEREAS the Seller and the Buyer are parties to that certain Royalty Purchase Agreement, dated as of January [_], 2021 (the "**Purchase Agreement**"), pursuant to which, among other things, the Seller has agreed to sell, transfer, assign and convey to the Buyer, and the Buyer has agreed to purchase, acquire and accept from the Seller, all of the Seller's right, title and interest in and to the Royalty, for the consideration described in the Purchase Agreement; and

WHEREAS the parties hereto now desire to evidence the transfer of all of the Seller's right, title and interest in and to the Royalty from the Seller to the Buyer pursuant to the Purchase Agreement by the execution and delivery of this Bill of Sale.

NOW, THEREFORE, in consideration of the premises and the mutual agreements set forth in the Purchase Agreement and of other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the parties hereto agree as follows:

1. The Seller, by this Bill of Sale, does hereby sell, assign, transfer and convey to the Buyer, and the Buyer does hereby purchase, acquire and accept from the Seller, all of the Seller's right, title and interest in and to the Royalty.

2. This Bill of Sale: (a) is made pursuant to, and is subject to the terms of, the Purchase Agreement and (b) shall be binding upon and inure to the benefit of the Seller, the Buyer and their respective successors and permitted assigns, for the uses and purposes set forth and referred to above, effective immediately upon its delivery to the Buyer.

3. THIS BILL OF SALE SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK WITHOUT GIVING EFFECT TO ANY CHOICE OR CONFLICT OF LAW PROVISION OR RULE THAT WOULD CAUSE THE APPLICATION OF THE LAWS OF ANY OTHER JURISDICTION.

4. This Bill of Sale may be executed in any number of counterparts and by facsimile or other electronic transmission, each of which counterpart shall constitute an original and all of which counterparts together shall constitute one and the same instrument.

5. The terms of the Purchase Agreement, including but not limited to the Seller's representations, warranties, covenants and agreements relating to the Royalty are incorporated herein *mutatis mutandis* by this reference. The parties hereto acknowledge and agree that the representations, warranties, covenants, agreements and indemnities contained in the Purchase Agreement shall not be superseded hereby but shall remain in full force and effect to the full extent

provided therein. In the event of any conflict or inconsistency between the terms of the Purchase Agreement and the terms hereof, the terms of the Purchase Agreement shall govern.

6. Notwithstanding anything contained herein to the contrary, it is expressly understood and agreed by the parties hereto that (i) this Bill of Sale is executed and delivered by Wilmington Trust, National Association, not individually or personally but solely in its trustee capacity, in the exercise of the powers and authority conferred and vested in it under the trust agreement of the Buyer, (ii) each of the representations, undertakings and agreements herein made on the part of the Buyer is made and intended not as a personal representation, undertaking and agreement by Wilmington Trust, National Association, but is made and intended for the purpose of binding only the Buyer and, (iii) nothing herein contained shall be construed as creating any liability on Wilmington Trust, National Association, individually or personally, to perform any covenant either expressed or implied contained herein, all such liability, if any, being expressly waived by the parties hereto and by any Person claiming by, through or under the parties hereto, (iv) Wilmington Trust, National Association has made no investigation as to the accuracy or completeness of any representations and warranties made by the Buyer in this Bill of Sale, and (v) under no circumstances shall Wilmington Trust, National Association be personally liable for the payment of any indebtedness or expenses of the Buyer or be liable for the breach or failure of any obligation, representation, warranty or covenant made or undertaken by the Buyer under this Bill of Sale or any related documents.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties hereto have executed this Bill of Sale as of the day and year first written above.

MINERVA NEUROSCIENCES, INC.

By: /Remy Luthringer/
Name: Remy Luthringer
Title: Chairman and CEO

[*Signature Page to Bill of Sale*]

IN WITNESS WHEREOF, the parties hereto have executed this Bill of Sale as of the day and year first written above.

RPI 2019 INTERMEDIATE FINANCE TRUST

By: Wilmington Trust, National Association, not in its individual capacity but solely in its capacity as owner trustee

By: /Cynthia L Major/
Name: Cynthia L Major
Title: Banking Officer

[*Signature Page to Bill of Sale*]

Exhibit C

Form of Instruction Letter

January [_], 2021

ARTICLE 9VIA E-MAIL

Janssen Pharmaceutica, N.V.
[Insert Address]
Attn: [Insert]

RE: Notice of Royalty Assignment and Payment Direction

Ladies and Gentlemen:

Reference is hereby made to: (i) that certain Co-Development and License Agreement, dated February 13, 2014, by and between Janssen Pharmaceutica, N.V. ("**you**") and Minerva Neurosciences, Inc. ("**Minerva**"), as amended by that certain Amendment No. 1, dated June 13, 2017 (collectively, the "**License Agreement**") and (ii) that certain Confidential Settlement Agreement dated June 24, 2020 by and between you and Minerva (the "**Settlement Agreement**" and together with the License Agreement, the "**Existing Agreements**"). Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to such terms in the License Agreement.

Pursuant to the Royalty Purchase Agreement, dated January [_], 2021 (the "**Purchase Agreement**"), by and between Minerva and RPI 2019 Intermediate Finance Trust, a Delaware statutory trust ("**Royalty Pharma**"), Minerva sold, assigned and transferred to Royalty Pharma all of its rights, title and interest in and to all amounts payable by you to Minerva under the Existing Agreements pursuant to Section 6.3(a) and Section 11.6(b)(iii) of the License Agreement with respect to worldwide Net Sales of the Licensed Products sold by you and your Affiliates and Sublicensees, and any payments by you under the Existing Agreements in lieu of such payments (collectively, the "**Royalty**"), from and after January [_], 2021.

Accordingly, we are hereby requesting that, unless instructed otherwise in writing by Royalty Pharma, you make 100% of all Royalty payments that would be payable to Minerva pursuant to terms of the Existing Agreements to Royalty Pharma by wire transfer in United States dollars to the following bank account:

[•••]

In addition, we are further requesting that, unless instructed otherwise in writing by Royalty Pharma, you deliver copies of the royalty reports deliverable by you to Minerva pursuant to Section 7.1(c) of the License Agreement, and any other notices or correspondence that you deliver or furnish to Minerva under the Existing Agreements, to Royalty Pharma simultaneous with delivery of the same to Minerva at the following address:

RPI 2019 Intermediate Finance Trust
110 E. 59th Street, Suite 3300
New York, New York 10022
Attention: George Lloyd
Email: glloyd@royaltypharma.com

Lastly, we are requesting that, in connection with the transactions contemplated by the Purchase Agreement, you agree that Minerva shall be permitted to share Confidential Information with Royalty Pharma. Royalty Pharma hereby agrees to treat all Confidential Information furnished to it in accordance with the confidentiality and limited use provisions of the License Agreement.

We would greatly appreciate your confirming that you consent and agree to the foregoing by signing and returning a counterpart of this letter (the provisions of which shall be governed by the laws of the State of New York, U.S.A. consistent with the License Agreement).

Thank you for your cooperation regarding this matter.

[*Remainder of Page Intentionally Left Blank*]

Very truly yours,

MINERVA NEUROSCIENCES, INC.

By: _____
Name:
Title:

RPI 2019 INTERMEDIATE FINANCE TRUST

By: RP Management LLC, its Administrator

By: _____
Name:
Title:

Acknowledged, agreed and consented:

ARTICLE 10JANSSEN PHARMACEUTICA, N.V.

By: _____
Name:
Title:

Exhibit D

License Agreement

This agreement was previously disclosed as Exhibit 10.7 to Amendment No. 1 to Form S-1 Registration Statement filed with the Securities and Exchange Commission by Minerva Neurosciences, Inc. on June 10, 2014

An amendment to this agreement was previously disclosed as Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission by Minerva Neurosciences, Inc. on June 14, 2017

Exhibit E

Settlement Agreement

This agreement was previously disclosed as Exhibit 10.2 to Form 10-Q filed with the Securities and Exchange Commission by Minerva Neurosciences, Inc. on August 3, 2020

Exhibit F

Royalty Report Certification

EXHIBIT F

ROYALTY REPORT CERTIFICATE

Date: _____, 202

This Certificate (this "Certificate") is given by Minerva Neurosciences, Inc., a Delaware corporation (the "Seller"), pursuant to Section 5.4 of that certain Royalty Purchase Agreement dated as of January [_], 2021 among the Seller and RPI 2019 Intermediate Finance Trust, a Delaware statutory trust (the "Buyer") (as such agreement may be amended, restated, supplemented, extended or otherwise modified from time to time, the "Purchase Agreement"). Capitalized terms used herein without definition shall have the meanings set forth in the Purchase Agreement unless otherwise indicated.

The officer executing this Certificate is the Chief [**Financial/Executive**] Officer of the Seller and as such is duly authorized to execute and deliver this Certificate on behalf of the Seller. By executing this Certificate, such officer hereby certifies to the Buyer, on behalf of the Seller (and not in **[his/her**] personal capacity) and to **[his/her]** reasonable belief, that:

1. The Seller is in receipt of a Royalty Report for the calendar quarter ended [_____], 20[_] with respect to the Royalty paid or payable for such quarter in the amount of $[ ];

2. The amount of such Royalty is based upon the Net Sales of the Licensed Products sold by Janssen and its Affiliates and Sublicensees for the applicable Calendar Quarter (as defined in the License Agreement), as reported in the Royalty Report, for each country in which Licensed Products were sold during such Calendar Quarter;

3. Such Net Sales appear on the face of the Royalty Report to have been calculated in accordance with the terms of the License Agreement; and

4. [No Royalty Reduction was applied to reduce the amount of the Royalty made to the Buyer for such Calendar Quarter];

OR

[A Royalty Reduction was applied by Janssen and reduced the amount of the Royalty for such Calendar Quarter, and the amount and nature of such Royalty Reduction are set forth below.]

- [*Insert description of the amount and nature of such Royalty Reduction*]

[*Signature Page to Follow*]

IN WITNESS WHEREOF, the Seller has caused this Certificate to be executed by its Chief [**Financial/Executive**] Officer this ___ day of _____, 202_.

MINERVA NEUROSCIENCES, INC.

By: _____
Name:
Title:

Exhibit G

[•••]

Exhibit 21.1

Subsidiaries of Minerva Neurosciences, Inc.

Name	Jurisdiction of Incorporation
Mind-NRG Sarl	Switzerland
Minerva Neurosciences Securities Corporation	Massachusetts

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-205764 and 333-226783 on Form S-3 and Nos. 333-242460, 333-225672, 333-223593, 333-222368, 333-216637, 333-210147, 333-203738, and 333-198753 on Form S-8 of our report dated March 8, 2021, relating to the consolidated financial statements of Minerva Neurosciences, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2020.

/s/ DELOITTE & TOUCHE LLP

Boston, Massachusetts
March 8, 2021

Exhibit 31.1

CERTIFICATIONS

I, Remy Luthringer, certify that:

1. I have reviewed this annual report on Form 10-K of Minerva Neurosciences, Inc.;

2. Based on my knowledge, this 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;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 8, 2021

/s/ Remy Luthringer, Ph.D.
Remy Luthringer, Ph.D.
Executive Chairman and
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Geoffrey Race, certify that:

1. I have reviewed this annual report on Form 10-K of Minerva Neurosciences, Inc.;

2. Based on my knowledge, this 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;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 8, 2021

/s/ Geoffrey Race

Geoffrey Race
Chief Financial Officer and
Chief Business Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATIONS PURSUANT TO 18 U.S.C. SECTION 1350 AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Remy Luthringer**,** Chief Executive Officer of Minerva Neurosciences, Inc. (the "Company"), and Geoff Race, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2020, to which this Certification is attached as Exhibit 32.1 (the "Annual Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 8, 2021

/s/ Remy Luthringer, Ph.D.	/s/ Geoffrey Race
Remy Luthringer, Ph.D.	Geoffrey Race
Executive Chairman and	Chief Financial Officer and
Chief Executive Officer	Chief Business Officer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Minerva Neurosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.