Minerva Neurosciences, Inc.
Form 10-K
March 26, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2014

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	(I.R.S. Employer
incorporation or organization)	Identification No.)
1601 Trapelo Road, Suite 284	
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: Common Stock, Par Value $0.0001 Per Share; Common stock traded on 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 x

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 x

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 x NO ¨

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). YES x NO ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of Registrant’s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definition of “large accelerated filer”, “accelerated filer”, and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

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

The registrant's common stock was not publicly traded as of the last business day of the registrant's most recently completed second fiscal quarter. The number of shares of Registrant’s Common Stock outstanding as of March 20, 2015 was 24,721,143.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant’s Definitive Proxy Statement relating to the Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

MINERVA NEUROSCIENCES, INC.

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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,” “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.

Part I

ITEM 1. Business

Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of a portfolio of product candidates to treat patients suffering from central nervous system, or CNS, diseases. Leveraging our deep domain expertise, we have acquired or in-licensed four development-stage proprietary compounds that we believe have innovative mechanisms of action with potentially positive therapeutic profiles. Our lead product candidate is MIN-101, a compound for the potential treatment of patients with schizophrenia. In addition, our portfolio includes MIN-202, a compound we are co-developing with Janssen Pharmaceuticals, or Janssen, for the treatment of patients suffering from primary and comorbid insomnia, MIN-117, a compound we are developing for the treatment of patients suffering from major depressive disorder, or MDD, and MIN-301, a compound we are developing for the treatment of patients suffering from Parkinson’s disease. We believe our innovative product candidates have significant potential to transform the lives of a large number of affected patients and their families who are currently not well-served by available therapies in each of their respective indications.

We plan to develop and, if approved by the applicable regulatory authorities, commercialize our product candidates for the CNS pharmaceutical market, including the diseases we are presently targeting, namely schizophrenia, MDD, insomnia and Parkinson’s disease. These CNS diseases affect large numbers of individuals with family members also bearing significant burdens. According to Datamonitor, an independent market research firm, in 2014 4.8 million people suffer from schizophrenia, 30 million suffer from MDD, 53 million suffer from insomnia and more than 2.0 million suffer from Parkinson’s disease in the United States, Japan and the five major European Union markets of France, Germany, Italy, Spain and the United Kingdom.

While there are numerous available therapies in the market for the treatment of the CNS diseases we are targeting, each of these therapies has significant limitations in addressing the needs of patients. We have pursued the development of our product candidates based on our deep knowledge of the pathophysiology of CNS diseases, the pharmacology of our portfolio of compounds and the limitations of current therapies. We believe our product candidates each represent a differentiated treatment option that could overcome the limitations of current therapies and address the unmet needs of patients.

Our management team has extensive experience in the pharmaceutical industry, in particular with respect to CNS products. Dr. Remy Luthringer, our Chief Executive Officer, President and Chief Scientific Officer, has participated in over 750 clinical trials in the CNS area, including trials for many products approved by the U.S. Food and Drug Administration, or the FDA. Our Executive Vice President and Chief Financial Officer, Geoff Race, has worked in the biotechnology industry since 1997 and has acted as a chief executive officer or chief financial officer in seven early stage development companies, including Funxional Therapeutics Ltd and PanGenetics BV.

Our Strategy

Our strategy is to develop and commercialize products with transformative potential addressing critical unmet medical needs in the CNS therapeutic area. Pursuing our strategy will be based on the following principles: innovative clinical development based on mechanisms behind the disease, patient safety and compliance, scientific rigor applied to drug development and the clinical trial process, leveraging patient and caregiver insights to drive scientific advancements, and integrity. Key elements of our strategy are:

- Advance the clinical development and obtain regulatory approval of our current product candidates.
- Selectively explore collaborations with leading pharmaceutical companies to maximize the value of our current product candidate portfolio.
- Serve the patient community upon any approval of a product candidate.
- Leverage our management team's expertise and current intellectual property portfolio to identify and explore additional indications relating to our current portfolio of compounds and to acquire additional product candidates.

We believe our compounds affect multiple CNS disease mechanisms and have the potential to address unmet medical needs in several major CNS disorders. We plan to leverage our management team's expertise to continue to evaluate our current product portfolio to explore additional indications and develop additional CNS product candidates from our existing intellectual property and acquire rights to additional product candidates that we believe have significant commercial potential and potential to be transformative and address unmet patient medical needs.

Our History

In November 2013, Cyrenaic Pharmaceuticals, Inc., or Cyrenaic, and Sonkei Pharmaceuticals, Inc., or Sonkei, merged and the combined company was renamed Minerva Neurosciences, Inc. Cyrenaic was incorporated in 2007, and exclusively licensed MIN-101 from Mitsubishi Tanabe Pharma Corporation, or MTPC. Sonkei was incorporated in 2008 and exclusively licensed MIN-117 from MTPC. We executed the merger as we saw an opportunity to better serve an underserved patient population through combining a portfolio of promising product candidates targeting CNS diseases. As a result of the merger, we have the rights to develop and commercialize MIN-101 and MIN-117 globally, excluding most of Asia.

We further expanded our product candidate portfolio in February 2014 by acquiring the shares of Mind-NRG SA, or Mind-NRG, which had exclusive rights to develop and commercialize MIN-301. 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, pursuant to which we will develop MIN-202 and have the right to commercialize MIN-202 in Europe, subject to royalty payments to Janssen, with Janssen having commercialization rights outside of the European Union, subject to royalty payments to us.

Our Pipeline

Program	Primary Indication	Phase I	Phase II	Rights
MIN-101	Schizophrenia	•6 trials completed •Once a day formulation completed	•Phase IIa completed •Phase IIb submission ongoing; enrollment expected to occur in last 3 quarters of 2015	Global ex-Asia
MIN-117	Major depressive disorder (MDD)	•2 trials completed	•Phase IIa expected to begin enrolling in second quarter of 2015	Global ex-Asia
MIN-202	Insomnia	•Phase Ib in MDD patients completed •Bioavailability study in healthy volunteers completed •Multiple ascending dose study in healthy volunteers completed •Phase Ib in comorbid insomnia expected to initiate in mid 2015	•Phase IIa in primary insomnia expected to initiate in mid 2015	European union (Co-development with Janssen)
MIN-301	Parkinson's disease	•Pre-clinical studies ongoing in preparation for IMPD or IND filing expected in 2016 with a Phase I expected to initiate thereafter		Global

MIN-101

MIN-101 is a compound we are developing for the treatment of patients with schizophrenia. It is an innovative antagonist of 5-HT2A and sigma2 receptors. The pharmacological effects of MIN-101 are caused by MIN-101 blocking serotonin receptors and sigma receptors, two receptors in the brain that are involved in the regulation of mood, cognition, sleep and anxiety. MIN-101 is meant to block a specific subtype of serotonin receptor called 5-HT2A. When 5-HT2A is blocked, certain symptoms of schizophrenia, such as hallucinations, delusions, agitation and thought and movement disorders, as well as the side effects of antipsychotic treatments can be minimized. Additionally, blocking 5-HT2A promotes slow wave sleep, a sleep stage, which is often disrupted in patients with schizophrenia. MIN-101 is also meant to block a specific subtype of sigma receptor called sigma2, which is involved in movement control, psychotic symptom control and learning and memory. Blocking sigma2 also modulates other neurotransmitters in the brain, in particular dopamine, which is important as individuals with schizophrenia often have elevated levels of dopamine in their brains. Blocking sigma2 also increases calcium levels in neurons in the brain, which can improve memory. Recent literature also indicated that a sub-type of progesterone protein complex might also be a putative binding site for sigma2 receptors and might explain the effects on cognition of MIN-101.

We believe MIN-101 reflects scientifically supported and innovative mechanisms of action to potentially address the unmet needs of this patient population. We plan to initially seek approval of MIN-101 as a first line monotherapy. We will also study its use as an adjunctive therapy. We believe that MIN-101, could treat the majority of patients diagnosed with schizophrenia if approved. We have recently completed the development of a once-a-day tablet delivery of MIN-101, which is more convenient for patients than the twice-a-day formulation, which was used in previous trials.

In a Phase IIa clinical trial conducted by Cyrenaic in 2009, MIN-101 suggested positive treatment effects and suggested that, in future trials at the intended therapeutic dose and dosing schedule, a favorable safety profile may be seen. MIN-101 has also undergone extensive pre-clinical studies, five Phase I clinical trials in healthy volunteers and one Phase I clinical trial in subjects with schizophrenia. We have exclusively licensed MIN-101 and a number of back-up compounds from MTPC. MTPC has retained commercialization rights to MIN-101 in most of Asia. The recently completed development of the once a day formulation will be used in the Phase IIb clinical trial of MIN-101 of approximately 234 subjects in Europe, which is scheduled to enroll over the last three quarters of 2015.

Background of the Disease

Schizophrenia is a chronic, severe and debilitating mental disease where patients suffer from positive, negative and cognitive symptoms. “Positive” symptoms in patients are psychotic behaviors not typically seen in healthy people, including hallucinations, delusions, agitation and thought and movement disorders. “Negative” symptoms are disruptions to normal emotions and behaviors that may signal social withdrawal such as mood flatness, lack of pleasure in daily life and the inability to initiate and maintain social interaction. Patients may lack the ability to begin and sustain planned activities, or speak little, even when forced to interact. “Cognitive” symptoms interfere with the patient’s ability to engage in and maintain daily routines and include: difficulty focusing and paying attention, decreased ability to understand information and make decisions, disrupted working memory or speech difficulty. Overall, this lack of cognitive focus has been shown to interrupt “executive function,” making it harder for patients to sustain relationships or employment. In addition, about half of patients with schizophrenia experience sleep disorders, which further exacerbates the positive and negative symptoms of schizophrenia. Sleep disorders include difficulty in falling asleep, staying awake or poor sleep quality.

Symptoms such as hallucinations and delusions usually begin in late adolescence or early adulthood, and patients may first present with symptoms between the ages of 15 and 30. Genetic and environmental factors are believed to contribute to the disease, and patients with schizophrenia have been observed to have physical differences in brain chemistry and structure. The symptoms of schizophrenia are important for selecting treatment options and may predict the long-term health and well-being of the patient.

Positive symptoms are often experienced periodically in an individual with schizophrenia while negative symptoms persist chronically throughout an individual’s lifetime and increase with severity over time. Patients with negative symptoms often have a projected outcome worse than those suffering from positive symptoms, particularly those with persistent chronic negative symptoms. This is because patients suffering from negative symptoms often do not recognize they need help and therefore do not seek treatment.

According to Datamonitor, 4.3 million patients suffered from schizophrenia in 2014 in the United States and the five major European Union markets and the number of patients is expected to steadily increase in line with population growth. Patients with predominantly negative symptoms represented 48% of the overall patient population in 2012 within the United States and the five major European Union markets. In addition, 80% of the overall patient population in 2012 within the United States and the five major European Union markets suffered from cognitive impairment. Further, approximately half of the number of patients with schizophrenia, experience sleep disorders, which further exacerbates positive and negative symptoms of schizophrenia. Datamonitor estimated schizophrenia-specific sales revenue of antipsychotic drugs across the United States and the five major European Union markets was $4.5 billion in 2014. It is expected that growth of the schizophrenia sales market from 2014 to

2021 will be heavily dependent on pipeline products.

Current Treatment Options and Limitations of Current Therapy

Patients are usually first diagnosed with schizophrenia in conjunction with the onset of positive symptoms, such as hallucinations or delusions. Prescribed treatments are typically either “first-generation” antipsychotic medication or “second-generation” atypical antipsychotics designed to trigger immediate symptom relief by suppressing dopamine receptor activity. Both types of medication are reasonably effective at managing the periodic nature of positive symptoms, but many patients experience significant side effects and adverse events, such as sedation, involuntary movements, prolactin increase, metabolic syndrome, cognitive impairment, sleep disorders and weight gain which can further exacerbate the negative symptoms of the disease. Therapies currently approved for treatment of schizophrenia focus primarily on treating positive symptoms. No current treatments are specifically approved for treating negative or cognitive symptoms.

While “first-generation” antipsychotic medications, such as Thorazine and Largactil (chlorpromazine) and Haldol (haloperidol), can be effective against positive symptoms in acute cases, there have been concerns about the side effects causing atypical involuntary muscle contractions, leading to motion disorders, such as involuntary movements, or extrapyramidal syndrome, inability to initiate movement, or akinesia, a state of agitation or restlessness, or akathisia. Additional side effects often seen with these treatments include sedation, nausea and tremors. In the United States, according to Datamonitor, it is estimated that approximately 25% of patients receive first-generation antipsychotics as first-line therapy. They are also used more frequently in treatment-resistant patients.

Products in the “atypical antipsychotic” class, such as Clozaril (clozapine), Risperdal (risperidone), Seroquel (quetiapine), Zyprexa (olanzapine) and Abilify (aripiprazole), have a common mechanism of action, acting as antagonists to the dopamine and 5-HT receptors. Their side effect profiles include difficulty thinking, restlessness, sedation, insomnia, nausea, exacerbation of metabolic disorders, weight gain and prolactin increase, which can create sexual hormone imbalances. This has been a highly competitive class of treatments and manufacturers have refined these therapies to offer less frequent dosing schedules in an attempt to minimize side effects. Since schizophrenia has a wide range of symptoms, multiple therapeutics are often prescribed in an attempt to address all aspects of the disease, compounding the side effects. These side effects and the lack of efficacy on negative and cognitive symptoms contribute to a high rate of treatment discontinuation – according to Datamonitor, over the course of 18 months 60% to 80% of patients treated for schizophrenia will discontinue their medication.

We believe new products are needed to address negative and cognitive symptoms that are currently not addressed by the first-generation and atypical antipsychotic classes.

Over the last two decades several attempts have been made to develop new therapies focusing on the improvement of negative symptoms. Two 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. Even though there are several compounds still under development, recent clinical data of the most advanced molecules following these two mechanisms of action have shown limited effectiveness on all symptoms of schizophrenia, in particular on negative and cognitive symptoms. In addition, the product candidates with these mechanisms of action need to be co-administered with existing atypical antipsychotics.

Key Differentiating Attributes of MIN-101

We believe MIN-101, due to its unique pharmacological profile, has the potential to address, not only the positive symptoms of schizophrenia, but also the related negative symptoms, cognitive impairment symptoms, sleep disorders, and overall psychopathology of the disease. If approved, we believe MIN-101 would be a first-in-class compound for the treatment of schizophrenia including negative symptoms. Unlike currently available therapies that block the effect of dopamine, MIN-101’s mechanism of action only modulates the effect of dopamine and has been shown to temper the negative effects of dopamine without eliminating its physiological effect in the brain in its entirety, which may help prevent many of the side effects associated with typical and atypical antipsychotics, and effectively treat schizophrenia.

We intend to seek approval for MIN-101 initially as a first line monotherapy and also plan to study its use as an adjunctive therapy. We believe MIN-101 could address the existing treated population as well as those not being treated successfully with currently available therapies. In a Phase IIa clinical trial, a statistically significant improvement of negative symptoms and a non-statistically significant trend toward the improvement of positive and cognitive symptoms and overall psychopathology was observed after three months of administration of MIN-101 in a twice-a-day formulation. The trial also showed that MIN-101 could have sleep normalizing effects in contrast to currently available therapies and had no negative impact on sleep as measured by polysomnography.

Based on the clinical and pre-clinical data discussed below, we believe that MIN-101 has a number of potential advantages over currently available therapies:

- Addresses the Spectrum of Symptoms. In pre-clinical studies, MIN-101 has been shown to modulate dopamine, which is associated with improving positive symptoms, improving negative symptoms, positively impacting certain cognitive skills, such as motor speed, motivation, verbal fluency and memory, and reducing sleep disorders.
- Avoids Many of the Typical Side Effects Associated with Existing Therapies. Unlike existing therapies, MIN-101 does not operate as a dopamine blocker. As a result, we believe that MIN-101 will avoid causing involuntary movements, prolactin increase, sedation, weight gain and metabolic syndrome, which are side effects of existing therapies.

- Good Safety and Tolerability Profile. Based on the results of one of the most recent studies of MIN-101, a Phase IIa study that explored the effect of elevated doses administered twice daily, we believe that at the intended therapeutic dose and dosing schedule, MIN-101 may demonstrate a safety and tolerability profile comparable to placebo. We intend to evaluate the safety of MIN-101 at the therapeutic dose and dosing schedule in future studies.
- Single and Combination Treatment Option. MIN-101 may be effective as a monotherapy to address the spectrum of symptoms of schizophrenia and the simplicity of such treatment would avoid complications from using multiple pharmaceuticals. If approved, we expect MIN-101 to be used as a monotherapy for younger patients in the prodromal phase of the disease and in older patients suffering from predominantly negative symptoms. We also plan to study the use of MIN-101 with existing therapies to help moderate many of the typical side effects of those therapies as well as to improve the negative and cognitive symptoms, as well as sleep disorders, experienced by patients not addressed by currently available therapies.

Clinical and Pre-clinical Experience

Phase II

In 2009 we completed a Phase IIa trial of MIN-101 in subjects suffering from schizophrenia. Enrolled subjects had previously suffered from an acute episode requiring hospitalization. This was a double-blind, placebo controlled study with a three month treatment period in which 96 subjects were randomized and 30 completed the study protocol. Patients suffered from positive, negative and cognitive symptoms and had ceased to respond well to previously prescribed medication. Subjects received either placebo or MIN-101, including doses and at a dosing schedule that may differ from the final formulated dose. Subjects electing to participate were hospitalized for the first 28 days and allowed to return to their home environment for the remaining 56 days. Prior to initiating treatment with MIN-101 (or placebo), all subjects discontinued their previous medication for an average of eight days in order to establish an accurate baseline of symptoms related to their disease and to minimize the side effects induced by previous medication.

The primary endpoint of the study was the efficacy of MIN-101 versus placebo, as measured by the Positive and Negative Symptom Scale, or PANSS, total and subscores after one month of treatment. The PANSS is used to measure psychopathology in patients suffering from schizophrenia and can be split into either three factors (positive, negative and general psychopathology) or in five factors (positive, negative, activation, dysphoric mood and autistic thoughts). Secondary and exploratory endpoints included the efficacy of MIN-101 versus placebo through the PANSS total and sub scores after three months of treatment, as well as cognition, mood, anxiety and sleep using various psychological scales at various treatment time points.

In the Phase IIa trial, subjects treated with MIN-101 showed ongoing improvements in negative symptoms, as compared to baseline, throughout the duration of the trial. After one month, improvements on the PANSS negative symptoms scale were observed. Because this Phase IIa trial was not powered to show results with statistical significance, the study's primary endpoint was not met. After three months of treatment, the MIN-101 group showed improvements in negative symptoms as compared to placebo. The negative symptom score was assessed using both the 3 factor and the 5 factor scores in both the per protocol completers set, or PPC and the full analysis set, or FAS. The PPC consisted of subjects who took the study drugs, placebo or MIN-101, for the entire duration of the study, as outlined in the protocol. The FAS consisted of subjects who took at least one dose of the study drugs and for whom at least one evaluation of the main efficacy criteria was available, including those that did not complete the study. Treatment effects are more likely to be seen in the PPC group than the FAS group as they completed the study. However, detecting a treatment effect within the FAS potentially provides stronger evidence of efficacy. Notwithstanding the relatively small trial design and that the study was not powered for statistical significance, statistical significance was reached in both the PPC and the FAS for the 5 factor negative score after three months of treatment. The 3 factor negative scores were nearly statistically significant (p=.0581 and p=.062 for the PPC and the FAS respectively) after three months of treatment. In addition to the above effects seen on negative symptoms, MIN-101 showed potential to improve positive symptoms as well as the overall total PANSS score and psychopathology, based upon measurements taken after three months of treatment as compared to baseline

measurements, which was a secondary endpoint.

Subjects participating in this clinical trial receiving MIN-101 or placebo experienced adverse events, including, but not limited to gastrointestinal, nervous system, psychiatric, and cardiac events, with two subjects with increased heart rate and one subject with decreased heart rate that were deemed to be possibly related to MIN-101 by investigators. Generally, with the exception of cardiac events, which occurred in the MIN-101 subjects alone, similar adverse events were seen in the placebo group tested in this study, although at different rates. The safety results of the Phase IIa study supported the Phase I results observed in healthy volunteers described below, and will be further assessed in future clinical studies that explore the intended therapeutic dose and dosing schedule.

Phase I

MIN-101 was studied in five Phase I clinical trials in healthy volunteers and one Phase I clinical trial in subjects with schizophrenia conducted by MTPC prior to the company licensing this compound. These clinical trials primarily assessed the primary and secondary endpoints of safety, tolerability, and pharmacokinetics of MIN-101. One Phase I study also aimed to assess the preliminary efficacy of MIN-101, a secondary endpoint. Two studies also examined the pharmacodynamic profile of MIN-101. Overall, the safety and tolerability profile of MIN-101 in these Phase I studies was generally comparable to placebo and the results indicated that MIN-101 may not display many of the typical side effects of currently marketed first generation or atypical antipsychotics for both single and repeated administration. Adverse events experienced by subjects receiving MIN-101, included, but were not limited to dizziness, vital sign changes, central nervous symptom events, cardiac events, including QT/QTc prolongation, and gastrointestinal events. Additionally, one study was discontinued due to QT/QTc prolongation noted, especially in the higher dosage group, which contained three subjects receiving 48 mg of MIN-101 twice a day. Despite these adverse events, MIN-101 is not expected to pose a significant safety concern, as study subjects who experienced these adverse events received the study drug at different dosage levels and dosing schedules than will be used for therapeutic dosing.

In late 2014 we completed part 1 of a Phase I single-center, open-label trial to evaluate the safety, tolerability and pharmacokinetic profiles of several formulations of MIN-101 in a single dose administration setting. Plasma levels of parent compound MIN-101 as well as of the two main metabolites (BFB-520 and BFB-999) were assessed in 12 young healthy volunteers, who received three different formulations of MIN-101. Six adverse reactions of mild to moderate intensity were reported in five subjects: sleepiness (2); headache (3); and blurred vision (1). QTc measures stayed in the recommended values as given by ICH-E14 on Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs. The administration trial objectives were to develop a formulation of MIN-101 to allow for chronic daily administration by maintaining daily exposure of the compound and keeping the maximum plasma concentration (Cmax) and its two active metabolites (BFB-520 and BFB-999) below a level based on previous pharmacokinetic/pharmacodynamics analyses. The trial results show that the final formulation of MIN-101 lowers levels of BFB-520, which had been previously associated with prolongation of QT intervals at supra-therapeutic levels.

Pre-clinical

MIN-101 was explored in preclinical studies focused on safety, pharmacological profile and target activity. In terms of toxicology, six and nine month studies were completed in both rodent and non-rodent species, including monkeys. The results of the toxicological studies indicate that MIN-101 likely has an acceptable safety profile and a good safety margin at the expected therapeutic dose and dosing schedule and relative to other therapies currently used in patients with schizophrenia.

Development Strategy

We have initiated a Phase IIb clinical trial of MIN-101 in Europe with enrollment scheduled over the last three quarters of 2015. We expect this study to confirm the results of our Phase IIa trial and to form the basis for future pivotal studies. The trial will be conducted in stable subjects with schizophrenia suffering from predominantly negative symptoms. We intend to evaluate two doses of MIN-101 (32mg and 64mg) versus placebo, in a double-blind design in 234 subjects. The primary efficacy endpoint in this trial will be to evaluate the changes from baseline of negative symptoms after three months of drug administration, as measured from the baseline in PANSS. We plan to also investigate the effects on positive symptoms and overall symptoms of schizophrenia measured by PANSS and the Clinical Global Impression rating scales, as well as the effects of MIN-101 on sleep, cognition, anxiety and mood, and clinical and biological safety and drug plasma levels. Cognitive function, sleep, and improvement in function will be explored as well as secondary measures. Clinical and biological safety and pharmacokinetics will also be part of the study. Enrollment is expected to occur in the last three quarters of 2015. We anticipate topline results from this part of the study in the first half of 2016.

Patients improving their symptomatology during the first 3 months will be offered to enter into an extension phase of 6 months, which will provide additional long term safety and efficacy data. While we will initially be pursuing a first line monotherapy indication for MIN-101, we will also be studying the use of MIN-101 as an adjunctive therapy. During contemplated Phase III trials for MIN-101, we may also explore co-administration with atypical antipsychotics. In parallel to the phase IIb study, additional DDI (drug-drug interaction) studies will be performed, some CMC scale up work will be initiated and carcinogenicity studies will be started.

We believe there is also an opportunity which could be explored in future studies to use MIN-101 in neuropsychiatric diseases outside of schizophrenia, such as severe mood or neurodegenerative disorders.

MIN-117

MIN-117 is an innovative compound for the potential treatment of patients suffering from MDD, the most prominent subtype of depression. Patients suffering from MDD experience feelings of sadness, loss, anger or frustration that interfere with their ability to carry out and enjoy once-pleasurable activities. According to Datamonitor, there are currently 28 million cases of MDD in the United States and the five major European Union markets and MDD is one of the leading causes of disabling morbidity. The main cause of mortality linked to MDD is suicide, at a rate of 6%. While suicide is the leading cause of death in those with MDD, other factors, such as changes in immune function and susceptibility to disease, can also lead to early mortality.

We believe MIN-117 has the potential to address limitations of existing therapies, such as slow onset of action and poor safety and tolerability, without many of the typical side effects associated with currently approved therapies. The pharmacological effects of MIN-117 are related to serotonin and dopamine, two neurotransmitters in the brain. MIN-117 is meant to block a specific subtype of serotonin receptor called 5-HT1A. When 5-HT1A is blocked, anxiety and mood can be regulated. In addition, MIN-117 is meant to prevent the reuptake of serotonin and dopamine, which increases the amount of serotonin and dopamine in the brain, which is tied to an improvement in mood in individuals suffering from MDD. MIN-117 is also meant to modulate the levels of Alpha-1a and 1b, which further modulates serotonin and dopamine.

Two Phase I clinical trials of MIN-117 in healthy volunteers were completed in 2005 by MTPC and 2009 by Sonkei. These Phase I clinical trials demonstrated potentially positive safety and tolerability results. Since a drug's impact on sleep parameters may be a biomarker for MDD and potential MDD drug efficacy, the preliminary sleep findings from one Phase I study suggest that MIN-117 may show efficacy in treating MDD in later clinical trials. It is not yet known, however, whether the MIN-117 results found in healthy volunteers will translate to the MDD patient population.

Based upon these studies and other pre-clinical studies, we believe MIN-117 will demonstrate a safety profile comparable to placebo without many of the typical side effects of current MDD treatments, including cognitive impairment, sexual dysfunction, sleep disorders and weight gain. As part of our license agreement with MTPC, we may develop, sell, and import products related to the MIN-117 compound globally, excluding most of Asia. In the second quarter of 2015, we plan to initiate a Phase IIa clinical trial in Europe in 60 subjects with MDD to examine therapeutic doses comparing MIN-117 to Paroxetine and placebo over six weeks of treatment. Endpoints for the study will include Hamilton Depression Rating Scale or HAMD (2 and 6 weeks), cognition, sexual function, and sleep.

Background of the Disease

Depression is a complex disease encompassing multiple subtypes that include MDD, dysthymic disorder, psychotic depression, postpartum depression and seasonal affective disorder. MDD is the most prominent subtype of depression and the following symptoms are typically associated with MDD:

- Depressed Mood. People suffering from MDD typically have depressed spirit or mood, known as dysphoria, which can be worse in the morning, reduced energy and decreased activity level, as well as loss of libido. Lowered mood may vary little from day to day.
- Reduced Concentration and Overall Tiredness. People suffering from MDD also have a reduced capacity for enjoyment and their interest level in life and general concentration is reduced. In addition, these individuals can experience marked tiredness after minimal effort. MDD may be accompanied by so-called "somatic" symptoms, such as loss of interest in pleasurable feelings, or anhedonia, and early morning walking.
- Sleep Disturbance and Diminished Appetites. People suffering from MDD may also experience sleep disturbances, which is the difficulty falling or staying asleep, and they may also experience a diminished appetite, which can result in weight loss.

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Lowered Self-Esteem. People suffering from MDD may also experience a lowered self-esteem and reduced self-confidence. Ideas of guilt and worthlessness are often present.

While the exact cause of MDD is unknown, there are psychological, biological, genetic and environmental factors that contribute to its onset. Biologically, monoamines serotonin, or 5-HT, norepinephrine, and dopamine are three of the main neurotransmitters thought to be involved in MDD. When there is a chemical imbalance in these neurotransmitters, depression is likely to develop. The identification of these and other neurotransmitters linked to the development of MDD has been the focus for the development of a drug therapy to treat the symptoms of MDD.

MDD affects millions of people and causes significant morbidity and loss of productivity. According to Datamonitor, it is estimated that up to 30% of people will experience an episode of MDD at some point in their life in the United States and the five major European Union markets. However, due to lack of acknowledgement of symptoms and the stigma of mental illness, Datamonitor estimates that only around a quarter of prevalent cases are eventually diagnosed by a physician as MDD. MDD is one of the most common conditions leading to occupational disability in the United States and the five major European Union markets.

According to Datamonitor, it is estimated that sales of drugs for depression totaled $4.6 billion across the United States and the five major European Union markets in 2014. With a number of popular antidepressant drugs becoming generic over the next few years, the overall value of the antidepressant market is forecast to shrink slightly in the short term.

The market for first-line treatment is crowded, well-established and inexpensive due to the prevalence of generics. However, because of the high number of patients who do not respond to first-line treatment, who are known as partial responders or non-responders, we believe an antidepressant targeted for second-line treatment or in combination with additional therapies may potentially achieve high sales. The exact MDD indication that we will seek will be determined based on the results of future MIN-117 studies.

Current Treatment Options and Limitations of Therapy

There are many therapies currently approved for the treatment of MDD. However, we believe that existing therapies do not meet all needs of the MDD patient population and a large number of patients fail to respond or only partially respond to treatment. Further, some current treatment options take up to four weeks to have a noticeable effect, which can expose patients to a period of vulnerability during which they are at most risk of committing suicide. In addition, current available therapies have several side effects, including cognitive impairment, sexual dysfunction, sleep disorders and weight gain, that lead many patients to discontinue therapy and, if therapy is resumed, at the original therapeutic doses efficacy is generally reduced.

Treatment of MDD is based on severity of the patient’s symptoms, the availability of both pharmacological and non-pharmacological therapies, patient preference and contraindications, instructive guidelines and physician experience. Examples of non-pharmacological approaches for depression include cognitive behavioral therapy and interpersonal therapy, exercise, and neurostimulatory interventions for severe, treatment-resistant depression. Pharmacological treatment is the mainstay of treatment for depression in the United States and the five major European Union markets. According to a Datamonitor physician survey, on average 88.5% of diagnosed patients receive drug therapy, either as the sole therapy or in combination with non-drug intervention.

The first generation of antidepressants includes mainly MonoAmineOxydose-Inhibitors, or MAOIs, and Tricyclic molecules. MAOIs are effective because they are active on most of the neurotransmitter systems involved in mood disorders, but have many unwanted side effects, so they are not broadly used. The most severe side effect associated with MAOIs is the cardiovascular impact and severe blood pressure variations requiring strict diet regulation. Tricyclic molecules are effective because they also have a large spectrum of effects on several neurotransmitters. However, this broad activity causes severe side effects, such as sedation, weight gain and autonomic nervous system dysregulation, like hypotension, dry mouth, and glaucoma. These unwanted side effects prevent these molecules from being used as a first line therapy and today are only used in severe and resistant patients not adequately responding to current therapies like selective serotonin reuptake inhibitors, or SSRIs, or serotonin-norepinephrine reuptake inhibitors, or SNRIs.

Currently, the most prescribed antidepressants are SSRIs and SNRIs. The SSRIs generally function by blocking the reuptake of serotonin. Depending on the degree of SSRIs’ effect on other neurotransmitter systems, SSRIs may lead to varying levels of weight gain and impairment of cognitive skills and sexual function. SNRIs have an effect on noradrenegic neurotransmitter systems in addition to the effect on serotonin reuptake. This added pharmacological

activity improves the efficacy over SSRIs but doesn't improve their safety and tolerability profile. In some cases, the SNRIs have a worse safety and tolerability profile compared to SSRIs, in particular with respect to cardiovascular side effects. In addition, SSRIs and SNRIs are effective in only a part of the MDD patient population.

The severe side effects of first generation and current commonly prescribed anti-depressants can result in patients not continuing with their drug therapy. Once a patient has discontinued treatment, a subsequent course of treatment will generally have less efficacy in terms of relieving depression and improving mood.

Overall, less than half of patients receiving first-line drug treatment for depression enter into remission. According to Datamonitor, of those that do achieve remission, approximately 30% to 50% will later relapse while taking medication, indicating that the effect is often not sustained. Over one-third of patients fail to respond to two or more successive lines of antidepressant therapy. These patients are defined as having treatment-resistant major depression, or TRMD, and often require treatment with several antidepressants, such as an SSRI or SNRI, combined with an "adjunct" therapy such as an antipsychotic or mood stabilizer. These antipsychotic compounds, such as Seroquel (quetiapine) and Abilify (aripiprazole), and mood stabilizers, such as Topimax (topiramate), cause some slight improvements in efficacy but often have unacceptable side effects, including motor symptoms, sedation, lack of concentration, and weight gain.

In addition to the side effects described above, these antidepressants generally do not begin to take effect until a few weeks after initiating treatment, with no noticeable improvement before four weeks. It is during this lag period that the risk of suicide can in fact be higher than prior to initiation of therapy. Further, starting doses must be slowly scaled up over a period of time before a standard therapeutic dose can be taken. While ketamine and related compounds are now being used to address this slow onset of action, the long term efficacy and safety of this approach has not been confirmed. Ketamine is also not appropriate for chronic therapy due to the risk of hallucinations and delusions, as well as its potential for abuse.

Key Differentiating Attributes of MIN-117

MIN-117 acts through multiple mechanisms on several receptors associated with mood and the control of mood including SSRI, 5-HT1A auto-receptor and dopamine transporter, or DAT, and alpha-1A and B modulation.

We believe that existing therapies do not meet all needs of the MDD patient population and a large number of patients fail to respond or only partially respond to treatment. In addition, some current treatment options take up to four weeks to have a noticeable effect, which can expose patients to a period of vulnerability during which they are at most risk of committing suicide. Further, current available therapies have several side effects, including cognitive impairment, sexual dysfunction, sleep disorders and weight gain, that lead many patients to discontinue therapy and, if therapy is resumed, efficacy is generally reduced.

Based on the clinical and pre-clinical data described below, we believe that MIN-117 has a number of potential advantages over currently available therapies:

- Potential Faster Response Rate. Unlike existing therapies, which can take weeks before a patient begins to notice an improvement in symptoms, MIN-117 generated a reduction in modeled symptoms within a few days of treatment in pre-clinical studies involving animal models. Future studies of MIN-117 will determine whether a rapid response is experienced by human subjects.
- Avoids Side Effects Associated with Existing Therapies. Based upon Phase I and pre-clinical studies, we believe that MIN-101 will not display many of the typical side effects of existing therapies, including cognitive impairment, sexual dysfunction, sleep disorders and weight gain.
- Safety and Tolerability Profile. Based upon Phase I clinical trials in healthy volunteers at higher doses, we believe that MIN-117 will demonstrate a safety and tolerability profile comparable to placebo at the anticipated therapeutic doses, which will be explored in future studies.
- Low Starting Dose. Based upon pre-clinical studies, MIN-117 is expected to be effective at a low starting dose, which may eliminate the need to gradually move to a therapeutic dose and would be suitable for chronic use.
- Pharmacological Profile to Benefit Non- or Partial-Responders. Because MIN-117 acts through multiple mechanisms of action on several receptors associated with mood, we believe it could benefit non- or partial-responders, unlike current treatment options that do not target the same wide range of receptors.

Due to both its potential efficacy to treat MDD and its safety and tolerability profile, we believe that MIN-117 will be a promising treatment for patients suffering from MDD.

Clinical and Pre-clinical Experience

Phase I

Prior to being licensed by us, elevated doses of MIN-117 were evaluated by MTPC and Sonkei in two Phase I clinical pharmacology studies in healthy volunteers. The primary endpoint of these studies was to assess the safety and tolerability of MIN-117. The studies explored safety, the processing of the compound by the body, known as pharmacokinetics, or PK, and the effect of the compound on the body, known as pharmacodynamics, or PD, at doses above the anticipated therapeutic doses as secondary endpoints.

As part of the PD analysis, one study assessed the impact of MIN-117 on sleep as measured by PSG and the Leeds Sleep Evaluation Questionnaire. This study also explored the impact of MIN-117 on mood, as measured by the Profile of Mood Disorders, emotion, as measured by the Emotional Visual Analogue Scale, and cognitive function as measured by the Flanker/EEG task, which were other endpoints assessed in the study. 50 subjects were randomized in this study, of which 47 completed the study per the protocol. Because this was a Phase I study that primarily examined drug safety and tolerability, the study was not powered for statistical significance. Nevertheless, calculations of statistical significance were performed on some biomarkers exploring pharmacodynamic effects of MIN-117. Some statistically significant results were found when making these calculations. Based upon a PSG analysis, statistically

significant improvements, compared to placebo, were found in the density of ocular movements during REM sleep (at the 3 and 7.5 mg dose) as well as the number of ocular movements during rapid eye movement, or REM, sleep (at the 7.5 mg dose). This ocular activity in REM sleep may be a potential biomarker for MDD drug efficacy. While these results do not provide evidence of MIN-117 efficacy nor would they be the basis for a potential regulatory approval, these results suggest that further investigation is warranted to determine whether MIN-117 at the therapeutic doses promotes REM sleep and impact REM density and activity with repeated dosing. These results will help define hypotheses for our future efficacy studies carried out in subjects with MDD. This study further found that MIN-117 did not have a negative impact on mood, emotion, cognitive function and sleep in healthy volunteers. While these results may indicate a potential drug effect, because this study was conducted in healthy volunteers, it is not yet known whether these results will also be found in the patient population. It is also not known whether these results will be seen in larger, adequately powered clinical trials.

In addition, based upon the Phase I studies, as well as the pre-clinical studies discussed below, we believe that MIN-117 will display a safety and tolerability profile at anticipated therapeutic dose levels that does not include many of the typical side effects experienced by patients taking existing MDD pharmacologic therapies, including cognitive impairment, sexual dysfunction, sleep disorders and weight gain. While adverse events, such as nervous system and gastrointestinal events, did occur in subjects, the incidence of the observed adverse events, even at the highest doses of MIN-117 explored in these trials, was generally comparable to placebo and, in one trial, escitalopram, an antidepressant that was given as a control, had a higher incidence of certain adverse events. We plan to study the effect of the intended therapeutic doses in future studies. PK parameters also indicated that once a day administration may be possible. Further evaluation in MDD subjects is needed to confirm the potential therapeutic effect of MIN-117.

Pre-clinical

Extensive pre-clinical explorations of MIN-117 were conducted by MTPC. In terms of safety and toxicology, three-month toxicological studies were completed in rodents and non-rodents. These explorations showed the potential for a good safety and tolerability profile for MIN-117 at the intended therapeutic doses.

During pre-clinical evaluation of MIN-117 as an antidepressant drug, a number of behavioral tests simulating mood disorders were conducted on rodents. All tests carried out suggested that MIN-117 has beneficial effects on mood. In a mild chronic stress model, which simulated depression and measured the degree to which an animal is chronically stressed by reference to its reduction in sucrose intake, animals that were more stressed typically exhibited lower levels of sucrose intake. Very low doses of MIN-117 reversed the suppression of sucrose intake by animals and by implication removed the level of stress experienced by the animal.

Development Strategy

In the second quarter of 2015, we plan to begin enrolling a Phase IIa clinical trial in Europe in 60 subjects with MDD, comparing MIN-117 to Paroxetine and placebo over six weeks of treatment. Endpoints for the study will include HAMD (2 and 6 weeks), cognition, sexual function, and sleep. The study will be a randomized, double-blind, parallel group, placebo and active controlled study to evaluate the efficacy and safety of the molecule at a 0.5 mg daily dose in adult subjects with MDD. Patients with a minimum score of depression of 30 points assessed via the Montgomery-Asberg Depression Rating Scale, or MADRS, will be enrolled in the trial. The control molecule will be 20mg of Paroxetine, a dose that has shown in previous trials to be efficacious improving depressive symptoms in MDD patients suffering from a major depressive episode. The primary endpoint will be the efficacy of MIN-117 versus placebo in reducing the depressive symptoms measured by the change from baseline using MADRS, total score over 6 weeks of treatment. The main secondary endpoints are the efficacy of MIN-117 versus placebo in onset of antidepressant response as measured by the change from Baseline in MADRS total score over 2 weeks of treatment. In addition, we will also evaluate global change from baseline versus placebo in severity of illness and improvement using the Clinical Global Impression of Severity Scale and Clinical Global Impression of Improvement Scale, or

CGI S and CGI-I, over 6 weeks of treatment. The secondary endpoints include the evaluation of MIN-117 versus placebo and paroxetine on sexual functioning using the Arizona Sexual Experiences Scale, or A-SEX, on cognition (a battery of exploring several cognitive dimensions) and on objective (Polysomnography and V-Watch) and subjective sleep measures (PSQI, or Pittsburg Sleep Quality Index). Safety, tolerability and plasma levels will be evaluated, as well as other exploratory biomarkers such as heart rate variability, stress hormones (particularly cortisol), trophic factors (particularly brain-derived neurotrophic factor, or BDNF), inflammation factors (particularly TNF- , IL-1 , and IL-6) and some receptor polymorphisms, particularly 5-HTTLPR (serotonin-transporter-linked polymorphic region) and SSRI (selective serotonin reuptake inhibitors) response. The primary analysis will be carried out using a mixed model repeated measures, or MMRM, with treatment, time and time*treatment interaction and pooled investigational centers as fixed effect, with Baseline MADRS total score as covariate. An unstructured variance-covariance matrix will be used. In this analysis in which the MMRM is fitted to all post-Baseline data, subjects in the intent-to-treat, or ITT, analysis set who do not have complete data will still contribute to the estimates at Week 6, but will have less weight in the analysis than those subjects with complete data. Estimates for changes from Baseline at each time-point in each treatment group and for treatment difference will be provided with 95% confidence intervals and p-values using appropriate contrasts from the model.

MIN-202

MIN-202 is an innovative selective orexin 2 receptor antagonist we are currently developing in collaboration with Janssen for the treatment of insomnia. Insomnia is the repeated difficulty with sleep initiation, maintenance or quality that occurs despite adequate time and opportunity for sleep and results in some sort of daytime impairment. Insomnia can be the primary condition for patients or a secondary symptom of another medical or psychiatric condition, such as MDD or schizophrenia. We intend to evaluate MIN-202 as a treatment in primary insomnia, as well as in comorbid insomnia as an adjunctive therapy with an antidepressant for the treatment of mood disorders. According to Datamonitor, approximately one-third of adults globally experienced difficulty in falling or staying asleep during the past year.

In the brain, the orexin system is involved in the control of several key functions, including metabolism and wakefulness. MIN-202 seeks to inhibit the activity of the neurons that promote wakefulness by selectively blocking the orexin 2 receptor. Rather than making an individual sleepier, blocking the orexin 2 receptor reduces the level of the neurotransmitters that signal the brain to maintain vigilance and wakefulness, which can be helpful for patients with insomnia.

We are co-developing MIN-202 with Janssen and own the exclusive rights to develop and commercialize the compound in the European Union subject to royalty payments to Janssen and have the right to receive royalties on any sales outside the European Union. Janssen completed a Phase I single ascending dose study of MIN-202 in 2011 that suggested a relationship which supports a rapid induction and promotion of sleepiness.

Two Phase Ib clinical trials of a suspension formulation of MIN-202 in Europe were recently completed by Janssen and a bioavailability, food effect, safety and tolerability of a solid dosage formulation of MIN-202 was also recently completed by Janssen in the United States. Overall, these clinical studies confirm the pharmacological effect of MIN-202 that was observed in preclinical experiments. A safe and efficacious dose range has been identified with good safety margins relative to the No-observed-adverse-effect-level or NOAEL in 1-month good laboratory practice (GLP) toxicology experiments and the drug has been well-tolerated in all trials. Janssen also completed a single ascending dose study for MIN-202 in 2011 that suggested a relationship which supports a rapid induction and promotion of sleepiness.

Background of the Disease

Insomnia is defined as repeated difficulty with sleep initiation, maintenance or quality that occurs despite adequate time and opportunity for sleep and results in some sort of daytime impairment. Specific criteria vary, but common ones include taking longer than 30 minutes to fall asleep, staying asleep for less than six hours, waking more than three times a night, or experiencing sleep that is chronically non-restorative or poor in quality. Chronic insomnia, lasting more than one month, can be associated with impaired occupational and social performance, high absenteeism and higher healthcare use. It can also be a risk factor for depression, anxiety, alcohol addiction, substance abuse and suicide.

There are two main processes that regulate sleep and wakefulness: the circadian system, related to the 24 hour clock, and the homeostatic system, related to how long a person has been awake before going to sleep. Both systems involve a complex interplay between neurons that produce wakefulness-inducing neurotransmitters and sleep-promoting neurotransmitters. Light hitting the retina activates neurons, which initiates a chain of signals culminating in the activation of orexin producing neurons (involved in maintaining wakefulness), as well as the inhibition of the sleep-promoting hormone melatonin.

Recent research shows that the orexin system affects the secretion and control of stress hormones like the ones involved in the hypothalamic-pituitary-adrenal or HPA axis (e.g., adrenocorticotropic hormone and cortisol). The HPA axis is known to be overactive in depressed patients and, in addition, a significant proportion of depressed

patients suffer from insomnia. As a consequence, there is a strong rationale to explore the usefulness of orexin antagonists in comorbid insomnia, particularly in cases of depression.

Current Treatment Options and Limitations of Therapy

Depending on the individual and the underlying cause of insomnia, patients are treated using non-pharmacological methods, such as cognitive behavioral therapy, or with drug therapy.

Until recently, most of the pharmaceuticals on the market targeted neurotransmitter pathways involved in depressing the brain activity, such as the histamine and gamma-aminobutyric acid, or GABA, pathways, to induce a decrease in vigilance and attention, leading to sedation and sleep induction. GABA pathways are currently preferred to histamine pathways as the target pathway of pharmaceuticals because they have a more efficient effect on sleep and fewer side effects.

Several pharmacological tools have been used to affect GABA pathways in the brain to induce sedation. Barbiturates were initially used and showed good efficacy but had major side effects, such as daytime sleepiness and interaction with other drugs leading to, for example, liver damage. Until recently, benzodiazepines have been used extensively. These molecules have both anti-anxiety and sleep

inducing effects, but, again, show serious side effects. Benzodiazepines cause severe memory impairments and require a constant dosage increase in order to maintain efficacy. This dosage increase intensifies side effects and, as such, this class of drugs is generally not appropriate for chronic use, in particular with at-risk patient populations. The third generation of drugs affecting GABA pathways target the sedative effect of GABAergic drugs. The leading molecule among this third generation of molecules is zolpidem, often marketed under the name Ambien. The use of this drug over about the past two decades shows less severe side effects than those seen with the benzodiazepines, but still requires careful utilization to avoid tolerance and drug abuse. Finally, extensive sleep studies have demonstrated that zolpidem does not restore physiological sleep and does not allow restorative sleep, which prevents good daytime performance.

The major drawbacks of current insomnia medication are that immediate onset therapies taken at bedtime can interfere with natural sleep onset and slow wave sleep and patients can experience residual effects the following day, such as daytime sedation and cognitive impairment, particularly following middle of the night administration.

Drug development has shifted from activating sleep-promoting neurotransmitters to inhibiting wakefulness-promoting neurotransmitters such as orexin. The first orexin inhibitors developed antagonize both orexin 1 and orexin 2 sub-types of orexin receptors, which are known as dual orexin receptor antagonists, or DORAs. In August 2014, Merck & Co.'s DORA suvorexant was approved by the FDA, and is currently marketed under the name Belsomra®. The clinical data demonstrated that orexin antagonists have a number of differentiating factors as compared to GABAergic drugs:

- patients do not become tolerant over time;
- there is no psychomotor impairment;
- there is better safety and tolerability;
- there is no interaction with alcohol; and
- there is no 'rebound' of symptoms (to worse than baseline) once the therapy is stopped.

Nevertheless, DORAs induce some side effects due to their inhibition of orexin 1 pathways. These side effects are related to motor control and to rapid eye movement, or REM, sleep and thus can induce night walking, vivid dreams or nightmares.

Key Differentiating Attributes of MIN-202

We believe that a key differentiating factor for a new insomnia drug for primary and comorbid insomnia would be the preservation or restoration of sleep physiology, particularly preservation of REM sleep and restoration of deep sleep. The restoration of physiological sleep should occur without residual daytime functioning side effects, particularly preserved cognition and no daytime sedation or psychomotor impairment.

MIN-202 is among the most advanced molecules to treat insomnia, and is known as a selective orexin receptor antagonist, or SORA, that targets orexin 2 pathways only. In addition to potentially having better efficacy and safety as compared to current drug therapies, such as GABAergic drugs, we believe that MIN-202, a SORA, could have a number of differentiating factors as compared to DORAs:

- equal or superior efficacy, as only the orexin 2 pathway is required to be blocked in order to induce and maintain sleep, and the orexin 1 receptors counteract orexin 2 pathway blockades;
- less residual sedation and impaired daytime functioning; and
- preservation of appropriate levels of REM sleep, as initial studies indicate that DORAs increase REM sleep in animals and humans. The effects produced by DORAs on REM sleep explain the motor effects and other side effects seen with suvorexant.

Clinical and Pre-clinical Experience

Phase I

A single ascending dose trial of MIN-202 was carried out by Janssen in young healthy males in 2011. Fifty-seven (57) subjects were enrolled in the trial, and received at least one dose of medication, and were included in the PD and safety analyses. 38 actively treated subjects were included in the PK analysis. The objectives of the study were to investigate the safety, tolerability, pharmacokinetics and maximum tolerated dose of MIN-202. The safety and tolerability profile of the drug was good. In terms of PK characteristics, the time to maximum concentration was reached in 30 minutes and some sedative effects of the drug lasted from four to six hours and the effects were demonstrated to be dose dependent. The PK and PD parameters enabled sleep induction and sleep maintenance without major impairment of daytime performance.

Janssen also investigated the effect of MIN-202 in this Phase I clinical trial, measuring alertness using the Stanford Sleepiness Scale, or SSS, which ranges from 1 (alert) to 7 (sleep onset imminent). The observed effects of the drug showed that as the dose of MIN-202 was increased, there was a dose-proportionate increase in the sedation levels of subjects as measured by the SSS.

In January 2015, we announced results from a double-blind, placebo-controlled, randomized, 4-way crossover single dose study with MIN-202 in 20 male and female subjects with MDD and insomnia completed by Janssen in Europe. The primary endpoint in this study was the effect of MIN-202 (dosed PM) on latency to persistent sleep, LPS. Certain additional endpoints were evaluated by polysomnography or PSG. Preliminary results demonstrated a statistically significant effect on LPS of all three doses tested (10, 20, and 40mg). Treatment with MIN-202 also resulted in prolonged total sleep duration by approximately 45 minutes. This study was performed using a suspension formulation. MIN-202 was found to be safe and well-tolerated in this study.

In January 2015, we also announced results from a double-blind, placebo-controlled, randomized, multiple ascending dose study in sequential cohorts of male and female healthy subjects completed by Janssen in Europe. MIN-202 was administered in the morning at dose levels ranging from 5mg to 60mg for 10 days. A dose level as low as 5mg of MIN-202 elicits sedation while dose levels ≥ 20mg induce (daytime) somnolence. The MIN-202 plasma exposure is dose proportional from 5- to 20mg. At higher doses, the exposure is less than dose proportional. This study was performed using a suspension formulation and MIN-202 was found to be safe and well-tolerated. Pharmacodynamic assessments were incorporated into the clinical study to evaluate the effect of MIN-202 on alertness via PK/PD modeling.

Janssen also recently completed a bioavailability, food effects, safety and tolerability of a solid dosage formulation of MIN-202 in the United States in healthy male subjects. To support planned Phase Ib and Phase II activities, a solid dose formulation has been evaluated. The results of the study showed that similar absorption profiles were observed for both formulations thereby qualifying the solid dose to support further clinical experiments.

Overall, clinical studies performed over the last years confirm the pharmacological effect of MIN-202 that was observed in preclinical experiments. A safe, well-tolerated and efficacious dose range has been identified with good safety margins relative to the NOAEL in 1-month GLP toxicology experiments.

Pre-clinical

Janssen conducted extensive pre-clinical testing on MIN-202. A one-month toxicological study was conducted in rodents evaluating biological and clinical aspects and demonstrated a good safety profile.

Extensive testing was done in animals to explore the impact on sleep and wake cycles of several doses of MIN-202. The data from these studies suggests that MIN-202 acts in the manner desired by reducing the time to achieve deep

non-REM sleep and increasing the duration of non-REM sleep without increasing or impairing REM sleep. MIN-202 had no significant impact on REM sleep. We believe this supports our belief that MIN-202 will result in a restorative sleep pattern.

Development Strategy

We expect to initiate two additional studies in mid-2015. The first is a Phase IIa study in primary insomnia, and the second is a Phase Ib study in patients with MDD with comorbid insomnia.

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. 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 uses an Escherichia coli organism to produce neuregulin-1b1, a 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 GABA and glutamate in the brain, which are often unbalanced in individuals with Parkinson's disease. Further, ErbB4 promotes oxygenation and metabolism of neurons, which could indicate MIN-301 could reverse the damage caused by Parkinson's disease.

Parkinson's disease is a progressive and incurable disease that leads to disability and lower quality of life. According to Datamonitor, there were nearly 700,000 cases in the United States in 2014, and Parkinson's disease was identified as the 14th leading cause of death by the Centers for Disease Control and Prevention in 2011. 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.

In January 2015 we announced results from a non-human primate study showing 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 preclinical models. Currently, we are conducting material scale-up for Investigational Medicinal Product Dossier, or IMPD, or Investigational New Drug, or IND, application enabling studies of MIN-301 expected to be completed during the first half of 2016, with a Phase I study expected to commence in the second half of 2016.

Background of the Disease

Parkinson's disease is caused by the death of dopamine-generating cells in the brain and is a progressive and incurable disease that leads to disability and lower quality of life. It is the second most common neurologic disease after Alzheimer's disease. According to Datamonitor, prevalence of this disease rises from 1% of the population in patients over 60 years of age to 4% of the population over 80 years of age.

There is a lack of a reliable diagnostic test for Parkinson's disease, which affects both the ability to diagnose early stages of the disease and establish an explicit prevalence rate. According to the World Health Organization, patients meet the clinical diagnosis for Parkinson's disease when they exhibit two of the four cardinal features of the disease. These are:

- bradykinesia or slowness of movement;
- rigidity or stiffness of the limbs and trunk;
- tremor of the hands, arms, legs, jaw and face; and
- postural instability or impaired balance and coordination.

Early-stage patients are estimated to constitute approximately 35% to 42% of all cases, and are often undiagnosed and untreated. Age is the largest risk factor for Parkinson's, though a genetic predisposition is strong in patients under 50. One third of patients develop dementia during later stages of the disease and patients with Parkinson's have a shorter life expectancy than that of the general population. According to Decision Resources, there was $2.3 billion in drug sales related to Parkinson's disease in the United States, Japan and five major European Union markets 2012.

Current Treatment Options and Limitations of Therapy

Current treatments for Parkinson’s improve the symptoms of patients, but, at this time, none have been proven to slow or prevent the progression of the disease or reverse its effects. The goal of existing therapies is essentially to reduce symptoms, balanced against the side effects of treatment as the disease progresses, rather than slowing down or reversing the course of the disease. Approved drug treatment options fall into five broad categories: levodopa and dopaminergics, COMT-Inhibitors, dopamine agonists, Monoamine Oxidase B, or MAO-B, Inhibitors and anticholinergics.

The cornerstone of Parkinson's therapy is levodopa, as it is the most effective therapy for reducing symptoms of Parkinson's disease. Levodopa is a precursor to dopamine that can cross the blood-brain barrier and be converted to dopamine, thus addressing the key deficiency in the disease. While it is the 'gold standard' of therapy in Parkinson's, as an oral therapy it needs to be delivered in large doses, which cause unpleasant systemic side effects such as involuntary movements called dyskinesias. To manage these side effects, dopaminergics such as dopa-decarboxylase inhibitors, or DDI, have been formulated to increase the effect of levodopa while maintaining a constant dose. They are available as controlled-release systems (Sinemet CR, Madopar HBS), oral tablets (Parcopa) and gel (Duodopa). Levodopa and dopaminergics have a high initial response rate; patients will commonly experience a satisfactory response to levodopa during the first one to five years of treatment. As this initial therapeutic response window closes, symptoms become increasingly difficult to control, they experience a pattern of motor complications that include motor fluctuations, dyskinesias, off-period dystonia, freezing and falls. While levodopa and dopaminergics are highly effective, there are advantages to deferring their use to later stages of the disease, or using them with complementary classes of therapy to reduce the side effects of motor fluctuations and dyskinesia that 50% of levodopa patients experience.

Complementary therapies such as the COMT (Catechol-O-methyltransferase)-Inhibitors extend the clinical benefit of levodopa, but offer no benefit on their own. Comtan, Tasmar and Stalevo are three examples, but are used more frequently in second-line therapy.

Dopamine agonists can be used as first-line monotherapy or in combination with levodopa. They directly stimulate dopamine receptors and are able to compensate for low dopamine levels associated with Parkinson's. Leading products are available in patch (Neupro) and self-injection (Apokyn) formulation. Serious side effect of this class are the development of impulse-control disorders and psychotic effects, such as hallucinations and delusions.

MAO-B Inhibitors may also be used as monotherapy in early stages of treatment or adjunct therapy for motor fluctuations. Leading products include Eldepryl, Azilect and Zelapar. The main side effect of such an approach is an increase in blood pressure necessitating strict dietetic control.

Anticholinergics are primarily used in younger Parkinson's patients for controlling tremors and may be used as first-line monotherapy or adjunct therapy. They are not recommended for patients older than 60 because they impair patient cognition.

Key Differentiating Attributes of MIN-301

Because current treatments do not delay or change the course of the disease, there is an unmet need in Parkinson's disease for disease modifying treatment.

MIN-301 is a recombinant protein comprised of the extracellular domain of NRG-1b1. The NRG-1b1 protein is involved in brain maturation and offers an alternative mechanism of action for the treatment of Parkinson's disease. This protein demonstrates activation of the ErbB4 target in brain tissues, offering not only cognitive improvement but also both neuroprotective and neurorestorative effects. By offering functional improvement without direct dopaminergic effects, MIN-301 represents an opportunity to improve cognitive function without the side effects observed with existing therapies. MIN-301 demonstrated activity in both 6-OH-dopamine and 1-methyl-4-phenyl-1, 2, 3, 6 tetrahydropyridine, or MPTP, animal models of Parkinson's disease, each of which induce Parkinson's-like syndromes and are among the key models to be applied in pre-clinical explorations.

Because MIN-301 offers a novel mechanism of action that targets neurological deficits, we believe that it has the potential, if approved for marketing, to be used not only as an early-stage monotherapy, but also as either a monotherapy or a complementary therapy to existing treatments in later stages of the disease.

Pre-clinical Experience

Prior to our acquisition of Mind-NRG, Mind-NRG explored MIN-301 in pre-clinical safety studies in non-primate models of Parkinson's disease and in experiments focusing on its mechanism of action and its brain penetration capabilities. In terms of safety, a preliminary one-month toxicological study has been performed with a dose 50 times higher than the expected therapeutic dose. The results of these studies showed a good safety profile.

In behavioral and functional animal models of Parkinson's disease using a rotarod treadmill as a functional read out, 6-OH-dopamine and MPTP were used to induce Parkinson's disease-like symptoms. A faster rod speed means that the animal has better coordination and endurance. The rod speed is documented by the time when the animal fell from the treadmill. An animal with poor coordination will not be able to tolerate increased speeds and will fall at a lower rod speed than an animal with normal coordination. Animals that had Parkinson's disease-like symptoms induced with MPTP but which were also treated with MIN-301 had increased rod speeds, as measured by the mean revolutions per minute, as compared to animals that did not receive MIN-301. These increased rod speeds were comparable to the control animals. The observed improvements seen in the MPTP model have also been observed in the 6-OH-dopamine model, another common model for Parkinson's disease. This suggests that MIN-301 may be able to provide relief from

Parkinson’s disease-like symptoms related to coordination. In animal models, improvement in cognition and attention was also evident following administration of MIN-301.

Primate model with MIN-301 analog

In a pre-clinical study conducted during 2014, Parkinson’s disease symptoms were induced in marmosets by a standard protocol using subcutaneous injections of MPTP neurotoxin. Daily treatment with either the analog or saline vehicle was initiated one week prior to Parkinson’s induction with MPTP and continued for eight weeks. In both treatment groups, disease-modifying efficacy was measured as it related to changes in clinical signs, motor symptoms and motor function. Clinical signs were scored on a semi-quantitative scale of clinical Parkinsonian symptoms. Motor symptoms were assessed using the abnormal involuntary movements scale, or AIMS, which includes assessment of extremity and trunk movements, facial expressions, movements of the lips, peri-oral area, tongue and jaw. Motor function was evaluated using the Bungalow test, which records the number of compartment changes as a measure of locomotor activity.

Subjects treated with a daily subcutaneous injection of the MIN-301 analog showed greater improvements in Parkinsonian clinical score, AIMS and locomotor activity (Bungalow test) compared to vehicle. The strongest improvements in the analog-treated population were obtained during periods of slower disease progression. Previous research in rodent models of Parkinson’s disease have shown that MIN-301 has the potential to restore motor function in Parkinson's patients. Results from this study involving an analog of MIN-301 were consistent with these previous results.

Neuregulins play key roles in myelination, neuronal integrity and cognition-related signaling. Neuregulin-1 has been shown to have neurotrophic and neuroprotective effects on dopaminergic neurons. A number of studies have also demonstrated the association of neuregulin-1 with brain pathologies including schizophrenia, Alzheimer’s disease and Parkinson’s disease. These features, combined with the ability to cross the blood-brain barrier, make neuregulin-1 and its variants attractive for therapeutic purposes in Parkinson’s.

In previous research both the analog and MIN-301 have been found to have the same level of activity in vitro in phosphorylation of ErbB3 receptors. Research involving multiple preclinical models mimicking Parkinson’s symptoms has been carried out with MIN-301. The non-human primate MPTP model used in the Primomed study is the only animal model of early Parkinson’s that recapitulates the progressive development of symptoms alongside progressive neurodegeneration.

We are able to conclude from this study that treatment with an analog of MIN-301 resulted in improvements in a range of symptoms associated with Parkinson’s disease in primates.

Development Strategy

The mechanism of action of MIN-301 is still under further investigation, but we believe our protein has important characteristics, such as effects on oxidative stress reversal, effects on cell metabolism particularly adenosine triphosphate, or ATP, and effects on GABA and glutamate. Taken together, we believe the effects described above could protect dopaminergic neurons, which is a key element in the cause of Parkinson’s disease, and possibly on other sub-types of neurons and other brain cells such as gilial cells. This indicates that MIN-301 may have a novel neuro-protecting and neuro-restorative profile. In view of this MIN-301 mechanism of action and based on a number of other studies performed by other research labs on neuregulin, we believe several other indications of the molecule may be pursued, such as for Alzheimer’s disease and other neuro-degenerative disorders, such as multiple sclerosis, and for other psychological disorders, such as schizophrenia, stroke and traumatic brain injury.

Our next steps for the development for MIN-301 include continuing to conduct preclinical studies in preparation for an IND or IMPD filing in 2016, with a Phase I study expected to commence thereafter.

License Agreements

MIN-101 License Agreement with MTPC

We have entered into a license agreement with MTPC dated as of August 30, 2007, as amended, or the MIN-101 License Agreement. Under the terms of the MIN-101 License Agreement, we acquired an exclusive license to the lead compound known as CYR-101 (subsequently renamed MIN-101), 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 MIN-101 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 MIN-101 License Agreement. The initial $1.0 million licensing fee paid in 2007 was expensed as research and development expense as was an additional payment of $0.5 million in 2008 upon the onset of a Phase IIa study. 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 MIN-101 and up to $59.5 million for additional products.

In January 2014, we renegotiated the structure of the license for MIN-101 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. 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 MIN-101 in each country in our territory.

MIN-117 License Agreement with MTPC

Sonkei entered into a license agreement with MTPC dated September 1, 2008, as amended, or the MIN-117 License Agreement. Under the terms of the MIN-117 License Agreement, we acquired an exclusive license to the lead compound known as SON-117 (subsequently renamed MIN-117) and other data included within the valid claims of certain patents licensed to us under the MIN-117 License Agreement. Sonkei paid MTPC an initial license fee of $0.5 million. The license is for world-wide rights other than certain countries in Asia, including China, Japan, India and South Korea. We will pay a tiered royalty for net sales of product by it or any of its affiliates or sublicensees containing the licensed compound ranging from the high single digits to the low teens depending on net sales of products under the MIN-117 License Agreement. Through the date of the agreement, as amended, we were required to make payments up to $57.5 million upon the achievement of certain commercial milestones.

In January 2014, we renegotiated the structure of the license for MIN-117 such that we are required to make certain milestone payments upon the achievement of certain commercial milestones up to $47.5 million. 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. Under the terms of the amended agreement, we are required to meet a certain diligence obligation to initiate either a Phase IIa or Phase IIb study with the licensed compound in patients suffering major mood disorders, where initiation is defined as first patient enrolled in the study by the end of April 2015. We believe we will meet this milestone, however, if we fail to meet this milestone, we may elect to extend the milestone an additional year by making an extension payment of $0.5 million. The number of extension payments which may be made to extend the milestone is unlimited. If we fail to achieve this development milestone by end April 2015 or make an extension payment, MTPC may elect to terminate the agreement. This license agreement has a term of the later of 10 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 MIN-117 in each country in our territory.

MIN-202 Co-Development and License Agreement with Janssen

We have entered into a co-development and license agreement with Janssen, dated as of February 12, 2014, pursuant to which, among other things, Janssen has granted us an exclusive license (even as to Janssen), with the right to sublicense, in the European Union, Switzerland, Liechtenstein, Iceland and Norway, referred to as the Minerva Territory, under certain Janssen patent and patent applications to sell products containing any orexin 2 compound, controlled by Janssen and claimed in a Janssen patent right, as an active ingredient, or MIN-202, for any use in humans. In addition, upon regulatory approval in the Minerva Territory (and earlier if certain default events occur), we will have rights to manufacture or have a third party manufacture MIN-202. We have granted to Janssen an exclusive license, with the right to sublicense, under all patent rights and know-how controlled by us related to any orexin 2 compound, controlled by Janssen and claimed in a Janssen patent right, as an active ingredient, or MIN-202, to sell MIN-202 outside the Minerva Territory. This agreement will be in place until we have no further payment obligations, upon which we will have a non-exclusive, fully paid-up and royalty-free license in the Minerva Territory. We will also have the right of first negotiation for any sublicense that Janssen pursues in certain Asian and Latin American

countries and the United States. Our obligation to pay royalties begins upon the first commercial sale of a licensed product in each country in which we have licensing rights and continues until the later of 10 years, the expiration of the last to expire intellectual property right owned by Janssen or the end of the period during which the licensed product is subject to regulatory exclusivity in each country.

In consideration of the licenses granted, we made an initial upfront payment of $22.0 million and will pay a quarterly royalty in the high single digits (subject to certain customary adjustments) on the aggregate net sales for MIN-202 products sold by us, our affiliates and sublicensees in the European Union. Janssen will pay a quarterly royalty in the high single digits (subject to certain customary adjustments) on the aggregate net sales for MIN-202 products sold by Janssen outside the European Union.

We will pay 40% of MIN-202 development costs related to the joint development of any MIN-202 products. However, subject to certain exceptions, our share of aggregate development costs may not exceed (i) $5.0 million for the period beginning from the effective date of the Janssen license and ending following the completion of certain Phase Ib clinical trials and animal toxicology studies and (ii) $24.0 million for the period beginning from the effective date of the Janssen license and ending following the completion of certain Phase II clinical trials.

Janssen has a right to opt out at the end of certain development milestones, with the first milestone being the completion of a single day Phase I clinical trial in patients with MDD. Upon opt out, Janssen will not have to fund further development of MIN-202 and the Minerva Territory will be expanded to also include all of North America. We would then owe Janssen a reduced royalty in the mid-single digits for all sales in the Minerva Territory.

We have the right to terminate the Janssen license following certain development milestones, the first of which is the completion of a certain Phase Ib clinical trial in patients with insomnia and certain toxicology studies in animals. If we terminate the Janssen license within 45 days of this milestone, we must pay Janssen a termination fee equal to $3.0 million. If we terminate the Janssen license at any time following the last development milestone involving a certain Phase IIb clinical trial, we will be entitled to a royalty in the mid-single digits from sales of MIN-202 by Janssen.

Janssen may also terminate the agreement for our material breach or certain insolvency events, including if we are unable to fund our portion of the development costs.

MIN-301 Assignment Agreement with ProteoSys

Mind-NRG has acquired the rights to MIN-301 pursuant to an assignment agreement with ProteoSys. We paid a final license payment under the assignment agreement following the closing of our initial public offering and we have no further obligations under such assignment agreement.

Competition

The biopharmaceutical industry is highly competitive. We face competition from many different sources, including biopharmaceutical companies, generic drug and biosimilar companies, drug delivery companies and academic and research institutions. Many of our potential competitors have substantially greater financial, technical and human resources and greater experience in the development of product candidates, obtaining EMA, FDA and other regulatory approvals of products and the commercialization of those products. Consequently, our competitors may develop products for the treatment of the CNS diseases that we are targeting that are more effective, better tolerated, more useful and less costly. Further, the cause and pathophysiology of CNS diseases are not fully understood, and additional scientific understanding and future drug or non-drug therapies may make our product candidates obsolete. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic and biosimilar products. Generic products are currently on the market for the indications we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic products and potentially biosimilars.

We have described in more detail below the expected primary competition that each of our product candidates will face, if any are approved.

MIN-101: 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’s Largactil (chlorpromazine) and Johnson & Johnson’s Haldol (haloperidol), or second-generation “atypical antipsychotics,” such as Novartis’s Clozaril (clozapine), Johnson & Johnson’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 significant limitations. They have limited ability to improve negative symptoms, cognitive symptoms and insomnia. 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 current drug therapies on positive symptoms and their side effect profiles, we believe current drug therapies are unlikely to be directly competitive with MIN-101, which is intended to target the spectrum of schizophrenia symptoms. However, new drug therapies in addition to MIN-101 are being developed to address the limitations of current therapies. Two 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. Even though there are several compounds still under development, recent clinical data of the most advanced molecules following these two mechanisms of action have shown limited effectiveness. In addition, the product candidates with these mechanisms of action need to be co-administered with existing atypical antipsychotics.

A large part of the remaining late-stage pipeline for schizophrenia are additional atypical antipsychotics focused on the treatment of positive symptoms. There are also several mid-stage product candidates that offer novel mechanisms of action to address negative and cognitive symptoms that, if successful in clinical trials and approved, would compete directly with MIN-101.

MIN-117: Competition in the Pharmaceutical Market for the Treatment of MDD

The pharmaceutical market for the treatment of MDD is largely comprised of SSRIs, SNRIs and atypical antipsychotics. By the time of MIN-117's estimated launch, if approved by the FDA, a number of these high-selling antidepressants will be generic, and would be key competitors to MIN-117. These products include Forest's Lexapro/Cipralex (escitalopram), Pfizer's Zoloft (sertraline), GlaxoSmithKline's Paxil/Seroxat (paroxetine), Eli Lilly's Prozac (fluoxetine), Forest's Viibryd (vilazodone), Pfizer's Effexor (venlafaxine), Pfizer's Pristiq (desvenlafaxine), Eli Lilly's Cymbalta (duloxetine), AstraZeneca's Seroquel (quetiapine) and Bristol-Myers Squibb's Abilify (aripiprazole).

Both SSRIs and SNRIs have significant limitations. SSRIs may lead to varying levels of weight gain and the impairment of cognitive skills and sexual function. In some cases, SNRIs have a worse safety and tolerability profile compared to SSRIs, in particular with respect to cardiovascular side effects. In addition, SSRIs and SNRIs are effective in only a part of the MDD patient population. Over one-third of patients fail to respond to two or more successive lines of antidepressant therapy.

Patients with TRMD often require treatment with several antidepressants, such as an SSRI or SNRI, combined with an "adjunct" therapy such as an antipsychotic or mood stabilizer. These antipsychotic compounds, such as AstraZeneca's Seroquel (quetiapine) and Bristol-Myers Squibb's Abilify (aripiprazole), and mood stabilizers, such as Janssen Pharmaceuticals' Topamax (topiramate), cause some slight improvements in efficacy but often have unacceptable side effects, including motor symptoms, sedation, lack of concentration, and weight gain.

The current drug therapies also generally do not begin to take effect until a few weeks after initiating treatment, with no noticeable improvement before four weeks. It is during this lag period that the risk of suicide can in fact be higher than prior to initiation of therapy. While ketamine and related compounds are now being used to address this slow onset of action, the long term efficacy and safety of this approach has not been confirmed. Ketamine is also not appropriate for chronic therapy due to the risk of hallucinations and delusions, as well as its potential for abuse.

MIN-117 may have a faster onset of action, fewer side effects than existing treatments, and could benefit non- or partial-responders, but a number of products in development could also compete with MIN-117. Lundbeck's Vortioxetine (Brintellix), an SSRI with additional 5-HT receptor modulation activity, has been developed as a monotherapy and was recently approved by the FDA for use as a second-line therapy. Brintellix has been shown to have fewer side effects, in particular less impact on cognition, than existing therapies, though it does not show improved efficacy on depressive symptoms. In addition, Eli Lilly's edivoxetine, a norepinephrine reuptake inhibitor, and Naurex's GL4X-13 and AstraZeneca's AZD6765, both targeting the NMDA receptor, are expected to have a faster onset of therapeutic effect as compared to currently available therapies.

MIN-202: Competition in the Pharmaceutical Market for the Treatment of Insomnia

Most of the pharmaceuticals on the market for insomnia target neurotransmitter pathways involved in depressing the brain activity, such as the histamine and GABA pathways, to induce a decrease in vigilance and attention, leading to sedation and sleep induction. The leading molecule among the current third generation of GABAergic drugs is Sanofi's zolpidem, often marketed under the name Ambien, and is available in generic form. However, zolpidem requires careful utilization to avoid tolerance and drug abuse and extensive sleep studies have demonstrated that zolpidem does not restore physiological sleep and does not allow restorative sleep, which prevents good daytime performance.

Unlike existing therapies, MIN-202, if approved, is expected to inhibit wakefulness-promoting neurotransmitters, rather than activating sleep-promoting neurotransmitters. In August 2014, Merck & Co.’s DORA suvorexant was approved by the FDA, and is currently marketed under the name Belsomra®. We believe that Belsomra may be the only new insomnia pharmaceutical product to launch significantly in advance of MIN-202’s launch. However, if approved, we believe MIN-202, which is a SORA that targets orexin 2 pathways only, will have equal or superior efficacy, less residual sedation and impaired daytime functioning, and superior preservation of appropriate levels of REM as compared to Belsomra.

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, such as DDIs, 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, to the extent such protection is available. As more fully described below, patent applications have been filed by us or our licensors covering compositions of matter for and methods of using our product candidates MIN-101, MIN-117, MIN-202 and MIN-301, and other inventions. 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.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing valid and enforceable patents and other proprietary rights of third parties. We also rely on trade secrets and continuing technological innovation to develop, strengthen and maintain our proprietary position in the field of treatment of neurological, psychological, and sleep disorders.

Our intellectual property consists of patents and patent applications that are owned by us or licensed to us, as described more fully below. We plan to continue to expand our intellectual property by pursuing patent applications directed to dosage forms, methods of treatment, and manufacturing processes. We anticipate continuing to seek patent protection in the United States and internationally, when appropriate, for compositions of matter, the use of these compounds in a variety of therapies, and formulations and the processes for manufacturing these compounds.

The patent positions of biopharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and the patent's scope can be modified after issuance. Consequently, we do not know whether any of our product candidates will remain protected by enforceable patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

Because many patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we will be able to obtain patent protection for the inventions disclosed and/or claimed in our pending patent applications. Moreover, we may have to participate in interference proceedings declared by the United States Patent and Trademark Office or a foreign patent office to determine priority of invention or in post-grant challenge proceedings, such as oppositions, inter-parties review, post grant review or a derivation proceeding, that challenge our entitlement to an invention or the patentability of one or more claims in our patent applications or issued patents. Such proceedings could result in substantial cost, even if the eventual outcome is favorable to us.

The patent portfolios for our product candidates are summarized below.

MIN-101 (Formerly Developed by Cyrenaic Pharmaceuticals)

Our Owned Patent Applications Directed to MIN-101

We own several patent applications that claim methods of use of MIN-101 to treat schizophrenia, treat or diminish symptoms of schizophrenia, treat disorders or parameters of sleep, treat sigma-2 mediated disorders or conditions, and treat symptoms of sigma-2 mediated disorders or conditions. These applications include two international applications filed under the Patent Cooperation Treaty, or PCT, and published as International Publication Nos. WO 2012/012542 and WO 2012/012543. Applications, based on these two international applications or the associated priority applications, are pending as national applications in Brazil, Canada, China, Europe, Hong Kong, Indonesia, Japan, Korea, Russia, Taiwan and the United States. We also recently filed a provisional patent application in the U.S. directed to the formulation and dosing schedule of MIN-101.

If granted, the patent terms are expected to expire no earlier than July 20, 2031.

MIN-101 Patents and Applications Licensed to Us

Our MIN-101 patent portfolio further consists of licensed patent rights, including MIN-101 compositions of matter U.S. Patent No. 7,166,617 expected to expire no earlier than May 2021. As part of the license agreement, we may make, sell, and import products related to the MIN-101 compound in the rest of the world except in MTPC's territory. For purposes of clarity, MTPC's territory covers the Asia-Pacific region and specifically consists of the countries of Bangladesh, Brunei, India, Indonesia, Japan, Malaysia, Pakistan, the People's Republic of China (including Hong Kong), the Philippines, Singapore, South Korea, Sri Lanka, Taiwan, Thailand, and Vietnam.

For the owned patent applications and the U.S. '617 patent, patent term extensions of up to five years may be available in the United States, for one patent.

We are also the exclusive licensee of European Patent No. 1260512, or the EP '512 patent, which protects pharmaceutical compositions of MIN-101 and methods of treating central nervous system diseases using MIN-101 that can be treated by the nerve controlling function of a sigma ligand.

The EP '512 patent is validated in the following EU states: Albania, Austria, Belgium, The Republic of Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia, Monaco, The Netherlands, Portugal, Romania, Slovenia, Spain, Sweden, Switzerland, Turkey, and The United Kingdom.

The patents validated in the above countries, based on EP '512 patent, are expected to expire no earlier than February 26, 2021.

Other licensed patents with similar coverage have been granted in Canada, Australia, New Zealand, the Russian Federation, and Israel.

Ongoing development and clinical studies may lead to additional patent applications.

MIN-117 (Formerly Developed by Sonkei Pharmaceuticals)

Our Owned Patent Applications Directed to MIN-117

We own three U.S. provisional patent applications that claim low dose compositions and rapid onset methods of using MIN-117 to treat depression without cognition impairment. These applications have not yet been published or converted to PCT filings. Anticipated national applications may be filed in Australia, Brazil, Canada, Chile, China (including Hong Kong), Colombia, Europe, India, Israel, Japan, South Korea, Mexico, New Zealand, Peru, Russia, South Africa, Taiwan and the United States.

If granted, the patent terms are expected to expire no earlier than 2034.

For the owned patent applications, patent term extensions of up to five years may be available in the United States.

MIN-117 Patents and Applications Licensed to Us

Our MIN-117 patent portfolio also consists of licensed patent rights. We are the exclusive licensee of U.S. Patent No. 6,720,320, or the U.S. ‘320 patent, which claims pharmaceutical compositions and uses of MIN-117 to treat depression. The U.S. ‘320 patent is licensed to Sonkei by MTPC. Sonkei owns an exclusive license to develop, sell, and import products related to MIN-117 under the U.S. ‘320 patent in the rest of the world, except in MTPC’s territory. For purposes of clarity, MTPC’s territory covers the Asia-Pacific region and specifically consists of the countries of Bangladesh, Brunei, India, Indonesia, Japan, Malaysia, Pakistan, the People’s Republic of China (including Hong Kong), Philippines, Singapore, South Korea, Sri Lanka, Taiwan, Thailand, and Vietnam.

The U.S. ‘320 patent is expected to expire no earlier than August 13, 2020.

We are also the exclusive licensee of European Patent No. 1188747, or the EP ‘747 patent, which protects pharmaceutical compositions and uses of MIN-117 to treat depression, and is expected to expire no earlier than May 22, 2020. The EP ‘747 patent is validated in the following countries: Germany, Spain, France, Italy, the Netherlands, and the United Kingdom. Canadian Patent No. 2375008 similarly protects pharmaceutical compositions and methods of using MIN-117 to treat depression.

The European patents are predicted to expire no earlier than May 22, 2020.

Ongoing development and clinical studies may lead to additional patent filings.

MIN-202

Our MIN-202 patent portfolio consists of patent rights licensed from Janssen Pharmaceutica NV. We are the exclusive licensee of European Patent Application EP 2491038 A1, which claims a genus of compositions of matter that encompasses MIN-202 and other orexin receptor modulators, and methods of using these compositions to treat diseases, including diseases mediated by orexin receptor activity. If granted, the patent term is expected to expire no earlier than October 21, 2030.

MIN-301

Our MIN-301 patent portfolio includes four families of patents and patent applications directed to MIN-301 and its use in the treatment of neurologic and psychiatric diseases. The MIN-301 portfolio was assigned to Mind-NRG by ProteoSys, Inc.

The first family of patents and patent applications has claims directed to certain isolated neuregulin-b isoforms and methods of using these isoforms as diagnostic indicators. The issued patents include U.S. Patent Nos. 7,538,197, 7,919,582, and 8,546,086 and the corresponding EP Patent No. 1252186. U.S. Patent No. 7,538 is expected to expire no earlier than June 20 2022, with the other patents estimated to expire no earlier than February 9, 2021. An application is pending in Canada.

A second patent family includes patents and applications directed to methods of screening for agents. U.S. Patent No. 7,824,923 claims a method of screening for agents that increase or decrease the expression level of a specific neuregulin-b isoform, comprising certain steps. This patent expires no earlier than December 16, 2022. This family also includes two pending European applications (EP 1 417 230 and EP 2 418 218), which if granted are also expected to expire no earlier than August 6, 2022. The patent application EP 2 418 218 is directed at the use of specific neuregulin-b isoforms for the diagnosis of a neuronal degenerative disease.

A third patent family is based on PCT International Publication No. WO 2009/062750. Patents and patent applications belonging to this family have claims that are mainly directed at the medical use of a specific neuregulin isoform as

well as compositions comprising said neuregulin isoform and a further medicament.

The third patent family includes European Patent No. EP2 219 662 B1, Australian patent No. AU 2008323169 B2 and Russian Patent No. 2491955. The European patent was validated in the following EPC member states: Austria, Switzerland, Germany, Denmark, Spain, France, United Kingdom, Greece, Ireland, Italy, Netherlands, Norway, Portugal, Sweden, Belgium and Turkey.

The third family also includes pending U.S. Patent Application No. 12/742,983 and corresponding patent applications Brazil, Canada, China, Japan, and Mexico.

If granted, the patent terms are expected to expire no earlier than November 17, 2028. Patent term extensions may be available in some countries.

A fourth patent family is based on PCT application WO 2011/147981 A2 and includes applications in the United States, Australia, Brazil, Canada, China, Europe, India, Japan, Korea, Mexico, Russia, New Zealand, South Africa and Israel.

The applications have claims directed to a polypeptide composition, a pharmaceutical composition based on the polypeptide, use of the polypeptide to treat neurological conditions and diagnostic methods.

Ongoing development and clinical studies may lead to additional patent filings. The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a PCT application or a non-provisional patent application, subject to any disclaimers or extensions. The term of a patent in the United States can be adjusted and extended due to delays in the patent examination process by the United States Patent and Trademark Office. In the United States, the patent term of a patent that covers an FDA-approved drug that contains an active ingredient or salt or ester of the active ingredient that has not previously been marketed may also be eligible for patent term extension, which permits patent term restoration to account for a portion of the patent term lost during the FDA regulatory review process.

The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is based upon one half of the time between the IND effective date and a company's initial submission of a marketing application, plus the entire time between the submission of the marketing application and FDA's approval of the application. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. The amount of patent term restoration that a company is eligible for may further be reduced by any time the company did not act with due diligence in development of the drug. Similar provisions are available in Europe and other non-United States jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when any of our pharmaceutical product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those products. Although, we intend to seek patent term extensions to any of our issued patents in any jurisdiction where these are available, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

Moreover, one or more of our product candidates may qualify as a new chemical entity, or NCE, and following submission and approval of an NDA, if we are the first applicant to obtain NDA approval, we may be entitled to five years of data and market exclusivity in the United States with respect to such NCEs. Analogous data and market exclusivity provisions, of varying duration, may be available in Europe (for example, 10 years data exclusivity in Europe), and other foreign jurisdictions. If MIN-301 is regulated as a biologic under the PHSA, and the FDA approves a BLA, the product may be eligible for twelve years of exclusivity.

We also rely on trade secret protection for our confidential and proprietary information. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property.

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

We have not yet established a sales, marketing or product distribution infrastructure. We have global, except for most of Asia, commercialization rights for two of our product candidates, MIN-101 and MIN-117, and European Union commercialization rights for MIN-202. We have worldwide rights for MIN-301. We believe that it will be possible for us to access European and, in the case of MIN-101, MIN-117 and MIN-301, the United States and Latin America markets through a focused, specialized task force where the population dynamics would prove efficient. Alternatively, we may enter into distribution and other marketing arrangements with third parties 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 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.

We plan to build a marketing and sales management organization to create and implement marketing strategies for any products we commercialize ourselves. In parallel with building this organization, we plan to develop educational initiatives with respect to approved products and relationships with thought leaders in relevant fields of medicine. As part of our commitment to supporting optimal patient care and sustainable healthcare systems globally, we recognize the importance of fully understanding the needs of the patient communities we serve. We have learned that one of the best ways to accomplish this is by working with patient organizations, who are closely connected to patients' most important concerns and interests.

Government Regulation and Product Approval

Obtaining a Marketing Authorization in the European Union

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

There are three procedures for submitting a Marketing Authorization Application, or MAA, in the EU: (i) the mutual recognition procedure, or MRP; (ii) the decentralized, or DCP and (iii) 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 medicinal products which are produced by biotechnology processes, advanced therapy medicinal products and orphans. Besides the products falling under the mandatory scope, the centralized procedure is also open for other innovative products are new active substances or other 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.

The centralized procedure leads to approval of the product in all 27 EU member states and in Norway, Iceland and Liechtenstein. Submission of one MAA thus leads to one assessment process and one authorization that allows access to the market of the entire EU. The process of the centralized procedure is triggered when the applicant sends the letter announcing the intent to submit a MAA (letter of intent). 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.

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 und results of the assessment.

Regulatory Data Protection

The rationale for granting data and market exclusivity is to compensate the innovator company for the investment it has put in to generating the data required to obtain a marketing authorization. The regulatory regime permits generic companies, who subsequently wish to gain their own approval for the same drug substance, to rely on information filed by the innovator company that made the first application. In order to be able to benefit from the data provided by the innovator in their regulatory filings for that medicinal product - the "reference medicinal product" - a generic company must show that their product has the same qualitative and quantitative composition as that product and that it

is bioequivalent.

However 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 in 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.

Pediatric Rights and Obligations

The Pediatric Regulation provides that an application for a new marketing authorization must include the results of all studies performed and details of all information collected in compliance with an agreed pediatric investigation plan, or PIP, unless a specific exemption is granted 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).

European Bribery/Sunshine Laws

While there is no EU-wide harmonized laws on bribery or influencing healthcare professional all EU countries are members of the OECD Anti-bribery Convention and there are widespread national laws. For instance, the UK Bribery Act came into force in July 2011. This act has extensive extra-territorial application, implements significant changes to existing UK anti-bribery legislation and broadens the scope of statutory offences and the potential applicable penalties, including, organizational liability for any bribe paid by persons or entities associated with an organization where the organization failed to have adequate preventative procedures in place at the time of the offence. There is also an increase in the maximum applicable penalties for bribery, including up to 10 years' imprisonment and unlimited fines. There have also been increased enforcement efforts in the UK by the Serious Fraud Office. In addition the French government has recently introduced a law requiring healthcare professional benefits and agreements be publicly available.

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. 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 approve pending investigational New Drug Applications, or INDs, and NDAs, withdrawal of a marketing approval, imposition of clinical holds or termination of clinical trials, or issuance of Warning, Cyber, 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. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

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 I, 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 II 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 II evaluations, generally two adequate and well-controlled Phase III 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 studies are typically referred to as Phase IV studies. 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 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 under the Federal Food, Drug, and Cosmetic Act.

Phase I, Phase II and Phase III clinical trials may not be completed successfully within any specified period, or at all. Furthermore, 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. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of most marketing applications is additionally subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved application are also subject to annual product and establishment fees per product and per establishment. These fees are typically increased annually. Application user fees must be filed at the time of the first submission of the application, even if the application is being submitted on a rolling basis. A waiver from the application user fee may be sought by an applicant. One basis for a waiver of the application user fee is if the applicant employs fewer than 500 employees, including employees of affiliates, the applicant does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce, and the applicant, including its affiliates, is submitting its first human drug application.

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. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

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. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. 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 current Good Manufacturing Practices, or 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 studies 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. There also are continuing annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies list drugs manufactured at their facilities with FDA, and 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. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

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 studies 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, Cyber 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 recently enacted Drug Quality and Security Act imposes new obligations on manufacturers of pharmaceutical products, among others, related to product and tracking and tracing. Among the requirements of this new legislation, manufacturers will be required to provide certain information regarding the drug products to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this new legislation, manufactures will have drug product investigation, quarantine, disposition, and FDA and trading partner notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences of death.

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 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 law 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. 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, imprisonment, exclusion from participation in government

healthcare programs, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, 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, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

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. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. 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 paid by health maintenance organizations, managed care organizations, pharmacy benefit and similar healthcare management organizations, and reimbursed by government health administration authorities, such as Medicare and Medicaid, private health coverage insurers and other 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.

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. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. 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 PPACA, which substantially changed healthcare financing and delivery by both governmental and private insurers, and significantly impact the

pharmaceutical industry. Among other things, PPACA expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for singlesource, multiple source, innovator and non-innovator drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices. This could increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also extended Medicaid drug rebates, previously due only on fee-for-service utilization, to Medicaid managed care utilization, and created an alternate rebate formula for new formulations of certain existing products that is intended to increase the amount of rebates due on those drugs. PPACA also expanded the types of entities eligible for the 340B drug discount program that mandates discounts to certain hospitals, community centers and other qualifying providers. With the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, because 340B pricing is determined based on AMP and Medicaid drug rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discounts to increase. Furthermore, PPACA established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D. Finally, PPACA establishes an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents and expands Medicaid benefits.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, in August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This included reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and will stay in effect through 2024 unless additional Congressional action is taken. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals and imaging centers.

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.

Exclusivity and Approval of Competing Products

Hatch-Waxman Patent Exclusivity. In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's product or a method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA, or 505(b)(2) NDA. Generally, an ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths, dosage form and route of administration as the listed drug and has been shown to be bioequivalent through in vitro or in vivo testing or otherwise to the listed drug. ANDA applicants are not required to conduct or submit results of pre-clinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the reference listed drug. 505(b)(2) NDAs generally are submitted for changes to a previously approved drug product, such as a new dosage form or indication.

The ANDA or 505(b)(2) NDA applicant is required to provide a certification to the FDA in the product application concerning any patents listed for the approved product in the FDA's Orange Book, except for patents covering methods of use for which the applicant is not seeking approval. Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable, or will not be infringed by the new product.

Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except when the ANDA or 505(b)(2) NDA applicant challenges a listed patent or indicates that it is not seeking approval of a patented method of use. A certification that the proposed product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification.

If the ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of notice of the Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, decision in the infringement case that is favorable to the ANDA applicant or such shorter or longer period as may be ordered by a court.

Hatch-Waxman Non-Patent Exclusivity. Market and data exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications for competing products. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA, or supplement to an existing NDA or 505(b)(2) NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant, are deemed by the FDA to be essential to the approval of the application or supplement. Three-year exclusivity may be awarded for changes to a previously approved drug product, such as new indications, dosages, strengths or dosage forms of an existing drug. This three-year exclusivity covers only the conditions of FDA approval associated with the new clinical investigations and, as a general matter, does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the pre-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Regulation of Biologics

One of our product candidates, MIN-301, is a protein, and, as a protein, will likely be considered to be a biologic by the FDA. Biologics are regulated under the PHSA and FDCA. Because biologics also meet the FDCA's definition of a drug, many aspects of the FDA's regulation of biologics are the same as or similar to drugs, though there are some differences. As with drugs, a product sponsor must conduct pre-clinical testing, obtain an IND for the conduct of clinical studies, and conduct clinical studies in accordance with FDA's requirements to support a marketing application. Following completion of clinical testing, however, the product sponsor usually will be required to submit a BLA to FDA. Rather than demonstrating safety and efficacy, as in the case of an NDA, a BLA must demonstrate that the biologic is safe, pure and potent. Accordingly, different information must be included in the BLA to meet the FDA's approval standards. Similarly, following product approval, biologics are subject to many of the same regulatory requirements as drugs, including requirements pertaining to record keeping, periodic reporting, distribution, labeling, post-approval studies, REMS, advertising and promotion, reporting of adverse experiences and product shortages, and the manufacture of products in accordance with cGMPs. Unlike drugs, biologics are also subject to lot-release requirements, which require submission of product samples and testing information to the FDA. The products may not be distributed until the lot is released by the FDA. Biologics are further subject to the same fraud and abuse, data privacy, security, and transparency laws as drugs. Generally, brand biologics are covered and reimbursed by government and commercial health plans as single-source drugs.

A key difference between drugs and biologics are the PHSA's provisions pertaining to the entry of competing products on the market and exclusivity. Following the approval of a BLA, other companies may pursue approval of similar biologic products using an abbreviated pathway. This abbreviated pathway is available to products with a showing of biosimilarity. A biosimilar product is a product that is highly similar to the reference product, notwithstanding minor differences in clinically inactive components and for which there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. Biosimilarity is demonstrated through data from analytical, animal, and clinical studies. Biosimilar products can also be deemed to be interchangeable with the reference product. To meet the higher standard of interchangeability, an applicant must show biosimilarity and demonstrate that the product can be expected to produce the same clinical results as the reference product, and, if intended for repeated dosing, the safety or diminished efficacy risk of switching between the product and reference product is no greater than using the reference product without switching. Interchangeable products may be substituted for a reference product without the intervention of the prescribing healthcare provider. The FDA has not

yet promulgated regulatory standards for determining interchangeability and the naming of biosimilars. In addition, there are state laws governing the prescribing of biosimilars by pharmacies.

The PHSA also includes provisions to protect reference products that have patent protection. The biosimilar product sponsor and reference product sponsor must exchange certain patent and product information for the purpose of determining whether there should be a legal patent challenge. Based on the outcome of negotiations surrounding the exchanged information, the reference product sponsor may bring a patent infringement suit and injunction proceedings against the biosimilar product sponsor.

For biologics, market and data exclusivity under the PHSA can delay the submission and approval of certain competing products. The PHSA provides for twelve years of non-patent exclusivity for biologics licensed via a BLA. During this time, a biosimilar product approval may not be made effective by the FDA. Moreover, the FDA may not accept such an application until four years after the reference product is first approved.

Clinical Trials in the European Union

In Europe, a clinical trial application, or CTA, must 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. In all cases, the clinical trials must be conducted in accordance with good clinical practices and other applicable regulatory requirements.

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.

Employees

As of December 31, 2014, we had 7 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.

Available Information

We file reports with the Securities and Exchange Commission, or 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 public may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. 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.

We are not profitable and have incurred losses in each period since our inception in 2007. For the years ended December 31, 2014 and 2013, we reported net losses of $56.9 million and $3.3 million, respectively. As of December 31, 2014, we had an accumulated deficit of $74.7 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. We expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our product candidates into clinical trials.

As of December 31, 2014, we had cash and cash equivalents of $18.5 million. We believe that our existing cash and cash equivalents, together with amounts drawn or available under our credit facility with Oxford Finance LLC and Silicon Valley Bank and the net proceeds from our private placement of common stock and warrants to purchase common stock, which was completed in March 2015, will fund our projected operating requirements through 2016. In particular, we expect these funds will allow us to complete our Phase IIb trial for MIN-101, our Phase IIa trial for MIN-117, our portion of the funding for the Phase IIa trial in primary insomnia for MIN-202 with Janssen, our portion of the funding for the Phase Ib trial in comorbid insomnia for MIN-202 with Janssen and additional pre-clinical development for MIN-301. However, circumstances may cause us to consume capital more rapidly than we currently anticipate. In any event, we will require significant additional capital to fund future clinical trials of our product candidates, and to obtain regulatory approval for, and to commercialize, our product candidates.

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 and clinical studies for our product candidates and future product candidates we may develop;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the European Medicines Association, or EMA, United States Food and Drug Administration, or 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 plan to use potential future operating losses and our federal and state net operating loss, or NOL, carryforwards to offset taxable income from revenue generated from operations or corporate collaborations. However, our ability to use existing NOL carryforwards may be limited as a result of issuance of equity securities.

As of December 31, 2014, we had approximately $26.4 million of Federal NOL carryforwards. These Federal NOL carryforwards will begin to expire at various dates beginning in 2027, if not utilized. We plan to use our operating losses to offset any potential future taxable income generated from operations or collaborations. To the extent we generate taxable income, we plan to use our existing NOL carryforwards and future losses to offset income that would otherwise be taxable. However, under the Tax Reform Act of 1986, the amount of benefits from our NOL carryforwards may be impaired or limited if we incur a cumulative ownership change of more than 50%, as interpreted by the U.S. Internal Revenue Service, over a three year period. We have not performed a detailed analysis to determine whether an ownership change occurred upon consummation of the merger between us and Sonkei, upon the acquisition of Mind-NRG or our initial public offering or the concurrent private placements. However, as a result of these transactions, it is likely that an ownership change has occurred. Therefore, it is likely that some or all of our existing NOL carryforwards would be limited by the provisions of Section 382 of the United States Internal Revenue Code of 1986, as amended. Further, state NOL carryforwards may be similarly limited. We had approximately $21.4 million of state net operating carryforwards at December 31, 2014. It is also possible that future changes in ownership, including as a result of subsequent sales of securities by us or our stockholders, could similarly limit our ability to utilize NOL carryforwards. It is possible that all of our existing NOL carryforwards have been or will be disallowed. 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.

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.

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.

We currently hold no Investigational New Drug, or IND, approvals in the United States (other than the IND held by Janssen, our co-development partner for MIN-202), and as a result do not intend to initiate human clinical trials of our product candidates in the United States (other than the clinical trial being initiated in the United States by Janssen, our co-development partner for MIN-202) until 2015 or later. 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, or NDA, 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.

Initially, we plan to conduct clinical trials in Europe. Applications to commence clinical trials in the European Union are made to member state regulatory authorities. Good Clinical Practice (in the European Union under ICH 1997), or GCP, as incorporated into the EU Clinical Trials Directive 2001/20 and national implementing regulations, set forth the majority of the requirements and procedures for the conduct of trials but national divergences exist especially in relation to insurance and compensation, which will require that we develop a thorough understanding of the specific procedures and requirements for the individual member states in which we chose to conduct the clinical trials. Clinical trials in the European Union also require an ethics committee or institutional review board opinion, and there is often inconsistency as to ethics committee decisions. An ethics committee may ask questions and/or require re-writing or amending a trial protocol, any of which may require that we incur additional expense in order to commence a clinical trial. Even after re-submission to the relevant ethics committee, the application may still ultimately be rejected. After clinical trial authorization, we may be inspected for compliance with GCP by inspectors from the national regulatory authorities. If the inspections provide warnings or require changes, this will cause further delays and cost and we may be restricted from completing the trials.

If, following submission, our NDA or marketing authorization 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 sufficient any additional required trials, data or information that we perform or provide, 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, studies 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 studies. 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 III 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;
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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 two of our product candidates, MIN-101 and MIN-117;

- 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:

(1) failure to conduct the clinical trial in accordance with regulatory requirements, the trial protocols and applicable laws;
(2) 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;
(3) unforeseen safety issues; or
(4) 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 II, 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 II, 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 MIN-101 and MIN-117 due to the mental health of the subjects that we will need to enroll.

For instance, according to Datamonitor, roughly one-third of purported schizophrenia patients may not receive an accurate diagnosis, with negative symptoms more difficult to recognize. The patient discontinuation rate for current schizophrenia drugs is also high. For instance, 66 out of 99 subjects ceased to participate in the Phase IIa clinical trial of MIN-101. As a result, the process of finding, diagnosing and retaining subjects throughout a clinical trial targeting the negative symptoms of schizophrenia or MDD may prove difficult and costly.

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 efficacy of the product candidate studied for the target indication. For instance, our clinical studies of MIN-101 and MIN-117 did not show statistically significant differences favorable to the investigational products between the treatment and comparator groups on all the studies' primary, secondary and/or exploratory endpoints. While these studies were not powered for statistical significance, regulatory authorities may find that the 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 MIN-101 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 candidates, MIN-101 and MIN-117, we are seeking to develop treatments for schizophrenia and MDD, which adds a layer of complexity to our clinical trials and may delay regulatory approval. We do not fully understand the cause and pathophysiology of schizophrenia and MDD, and our results will rely on subjective subject feedback, 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, MIN-101. As a result, we may forego or delay pursuit of opportunities with other product candidates, including MIN-117, MIN-202 and 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 more narrow 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 thought 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, Cyber 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;
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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 protein, and, as a protein, 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, insomnia and Parkinson's disease. Our projections of both the number of people who have these disorders or disease, as well as the subset 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, other than MIN-202, in 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 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 no marketing and sales organization. If we are unable to establish 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 do not have a 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, and 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.

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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 also 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, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, 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, 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. 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.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for certain pharmaceutical products. The legislation expanded Medicare coverage for outpatient prescription drugs dispensed to the elderly by establishing Medicare Part D and also introduced a new reimbursement methodology based on average sales prices for physician-administered drugs under Medicare Part B. In addition, this legislation provided authority for limiting the number of outpatient prescription drugs that Medicare will cover in any therapeutic class under the Medicare Part D program. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and reimbursement rate that we receive for any of our approved products. While the MMA applies only to pharmacy benefits for Medicare beneficiaries, private payors often follow Medicare and Medicaid coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

More recently, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the PPACA, a law intended to, among other things, broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers and impose additional health policy reforms. Among other things, the PPACA expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for single-source, multiple source innovator and non-innovator drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices. This could increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The PPACA further created a separate AMP for certain categories of drugs generally provided in non-retail outpatient settings. The legislation also extended Medicaid drug rebates, previously due only on fee-for-service utilization, to Medicaid managed care utilization, and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the amount of rebates due on those drugs. The PPACA also expanded the types of entities eligible to receive discounted 340B pricing, although, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs used in orphan indications. In addition, because 340B pricing is determined based on AMP and Medicaid drug rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discounts to increase. The PPACA also imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Furthermore, the PPACA changed the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount off the

negotiated price of applicable brand drugs to certain eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D. The PPACA further created a new approval pathway for biosimilars intended to encourage competition and lower prices, and it amended Medicare Part B reimbursement rules for physician-administered biologic products by making the purchase of lower cost biosimilars more attractive to providers reimbursed by Medicare Part B. As the FDA approves biosimilars, it is possible that similar rules will be adopted by commercial managed care organizations. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners. Notably, a significant number of provisions are not yet, or have only recently become, effective.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, in August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013.

Moreover, the recently enacted Drug Quality and Security Act imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements of this new legislation, manufacturers will be required to provide certain information regarding the drug products they produce to individuals and entities to which product ownership is transferred, label drug products with a product identifier, and keep certain records regarding the drug products. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, and FDA and trading partner notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death. In the European Union, the Falsified Medicines Directive imposes similar requirements, which are expected to add materially to product costs.

We expect that the PPACA, as well as other federal and state healthcare reform measures that have been and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

The full impact of these new laws, as well as laws and other reform measures that may be proposed and adopted in the future, remains uncertain, but may continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs, which could have a material adverse effect on our business operations.

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 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 and cash equivalents, including the remaining net proceeds from the initial public offering and the concurrent 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 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, or political instability in particular foreign economies and markets;
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- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- 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 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, 2014, we had seven 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.

We are party to a loan and security agreement that contains operating and financial covenants that may restrict our business and financing activities.

On January 16, 2015, we entered into a Loan and Security Agreement with Oxford Finance LLC and Silicon Valley Bank, providing for term loans to us in an aggregate principal amount of up to $15 million, in two tranches. Borrowings under this loan and security agreement are secured by substantially all of our assets, excluding certain intellectual property rights. The loan and security agreement restricts our ability, among other things, to:

- sell, transfer or otherwise dispose of any of our business or property, subject to limited exceptions;
- make material changes to our business or management;
- enter into transactions resulting in significant changes to the voting control of our stock;
- make certain changes to our organizational structure;
- consolidate or merge with other entities or acquire other entities;
- incur additional indebtedness or create encumbrances on our assets;
- pay dividends, other than dividends paid solely in shares of our common stock, or make distributions on and, in certain cases, repurchase our stock;
- enter into transactions with our affiliates;
- repay subordinated indebtedness; or
- make certain investments.

In addition, we are required under our loan agreement to comply with various affirmative operating covenants. The operating covenants and restrictions and obligations in our loan and security agreement, as well as any future financing agreements that we may enter into, may restrict our ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. Our ability to comply with these covenants may be affected by events beyond our control, and we may not be able to meet those covenants. A breach of any of these covenants could result in a default under the loan and security agreement, which could cause all of the outstanding indebtedness under the facility to become immediately due and payable and eliminate our eligibility to receive additional loans under the agreement.

If we are unable to generate sufficient cash available to repay our debt obligations when they become due and payable, either as when such obligations become due, when they mature, or in the event of a default, we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our business operations and financial condition.

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;

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- 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, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it 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.

We have previously identified material weaknesses and significant deficiencies in our internal control over financial reporting.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner. In connection with the preparation of our financial statements for the year ended December 31, 2013, we concluded that there were material weaknesses and significant deficiencies in our internal control over financial reporting during 2013. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses that we identified related to (1) lack of segregation of duties, (2) lack of personnel competent to perform complex accounting, including stock-based compensation, the convertible promissory notes beneficial conversion features and income tax disclosures, (3) lack of financial statement disclosure controls, and (4) not performing a risk assessment. During 2014 we addressed these control deficiencies and believe they have been remediated as of December 31, 2014, except for a significant deficiency related to income tax disclosure.

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.

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. These require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of our internal control over financial reporting commencing with our second annual report. This assessment will need to include the disclosure of any material weaknesses or significant deficiencies in our internal control over financial reporting identified by our management or our independent registered public accounting firm.

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 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 be in compliance 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, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, 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 are and will 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 fraud and abuse 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 privacy regulation by the federal government, state governments and foreign jurisdictions in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits, among other things, 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 civil federal 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 criminal federal 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 new 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 Payment Sunshine Act, created under the PPACA, 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.
- Federal government price reporting laws, changed by the PPACA to, among other things, (1) increase the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program and offer such rebates to additional populations and (2) require pharmaceutical companies to calculate and report complex pricing metrics to government programs, with such reported prices to be used in the calculation of reimbursement and/or discounts on a company's marketed drugs. Participation in these programs and compliance with the applicable requirements may subject a pharmaceutical company to potentially significant discounts on its products, increased infrastructure costs and potential limitations on its ability to offer certain marketplace discounts, with any failure to report accurate pricing information resulting in potential exposure to federal False Claims Act liability.
- The Foreign Corrupt Practices Act, or FCPA, a United States law that generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments, offers or promises to foreign officials for the purpose of obtaining or retaining business or other advantages. In addition, the FCPA imposes recordkeeping and internal controls requirements on publicly traded corporations and their foreign affiliates, which are intended to, among other things, prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of "off books" slush funds from which such improper payments can be made.
- 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) and (3) 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.

Recent health care reform legislation has strengthened these laws. For example, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and HIPAA criminal healthcare fraud statutes such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. Moreover, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal Civil False Claims Act.

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, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

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 collaborations with Mitsubishi Tanabe Pharma Corporation, or MTPC, and Janssen and could be seriously harmed if our license agreements with MTPC and Janssen were terminated.

We exclusively license MIN-101 and MIN-117 from MTPC, with the rights to develop, sell and import MIN-101 and MIN-117 globally, excluding most of Asia. Under the MIN-117 license agreement, we must have the first subject with MDD enrolled in either a Phase IIa trial or a Phase IIb trial with a product containing MIN-117 by the end of April 2015. If we fail to achieve this milestone, we may elect to extend the timeline to achieve the milestone by one year increments by making an extension payment of $0.5 million. The number of extension payments which may be made is unlimited. Subject to any extensions, if we fail to achieve this development milestone, MTPC may elect to terminate the MIN-117 license agreement. MTPC may also terminate the licenses following a material breach by us or certain insolvency events. If our license agreements with MTPC are terminated, our business would be seriously harmed.

Our co-development and license agreement with Janssen provides us with European Union commercialization rights for MIN-202 and the right to royalties on any sales of MIN-202 outside of the European Union. We are obligated to pay 40% of the development costs for MIN-202, subject to certain limits, and will only realize revenues from MIN-202 if it is approved and if our license agreement with Janssen is not terminated by Janssen. Janssen may terminate our license agreement following a material breach by us or certain insolvency events, including if we are unable to fund our portion of the development costs. As a result, we may never realize any revenues from the commercialization of MIN-202, even if approved. In addition, at certain development milestones, including the completion of a single dose Phase I clinical trial of MIN-202 in patients with MDD, Janssen has the right to opt out of its obligation to fund further development, and we may be unable to fund such development without Janssen's financial support.

Even if we receive revenues on European Union sales or royalties on sales outside of the European Union under the Janssen license agreement, we may not receive revenues that equal or exceed to the amount we are obligated to invest in MIN-202's clinical development under the agreement. As a result, the license agreement for MIN-202 may never result in any profits to us and may have a material adverse effect on us or our business prospects.

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 are collaborating with Janssen on the development of MIN-202. We may also seek to enter into additional 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 MIN-101, respectively, are expected to expire as soon as 2021. In addition, our in-licensed U.S. and European patents relating to pharmaceutical compositions and uses of MIN-117 to treat depression are expected to expire as soon as 2020. Finally, certain of our U.S. patents relating to methods of diagnostic indication and methods of screening for agents for MIN-301 are expected to expire as early as 2021 and 2022, respectively. 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 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 Leahy-Smith 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 Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, are now effective. While it is still not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business, the Leahy-Smith 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 patent or pending patent application 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.

In addition, companies listed on The NASDAQ Global Market, and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this “Risk Factors” section, could have a dramatic and material adverse impact on the market price 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.

To our knowledge, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially own approximately 81% of our voting stock as of December 31, 2014. 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 initial public offering, private placements and term 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 initial public offering, private placements and term 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 and concurrent private placements, their ultimate use may vary substantially from their currently intended use. If we do not invest or apply the net proceeds from our initial public offering, private placements and term loans in ways that enhance stockholder value, we may fail to achieve the expected financial results, which could cause our stock price to decline.

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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 we 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 4,281,333 stock options 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 are an “emerging growth company” and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act, or JOBS Act, and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including not being required to comply with the auditor attestation requirements of section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we completed our initial public offering, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds $700.0 million as of any June 30 before that time or if we have total annual gross revenue of $1.0 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 or, if we issue more than $1.0 billion in non-convertible debt during any three year period before that time, we would cease to be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may continue to qualify as a “smaller reporting company” which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

As a newly 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.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile, and in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

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 284, Waltham, Massachusetts. We sublease this facility, which consists of approximately 4,043 square feet of office space, and the term of our sublease expires on September 30, 2016. We believe that our existing facility is sufficient for our current needs for the foreseeable future.

ITEM 3. Legal Proceedings

From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, as of the date of this Form 10-K, we do not believe we are party to any claim or litigation, the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

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. Prior to that time, there was no public market for our common stock. The following table sets forth the high and low sale prices per share for our common stock on the NASDAQ Global Market for the periods indicated:

	High	Low
2014		
Third Quarter	$7.90	$5.57

Fourth Quarter	$6.91	$4.08

At March 20, 2015, there were approximately 50 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.

We have never declared or paid any cash dividends on our common stock and our ability to pay cash dividends is currently prohibited by the terms of our debt financing arrangements. We do not anticipate paying cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, on our common stock will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, anticipated cash needs, and plans for expansion.

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

On March 18, 2015, pursuant to a securities purchase agreement with certain accredited investors dated March 13, 2015, we sold in a private placement 6,281,661 shares of our common stock at a price per share of $4.81 and warrants to purchase up to an aggregate of 6,281,661 shares of our common stock at a purchase price of $0.125 per warrant share, with an initial exercise price of $5.772 per share, for gross proceeds of approximately $31 million, and net proceeds of approximately $28.8 million after deducting placement agent fees. The warrants will expire on March 18, 2017, two years after the date on which they were initially issued. We sold the shares and the warrants to “accredited investors,” as that term is defined in the Securities Act of 1933, as amended, or the Securities Act, and in reliance on the exemption from registration afforded by Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated under the Securities Act and corresponding provisions of state securities or “blue sky” laws.

On January 16, 2015, we entered into a Loan and Security Agreement with Oxford Finance LLC and Silicon Valley Bank. In connection therewith, we agreed to issue the lenders warrants to purchase shares of our common stock, upon our draw of each tranche of the term loans contemplated by the Loan and Security Agreement. The aggregate number of shares of our common stock issuable upon exercise of the warrants is equal to 2.25% of the amount drawn of such tranche, divided by the average closing price per share of our common stock reported on the NASDAQ Global Market for the ten consecutive trading days prior to the applicable draw. On

January 16, 2015, we issued the lenders warrants for an aggregate of 40,790 shares of our 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 offer and sale of the warrants have not been registered under the Securities Act of 1933, as amended, or the Securities Act. The warrants were offered and sold to accredited investors in reliance upon the exemptions from registration under Section 4(a)(2) of the Securities Act.

On July 7, 2014, concurrent with the completion of our initial public offering described below, certain of our stockholders purchased 666,666 shares of our common stock for $6.00 per share in a private placement, resulting in total net proceeds from this transaction of approximately $3.7 million and Janssen Pharmaceutica N.V. purchased 3,284,353 shares of our common stock for $6.00 per share in a private placement, resulting in total net proceeds from this transaction of approximately $19.7 million. The sales of these shares were not registered under the Securities Act of 1933, as amended, in reliance on the exemptions set forth under Section 4(a)(2) thereof and Rule 506 of Regulation D thereunder.

On February 11, 2014, we acquired Mind-NRG, a development stage biopharmaceutical company focused on the development and commercialization of an experimental drug for the treatment of Parkinson’s Disease. The purchase price consisted of 1,481,583 shares of our common stock with an estimated fair value of $11.17 per share, or approximately $16.5 million.

Initial Public Offering

On July 7, 2014, we closed our initial public offering, in which we issued and sold 5,454,545 shares of common stock at a public offering price of $6.00 per share, for aggregate gross proceeds to us of $32.7 million. All of the shares issued and sold in our initial public offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-195169), which was declared effective by the SEC on June 30, 2014. Jefferies LLC acted as sole book-running manager and representatives of the several underwriters. The offering commenced on June 30, 2014 and did not terminate before all of the securities registered in the registration statement were sold.

Net proceeds to us from the offering were approximately $28.2 million, after deducting the underwriting discount and expenses of approximately $3.1 million.

There has been no material change in the planned use of proceeds from our initial public offering as described in our prospectus dated June 30, 2014, filed pursuant to Rule 424(b)(4) under the Securities Act, with the Securities and Exchange Commission on July 1, 2014.

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 a portfolio of product candidates to treat patients suffering from central nervous system, or CNS, diseases. Leveraging our deep domain expertise, we have acquired or in-licensed four development-stage proprietary compounds that we believe have innovative mechanisms of action with potentially positive therapeutic profiles. Our lead product candidate is MIN-101, a compound for the potential treatment of patients with schizophrenia. In addition, our portfolio includes MIN-202, a compound we are co-developing with Janssen Pharmaceuticals, or Janssen, for the treatment of patients suffering from primary and comorbid insomnia, MIN-117, a compound we are developing for the treatment of patients suffering from major depressive disorder, or MDD, and MIN-301, a compound we are developing for the treatment of patients suffering from Parkinson's disease. We believe our innovative product candidates have significant potential to transform the lives of a large number of affected patients and their families who are currently not well-served by available therapies in each of their respective indications.

We exclusively licensed MIN-101 from Mitsubishi Tanabe Pharma Corporation, or MTPC, in 2007 with the rights to develop, sell and import MIN-101 globally, excluding most of Asia. In November 2013, we merged with Sonkei Pharmaceuticals Inc., or Sonkei, a clinical-stage biopharmaceutical company and, in February 2014, we acquired Mind-NRG, a pre-clinical-stage biopharmaceutical company. We refer to these transactions as the Sonkei Merger and Mind-NRG Acquisition, respectively. Sonkei licensed MIN-117 from MTPC in 2008 with the rights to develop, sell and import MIN-117 globally, excluding most of Asia. With the acquisition of Mind-NRG, we obtained exclusive rights to develop and commercialize MIN-301. We have also entered into a co-development and license agreement with Janssen Pharmaceutica NV, or Janssen, for the exclusive rights to develop and commercialize MIN-202 in the European Union, subject to royalty payments to Janssen, and royalty rights for any sales outside the European Union.

We have not received regulatory approvals to sell 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.

On July 7, 2014, we closed our initial public offering, in which we issued and sold 5,454,545 shares of common stock at a public offering price of $6.00 per share, for aggregate gross proceeds to us of $32.7 million. All of the shares issued and sold in our initial public offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-195169), which was declared effective by the SEC on June 30, 2014. Net proceeds to us from the offering were approximately $28.2 million, after deducting the underwriting discount and transaction expenses of approximately $3.1 million.

The Company had issued $1.3 million 8% convertible promissory notes due June 30, 2014 to certain stockholders that were payable on demand at maturity. In addition, in conjunction with the merger of Sonkei on November 12, 2013, the Company assumed convertible promissory notes held by certain stockholders with a principal amount of €518,519. The convertible promissory notes were converted on July 7, 2014 at the IPO price of $6.00 per share into 352,000 shares of the Company's common stock.

Financial Overview

Presentation

On November 12, 2013, we merged with Sonkei, in order to acquire Sonkei's lead product candidate, MIN-117. The results of Sonkei are included in our accompanying financial statements commencing as of November 12, 2013.

On February 11, 2014, we acquired Mind-NRG in order to acquire Mind-NRG's lead product candidate, MIN-301. The results of Mind-NRG are included in our accompanying financial statements beginning February 11, 2014.

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.

Research and Development Expense

Research and development expense 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, bonuses and stock-based compensation granted to consultants in research and development functions.

We expense research and development costs as they are incurred, and Sonkei and Mind-NRG also expensed research and development costs as incurred. The historic direct costs relating to each of our product candidates are summarized as follows (in thousands):

	Years Ended December 31,	
	2014	2013
MIN-101 [1]	$3,693	$706
MIN-117 [2]	583	472
MIN-202 [3]	24,409	—
MIN-301 [4]	843	1,218
	$29,528	$2,396

[1] The expense for the year ended December 31, 2014 and 2013 excludes non cash stock-based compensation expense.
[2] The expense for the year ended December 31, 2013 was derived from a combination of Sonkei's unaudited financial statements up to the date of the Sonkei merger, and our financial statements subsequent to the Sonkei merger. The expense for the year ended December 31, 2014 is from our financial statements for the year ended December 31, 2014.
[3] The expense for the year ended December 31, 2014 includes a $22.0 million license fee paid to Janssen which has no alternative future use.
[4] The research and development expense for MIN 301 for the year ended December 31, 2013 was derived from the Mind NRG audited financial statements, as converted in U.S. dollars using the average exchange rate over the periods presented, which was 1.328 for the year ended December 31, 2013. Mind NRG had historically reported its financial results in Euros. As a result of the acquisition of Mind NRG by us in February 2014, the functional currency of Mind NRG changed to the U.S. Dollar and exchange rate gains and losses have been included in the results of operations. The expense for the year ended December 31, 2014 was derived from a combination of Mind NRG's unaudited financial statements up to the date of the Mind NRG acquisition, as converted in U.S. dollars using the average exchange rate of 1.1076, and our financial statements subsequent to the Mind NRG acquisition.

In the future, we expect research and development expense to consist of the items described above as well as expense incurred in performing research and development activities, including compensation and benefits for full-time

research and development employees and facilities expenses. These costs may also include non-cash stock-based compensation expense as part of our compensation strategy to attract and retain qualified staff. We expect research and development expense to be our largest category of operating expense and to increase as we continue our planned pre-clinical and clinical trials for our product candidates. Please see “Business — Our Pipeline” for additional details regarding our current plan for progressing clinical trials of our product candidates.

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 consulting and professional services costs for functions in executive, finance, business development, legal, auditing and taxes. Historically, substantially all of these services were provided by third party consultants, as none of the three former companies had employees prior to October 2013. Our general and administrative expense in 2014 and 2013 also includes stock based compensation expense with respect to option and warrant grants to such consultants and employees hired and directors who joined our board subsequent to October 2013. Other costs primarily include salaries, bonuses, facility costs and professional fees for accounting, consulting and legal services.

In the future, we expect general and administrative expenses to consist primarily of salaries and related benefits, including stock based compensation, facility costs, information technology, travel expenses and professional fees for auditing, tax and legal services. Other general and administrative expenses include allocated facility related costs not otherwise included in research and development expenses, travel expenses and professional fees for auditing, tax and legal services.

We expect that general and administrative expenses will increase as a result of the acquisition of Mind NRG and licensing MIN 202 from Janssen. We also expect to incur greater expenses relating to our operations as a public reporting company, including increased payroll and increased consulting, legal and compliance, accounting, insurance and investor relations costs.

Foreign Exchange (Gains) (Losses) and Other, Net

Foreign exchange gains (losses) and other, net has been primarily comprised of interest income and foreign currency exchange gains or losses resulting from clinical trial expenses denominated in Euros and Swiss Francs. We also incurred interest expense on the convertible promissory notes issued by us in November 2013 and assumed by us in the Sonkei merger as well as the debt assumed in connection with the Mind NRG acquisition. These notes and the accrued interest converted into common stock upon the closing of our initial public offering.

Other than general and administrative expenses and interest expense, we have incurred certain expenses in Euros and Swiss Francs, including research and development expenses. Since planned clinical trials are expected to be in Europe, we expect to continue to incur future expenses in Euros. We record expenses 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.

Net Operating Losses and Tax Carryforwards

As of December 31, 2014, we had approximately $26.4 million of federal net operating loss carryforwards. These federal net operating loss carryforwards will begin to expire at various dates beginning in 2027, if not utilized. As of December 31, 2014, we had approximately $21.4 million of state net operating loss carryforwards. These state net operating loss carryforwards will begin to expire at various dates beginning in 2015, if not utilized.

The Internal Revenue Code, or IRC, limits the amounts of net operating loss carryforwards that a company may use in any one year in the event of certain cumulative changes in ownership over a three year period as described in Section 382 of the IRC. We have not performed a detailed analysis to determine whether an ownership change occurred upon consummation of the merger between us and Sonkei or the acquisition of Mind NRG. However, as a result of these transactions, our initial public offering and the shares issued to JJDC and shareholders of Mind NRG as part of the private placements consummated concurrently with our initial public offering, it is likely that an ownership change would occur or has occurred. Such an ownership change could also be triggered by subsequent sales of securities by us or our stockholders. Such a change in ownership would limit the utilization of our net operating losses. As a result, we may not be able to take full advantage of these tax carryforwards for federal tax purposes.

Costs Associated with the Acquisitions and Financings

We incurred legal and other professional fees associated with the acquisition of Sonkei and Mind NRG, which costs are expensed as incurred. We also incurred professional fees associated with entering into the co development and licensing agreement with Janssen and engaging valuation specialists.

On November 12, 2013, Cyrenaic Pharmaceuticals, Inc., or Cyrenaic, merged with Sonkei, with Cyrenaic being the surviving company, which was renamed Minerva. In the merger, each share of Sonkei common stock was converted into 0.383 shares of Cyrenaic common stock, resulting in the issuance of 2,423,368 shares of Cyrenaic common stock to the former Sonkei stockholders. Although there were certain venture funds that were common stockholders of each of Sonkei and Cyrenaic, since the underlying investors in the venture funds were not "substantially similar", the merger was accounted for a business combination with Cyrenaic being treated as the acquirer. The results of Sonkei are included in our accompanying financial statements commencing November 12, 2013. We merged with Sonkei in order to acquire Sonkei's lead product candidate, MIN 117.

At the date of the merger, a Sonkei consultant held 1,112,500 shares of Sonkei common stock with a nonrecourse note due to Sonkei, which was being treated as a stock option for accounting purposes. In connection with the merger, we issued 426,176 shares of common stock to this consultant (discussed further in Note 9 — Stockholders' Equity to our December 31, 2014 financial statements appearing elsewhere in this Form 10-K) in order to replace the holder's common stock in Sonkei. Due to the nonrecourse note, these shares were treated as stock options for accounting purposes and the holder of the option could only vest in the stock options if the holder continues to provide services to us through the time of a change in control. As a change in control was not deemed probable as of the merger date, the value of the options was not included as part of the consideration transferred in the merger for accounting purposes. Rather, we recognized all of the compensation expense for these stock options in our statement of operations upon the closing of our initial public offering. The merger accounting purchase price was therefore determined based upon the remaining 1,997,192 shares of common stock issued in the merger at a valuation of $9.49 per share for a total purchase price of approximately $18.9 million. Merger expenses of $14 thousand were included in general and administrative expenses for the year ended December 31, 2013.

The fair value of our common stock issued in the merger was determined based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector, discounted cash flows and the likelihood of achieving a liquidity event, such as an initial public offering of common stock or our sale. Substantially all of the purchase price was allocated to in process research and development and goodwill. As part of the acquisition, we assumed $0.7 million of convertible notes, which were converted into 352,000 shares of our common stock on July 7, 2014 at our initial public offering price of $6.00 per share.

We acquired Mind NRG in February 2014, and the fair value of the 1,481,583 shares of common stock issued to the stockholders of Mind NRG was approximately $16.5 million. The fair value of the common shares issued and the allocation of the purchase price was based upon our valuation of our common stock as approved by our board of directors. Substantially all of the purchase price was allocated to in process research and development and goodwill. In connection with the acquisition, we entered into loan agreements for working capital up to a maximum of $0.6 million. The Mind NRG loans had an interest rate of 8% per annum, added to the principal. The Mind NRG loans, including accrued interest, were repaid in full in April 2014 for $0.5 million. We subsequently entered into two loan agreements for $0.6 million and $1.0 million, the April Bridge Loan and the May Bridge Loan, respectively. The April Bridge Loan and May Bridge Loan each had an interest rate of 8% per annum and were repaid in full out of the proceeds of our initial public offering. As part of the Mind NRG Acquisition, we also paid ProteoSys a final license payment of €0.5 million (or $0.7 million, as converted) upon the closing of our initial public offering.

Results of Operations

Comparison of the Years Ended December 31, 2014 and December 31, 2013 (in thousands)

	Years ended December 31,	
	2014	2013
Expenses		
Research and development	$42,909	$708
General and administrative	11,962	2,467
Total expenses	54,871	3,175
Loss from operations	(54,871)	(3,175)
Foreign exchange gains (losses)	19	(29)
Interest (expense) income	(2,050)	(58)
Net loss	$(56,902)	$(3,262)

Research and Development Expenses

Research and development expenses were $42.9 million for the year ended December 31, 2014 compared to $0.7 million for the same period in 2013, an increase of $42.2 million. The increase was primarily due to a $22.0 million license fee paid to Janssen pursuant to our co-development agreement for MIN-202 which has no alternative future use, $13.1 million in stock-based compensation expense, $3.0 million in higher development costs related to MIN-101 and $2.4 million in program costs related to MIN-202. Stock-based compensation expense for 2014 includes $10.5 million of expense associated with previously issued shares of restricted common stock, the vesting of which became probable upon our initial public offering.

General and Administrative Expenses

General and administrative expenses were $12.0 million for the year ended December 31, 2014 compared to $2.5 million for the same period in 2013, representing an increase of approximately $9.5 million. The increase was primarily due to $4.5 million in stock-based compensation expense, $0.7 million in higher legal and professional fees, and $4.3 million related to staffing, office leases and information systems necessary to support our operations as a public company.

Foreign Exchange Gains (Losses)

Foreign exchange gains were $19 thousand for the year ended December 31, 2014 compared to a loss of $29 thousand for the same period in 2013. The increase in foreign currency gains was principally due to certain expenses of Mind-NRG and certain clinical activities being denominated in Swiss Francs and Euros, with more positive currency movements in 2014.

Interest Expense, net

Interest expense was approximately $2.1 million for the year ended December 31, 2014 as compared to $58 thousand for the same period in 2013. For the year ended December 31, 2014, we recognized interest expense of approximately $2.0 million related to convertible promissory notes that were converted into 352,000 shares of our common stock in connection with our initial public offering, comprised primarily of the amortization of the debt discount created upon the allocation of proceeds to the beneficial conversion feature of the notes and $82 thousand in coupon interest. For the year ended December 31, 2014, we also recorded $16 thousand in interest expense related to our 8% short-term working capital loans.

Liquidity and Capital Resources

As of December 31, 2014, we had approximately $18.5 million in cash and cash equivalents. In connection with our initial public offering and concurrent private placements in July 2014, we received gross proceeds of approximately $55.0 million. Prior to our initial public offering, we had funded our operations through private placements of common stock and convertible promissory notes, which converted into shares of our common stock in connection with our initial public offering.

Our principal uses of cash have been to fund our operations and to pay licensing fees. In July 2014, we used $22.0 million of cash to pay fees due to Janssen in connection with our license agreement for MIN-202. We have incurred losses and cumulative negative cash flows from operations since our inception in April 2007 and, as of December 31, 2014, we had an accumulated deficit of approximately $74.7 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 incur additional costs to support our operations as a public company.

Sources of Funds

On March 18, 2015, pursuant to a securities purchase agreement with certain accredited investors dated March 13, 2015, we sold in a private placement 6,281,661 shares of our common stock at a price per share of $4.81 and warrants to purchase up to an aggregate of 6,281,661 shares of common stock at a purchase price of $0.125 per warrant share, with an initial exercise price of $5.772 per share. We received net proceeds of approximately $28.8 million, after deducting placement agent fees. The warrants will expire on March 18, 2017, two years after the date on which they were initially issued.

On January 16, 2015, we entered into a Loan and Security Agreement with Oxford Finance LLC and Silicon Valley Bank, providing for term loans to us in an aggregate principal amount of up to $15 million, in two tranches. We drew down the initial term loans in the aggregate principal amount of $10 million, which we refer to as the Term A Loan, on January 16, 2015. The Term A Loan bears interest at a fixed rate of 7.05% per annum. On or prior to March 31, 2016, we may borrow additional term loans, which we refer to as the Term B Loan, in the aggregate principal amount up to $5 million, subject to the satisfaction of certain borrowing conditions, including our achievement of primary endpoints on our Phase IIa trials for our MIN-117 and MIN-202 programs. The Term B Loans will bear interest at a fixed rate per annum of the greater of (i) 7.05% or (ii) the sum of (a) the prime rate reported in The Wall Street Journal three (3) business days prior to the funding date of the Term B Loan, plus (b) 3.80%.

While any amounts are outstanding under this credit facility, we are subject to a number of affirmative and restrictive covenants, including covenants regarding delivery of financial statements, maintenance of inventory, payment of taxes, maintenance of insurance, dispositions of property, business combinations or acquisitions, incurrence of additional indebtedness and transactions with affiliates, among other customary covenants. We are also restricted from paying dividends or making other distributions or payments on our capital stock, subject to limited exceptions.

Our obligations under the Loan and Security Agreement are secured by a first priority security interest in substantially all of our assets, other than our intellectual property. We have also agreed not to pledge or otherwise encumber our intellectual property assets, except that we may grant certain exclusive and non-exclusive licenses of our intellectual property as set forth in the Loan and Security Agreement. In addition, we pledged all of our equity interests in Minerva Neurosciences Securities Corporation and 65% of our equity interests in Mind-NRG as security for its obligations under the Loan and Security Agreement.

Upon the occurrence of certain events, including but not limited to our failure to satisfy our payment obligations under the Loan and Security Agreement, the breach of certain of our other covenants under the Loan and Security Agreement, or the occurrence of a material adverse change, the lenders will have the right, among other remedies, to declare all principal and interest immediately due and payable, and will have the right to receive a final payment fee of 4.45% (or, if the interest-only period is extended, 5.10%) of the total amount borrowed and, if the payment of principal and interest is due prior to maturity, a prepayment fee.

We believe, based on our current operations, that our cash and cash equivalents, borrowings available under our credit facility and the proceeds from our March 2015 private placement will be sufficient to fund our operations through the end of 2016.

Uses of Funds

To date, we have not generated any revenue. We do not know when, or if, we will generate any revenue from sales of our products or royalty payments from our collaboration with Janssen. 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 incur additional 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.

We anticipate that we will need substantial additional funding in connection with our continuing operations and to fund Phase III clinical trials of our lead product candidates.

Our future capital requirements will depend on many factors, including:

- the progress, costs, results and timing of our clinical trials;
- the outcome, costs and timing of seeking and obtaining EMA, FDA and any other regulatory approvals;
- the willingness of the FDA or other regulatory agencies outside the European Union to accept our trial data, as well as our other completed and planned clinical and non clinical studies and other work, as the basis for review and approval of our product candidates in the United States;

- the number and characteristics of product candidates that we pursue, including our product candidates in pre clinical development;
- the ability of our product candidates to progress through clinical development successfully;
- our need to expand our research and development activities;
- the costs associated with securing and establishing commercialization and manufacturing capabilities;
- market acceptance of our product candidates;
- the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;
- our ability to 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 the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional management and scientific and medical personnel;
- the effect of competing technological and market developments;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future.

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. If we are unable to obtain additional financing, future operations would need to be scaled back or discontinued. Based on our current operating plan, existing cash, the proceeds from our term loan and the March 2015 private placement, we expect to be able to fund our operations through the end of 2016.

Cash Flows

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

Comparison of the Years Ended December 31, 2014 and December 31, 2013

	Years ended December 31,	
	2014	2013
	(dollars in millions)	
Net cash provided by (used in):		
Operating activities	$ (36.0)	$ (2.2)
Investing activities	1.1	—
Financing activities	51.6	3.8
Net increase in cash	$ 16.7	$ 1.6

Net Cash Used in Operating Activities

Net cash used in operating activities of approximately $36.0 million during the year ended December 31, 2014 was due primarily to our net loss of $56.9 million, partially offset by stock-based compensation expense of $18.0 million, amortization of debt discount interest expense of $2.0 million and a $1.7 million increase in accounts payable and accrued expenses. The net loss included a $22.0 million license fee paid to Janssen pursuant to our co-development agreement for MIN-202.

Net cash used in operating activities of $2.2 million during the year ended December 31, 2013 was primarily a result of our net loss of $3.3 million, partially offset by stock-based compensation and changes in working capital.

Net Cash Provided by Investing Activities

Net cash provided by investing activities for the year ended December 31, 2014 primarily consisted of cash acquired in February 2014 in conjunction with the Mind-NRG Acquisition.

Net Cash Provided by Financing Activities

Net cash provided by financing activities of $51.6 million during year ended December 31, 2014 was due to the proceeds from our initial public offering and private placements of $55.0 million, partially offset by initial public offering costs paid during the period of $3.4 million.

Net cash provided by financing activities of $3.8 million during the year ended December 31, 2013 was due to the proceeds from the sale of common stock and the proceeds from the issuance of convertible promissory notes.

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.

Stock-Based Compensation

We established our stock option plan in the fourth quarter of 2013, and we amended and restated our stock option plan in the second quarter of 2014. The amended and restated plan provides for the issuance of up to 4,281,333 shares of common stock, subject to automatic annual increases pursuant to the terms of the plan, each to be issued at the then

fair value of our underlying common stock.

We recognize compensation expenses relating to stock-based payment transactions in operating results using a fair-value measurement method, in accordance with ASC Topic 718 Compensation-Stock Compensation. ASC-718 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. We determine 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, expected forfeiture rate and expected life of the options.

Grants to non-employees are accounted for in accordance with ASC Topic 505-50 Equity — Based Payments to Non-Employees. The date of expense recognition 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. We determine 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 and the fair value of each unvested award is adjusted at the end of each period for any change in fair value from the previous valuation until the award vests.

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. 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 expected 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.

In July 2014, we paid a $22.0 million license fee, which has been included as a component of research and development expense since the licensed rights were not deemed to have an alternative future use. We accounted for the co-development and license agreement pursuant to which the license fee was paid as a joint risk-sharing collaboration in accordance with ASC Topic 808, Collaboration Arrangements. Costs between us and the licensor with respect to each party's share of development costs that have been incurred pursuant to the joint development plan are recorded within research and development expense or general and administrative expense, as applicable, due to the joint risk-sharing nature of the activities.

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 fair value 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 make estimates of our accrued 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.

Business Combinations

For business combinations, we utilize the acquisition method of accounting in accordance with ASC Topic 805, Business Combinations. These standards require that the total cost of an acquisition be allocated to the tangible and intangible assets acquired and liabilities assumed based their respective fair values at the date of acquisition. The allocation of the purchase price is dependent upon certain valuations and other studies. Acquisition costs are expensed as incurred. We recognize separately from goodwill the fair value of assets acquired and the liabilities assumed. Goodwill as of the acquisition date is measured as the excess of consideration transferred and the acquisition date fair values of the assets acquired and liabilities assumed. While we use our best estimates and assumptions as a part of the purchase price allocation process to accurately value assets acquired and liabilities assumed at the acquisition date, our estimates are subject to refinement. As a result, during the measurement period, which may be up to one year from the acquisition date, we may retroactively record adjustments to the fair value of the assets acquired and liabilities assumed, with the corresponding offset to goodwill. Upon the conclusion of the measurement period or final determination of the fair value of assets acquired or liabilities assumed, whichever comes first, any subsequent adjustments are recorded to our consolidated statements of operations.

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 implied 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. The Company tested its goodwill for impairment as of November 30. There was no impairment of goodwill for the years ended December 31, 2014 and 2013.

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. In other words, an “emerging growth company” can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non emerging growth public companies. We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an “emerging growth company,” we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes Oxley Act of 2002, as amended, and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, known as the auditor discussion and

analysis. We will remain an “emerging growth company” until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission.

Recent Accounting Pronouncements

In June 2014 the Financial Accounting Standards Board (FASB) issued Accounting Standards Update 2014-10 Development Stage Entities (Topic 915) Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities. The amendments in this Update 2014-10 removed the definition of a development stage entity from the Master Glossary of the Accounting Standards Codification, thereby removing the financial reporting distinction between development stage entities and other reporting entities from U.S. GAAP. In addition, the amendments eliminated the requirements for development stage entities to (1) present inception-to-date information in the statements of income, cash flows, and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is

engaged and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. The Company early adopted this amendment in 2014.

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

Minerva Neurosciences, Inc.

We have audited the accompanying consolidated balance sheets of Minerva Neurosciences, Inc. and subsidiaries (the "Company") as of December 31, 2014 and 2013, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Minerva Neurosciences, Inc. and subsidiaries as of December 31, 2014 and 2013, and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ Deloitte & Touche LLP

Parsippany, New Jersey

March 26, 2015

MINERVA NEUROSCIENCES INC.

Consolidated Balance Sheets

	December 31, 2014	December 31, 2013
Assets		
Current assets		
Cash and cash equivalents	$18,545,702	$1,818,317
Restricted cash	35,014	—
Prepaid expenses	756,979	852
Total current assets	19,337,695	1,819,169
Equipment, net	43,446	3,232
In-process research and development	34,200,000	19,000,000
Goodwill	14,869,399	7,918,387
Deferred public offering costs	—	433,998
Total assets	$68,450,540	$29,174,786
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$641,813	$522,981
Accrued expenses and other current liabilities	1,645,258	815,239
Accrued collaborative expenses	1,222,420	—
Convertible promissory notes	—	58,270
Derivative liability	—	10,093
Total current liabilities	3,509,491	1,406,583
Deferred taxes	13,433,760	7,588,600
Other noncurrent liabilities	7,694	—
Total liabilities	16,950,945	8,995,183
Commitments and contingencies		
Stockholders' equity		
Preferred stock; $.0001 par value; 100,000,000 shares authorized; none issued or outstanding as of December 31, 2014 and 2013, respectively	—	—
Common stock; $.0001 par value; 125,000,000 shares authorized; 18,439,482 and 6,112,738 shares issued and outstanding as of December 31, 2014 and 2013, respectively	1,844	611
Additional paid-in capital	126,228,981	38,008,783
Accumulated deficit	(74,731,230)	(17,829,791)
Total stockholders' equity	51,499,595	20,179,603
Total liabilities and stockholders' equity	$68,450,540	$29,174,786

See accompanying notes to the consolidated financial statements.

MINERVA NEUROSCIENCES INC.

Consolidated Statements of Operations

	Year Ended December 31,	
	2014	2013
Expenses		
Research and development	$42,908,566	$708,489
General and administrative	11,961,865	2,466,490
Total expenses	54,870,431	3,174,979
Loss from operations	(54,870,431)	(3,174,979)
Foreign exchange gains (losses)	18,727	(28,977)
Interest (expense) income	(2,049,735)	(58,049)
Net loss	$(56,901,439)	$(3,262,005)
Net loss per share, basic and diluted	$(4.47)	$(0.78)
Weighted average shares outstanding, basic and diluted	12,724,395	4,186,104

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 December 31, 2012	3,562,454	$ 356	$ 14,586,449	$(14,567,786)	$ 19,019
Sale of common stock for cash at $3.50 per share	528,576	53	1,849,947	—	1,850,000
Issuance of shares for business acquisition	1,997,192	200	18,943,166	—	18,943,366
Beneficial conversion feature--convertible debt	—	—	1,973,500	—	1,973,500
Issuance of common stock to a consultant	24,516	2	232,532	—	232,534
Stock-based compensation	—	—	423,189	—	423,189
Net loss	—	—	—	(3,262,005)	(3,262,005)
Balances at December 31, 2013	6,112,738	611	38,008,783	(17,829,791)	20,179,603
Issuance of shares for business acquisition	1,481,583	148	16,541,686	—	16,541,834
Issuance of common stock pursuant to an initial public offering and concurrent private placements, net of issuance costs	9,566,557	956	51,600,030	—	51,600,986
Vesting of common shares issued	926,604	93	10,542,577	—	10,542,670
Stock-based compensation	—	—	7,423,941	—	7,423,941
Conversion of debt and interest to common stock	352,000	36	2,111,964	—	2,112,000
Net loss	—	—	—	(56,901,439)	(56,901,439)
Balances at December 31, 2014	18,439,482	$ 1,844	$ 126,228,981	$(74,731,230)	$ 51,499,595

See accompanying notes to the consolidated financial statements.

MINERVA NEUROSCIENCES, INC.

Consolidated Statements of Cash Flows

	Year ended December 31,	
	2014	2013
Cash flows from operating activities:		
Net loss	$(56,901,439)	$(3,262,005)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	33,869	—
Amortization of debt discount recorded as interest expense	1,952,309	36,231
Stock-based compensation expense	17,966,611	655,723
Unrealized foreign exchange loss	—	22,039
Change in fair value of derivative	(10,093)	117
Changes in operating assets and liabilities		
Prepaid expenses	(713,200)	8,143
Accounts payable	368,698	522,981
Accrued expenses and other liabilities	112,285	(143,472)
Accrued collaborative expenses	1,222,420	—
Other noncurrent liabilities	7,694	—
Net cash used in operating activities	(35,960,846)	(2,160,243)
Cash flows from investing activities:		
Cash acquired in business combination	1,167,869	—
Restricted cash	(35,014)	—
Purchases of equipment	(45,609)	(3,232)
Net cash provided by investing activities	1,087,246	(3,232)
Cash flows from financing activities:		
Cash acquired in business merger	—	631,478
Proceeds from issuance of convertible promissory notes	—	1,300,000
Proceeds from working capital loans	1,882,817	—
Repayments of working capital loans	(1,882,817)	—
Proceeds from sales of common stock in initial public offering	31,334,702	—
Proceeds from sales of common stock in private placements	23,706,118	1,850,000
Fees paid in connection with private placements	(280,000)	—
Public offering costs paid	(3,159,835)	—
Net cash provided by financing activities	51,600,985	3,781,478
Net increase in cash and cash equivalents	16,727,385	1,618,003
Cash and cash equivalents		
Beginning of period	1,818,317	200,314
End of period	$18,545,702	$1,818,317
Supplemental disclosure of noncash investing and financing activities		
Common stock issued as consideration for business combination	$16,541,834	$18,943,366
Plus liabilities assumed:		
Accrued expenses and other	321,417	334,423
ProteoSys milestone payable	681,600	—
Deferred tax liability	5,970,560	7,588,600

Convertible promissory notes	—	680,000
Derivative liability	—	3,476
Less assets acquired:		
Prepaid expenses	42,926	—
Equipment	28,204	—
In-process research and development	15,200,000	19,000,000
Goodwill	7,076,412	7,918,387
Cash acquired in business merger	$1,167,869	$631,478
Deferred public offering costs included in accrued expenses and other liabilities	$—	$433,998
Beneficial conversion feature	$—	$1,973,500
Cash paid for interest	$15,233	$—
Conversion of debt and interest to common stock	$2,112,000	$—

See accompanying notes to the consolidated financial statements.

MINERVA NEUROSCIENCES, INC.

Notes To Consolidated Financial Statements

December 31, 2014 and 2013

NOTE 1 — NATURE OF OPERATIONS AND LIQUIDITY

Nature of Operations

Minerva Neurosciences, Inc. ("Minerva" or the "Company"), formerly known as Cyrenaic Pharmaceuticals Inc. ("Cyrenaic") was incorporated on April 23, 2007. The Company is a biopharmaceutical company focused on the development of an experimental drug for the treatment of schizophrenia (discussed further in Note 6 — License Agreement). On November 12, 2013, Sonkei Pharmaceuticals, Inc. ("Sonkei"), a biopharmaceutical company focused on the development of an experimental drug for the treatment of depression and an affiliated company through certain common ownership, was merged into Cyrenaic with Cyrenaic being the surviving company. Subsequent to the merger, Cyrenaic changed its name to Minerva Neurosciences, Inc. In 2014 the Company formed Minerva Neurosciences Securities Corporation, a wholly-owned subsidiary.

On February 11, 2014, the Company acquired Mind-NRG (discussed further in Note 3 — Business Combinations). Mind-NRG is a Swiss development stage biopharmaceutical company focused on the development and commercialization of an experimental drug for the treatment of Parkinson's disease. The Company acquired 100% of the share capital of Mind-NRG largely to obtain the intellectual property estate which underpins Mind-NRG's lead product candidate, renamed MIN-301.

On February 12, 2014, subject to the completion of an initial public offering ("IPO"), the Company entered into a co-development and license agreement (discussed further in Note 8 — Co-Development and License Agreement) pursuant to which the licensor granted the Company an exclusive license, in certain territories, under 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, or MIN-202, for any use in humans. The license became effective on July 7, 2014 at the closing of the IPO and the payment of the $22.0 million license fee was made at that date.

Going Concern

The Company has limited capital resources and has incurred recurring operating losses and negative cash flows from operations since inception. As of December 31, 2014, the Company has an accumulated deficit of approximately $74.7 million. Management expects to continue to incur operating losses and negative cash flows from operations. The Company has financed its business to date from proceeds from the sale of common stock, loans and convertible promissory notes. On July 7, 2014, the Company sold shares in an IPO and two private placements resulting in proceeds to the Company of approximately $55.0 million.

In January 2015 the Company entered into a loan and security agreement and drew down on $10.0 million in term loans. In March 2015 the Company closed the sale of 6,281,661 shares of common stock and warrants to purchase an equal number of shares of common stock in a private placement resulting in net proceeds to the Company of $28.8 million (both discussed further in Note 15 – Subsequent Events). The Company believes that based on its operating plan, cash on hand at December 31, 2014 and the proceeds from the term loans and the private placement in March 2015 will be sufficient to fund the Company's operations through the end of 2016.

The Company will need to raise additional capital in order to continue to fund operations and fully fund its clinical development programs. The Company believes that it will be able to obtain additional working capital through equity financings or other arrangements to fund 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.

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 financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

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 SA 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.

Prior to the Company's IPO, the Company utilized significant estimates and assumptions in determining the fair value of its common stock. The board of directors has determined the estimated fair value of the Company's common stock based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector, discounted cash flows and the likelihood of achieving a liquidity event, such as an IPO of common stock or a sale of the Company.

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. 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 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 expected 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 July 2014, the Company paid a $22.0 million license fee, which has been included as a component of research and development expense since the licensed rights were not deemed to have an alternative future use. The Company accounts for the co-development and license agreement pursuant to which the license fee was paid as a joint risk-sharing collaboration in accordance with ASC 808, Collaboration Arrangements. Costs between the Company and the licensor with respect to each party’s share of development costs that have been incurred pursuant to the joint development plan are recorded within research and development expense or general

and administrative expense, as applicable, in the accompanying consolidated financial statements due to the joint risk-sharing nature of the activities. The Company has included $1.2 million in accrued expenses as of December 31, 2014 related to this agreement.

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 fair value 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, 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 IPR&D for the years ended December 31, 2014 and 2013.

Stock-based compensation

The Company recognizes compensation cost relating to stock-based payment transactions in operating results using a fair-value measurement method, in accordance with ASC Topic 718 Compensation-Stock Compensation. ASC-718 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, expected forfeiture rate and expected life of the options.

Grants to non-employees are accounted for in accordance with ASC Topic 505-50 Equity — Based Payments to Non-Employees. The date of expense recognition 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 and the fair value of each unvested award is adjusted at the end of each period for any change in fair value from the previous valuation until the award vests.

Prior to the IPO, the Company utilized various valuation methodologies in accordance with the framework of the 2013 American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation, to estimate the fair value of its common stock. The methodologies included a probability-weighted expected return methodology that determined an estimated value under an IPO scenario and a sale scenario based upon an assessment of the probability of occurrence of each scenario. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates include assumptions regarding future performance, including the successful completion of preclinical studies and clinical trials and the time to complete an IPO or sale.

Foreign currency transactions

The Company’s functional currency is the US dollar. The Company pays certain vendor invoices in the respective foreign currency. The Company records an expense in US 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.

Loss per share

Basic loss per share excludes dilution and is computed by dividing net loss by the weighted-average number of shares of common stock outstanding for the period. Diluted 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.

Income taxes

The Company utilizes the liability method of accounting for income taxes as required by FASB ASC Topic 740 Income Taxes. Under this method, 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 in accordance with this topic 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.

ASC Topic 740 also clarifies the accounting for uncertainty in income taxes recognized in the financial statements. The interpretation prescribes 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. ASC Topic 740 provides guidance on the recognition of interest and penalties related to income taxes. There was no interest or penalties related to income taxes for the years ended December 31, 2014 and 2013. The Company has elected to treat interest and penalties, to the extent they arise, as a component of income taxes. Income tax years beginning in 2011 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 and cash equivalents. 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 credit risk is reduced by placing such deposits with major financial institutions and monitoring their credit ratings.

Cash and cash equivalents

The Company considers all highly liquid investments with original maturities of three months or less to be cash equivalents.

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.

Deferred public offering costs

Deferred public offering costs included certain legal, accounting and other costs directly attributable to the Company’s proposed public offering of common stock. Upon completion of the initial public offering in 2014, these amounts were offset against the proceeds of the offering.

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, 2014 and 2013.

Business Combinations

For business combinations, the Company utilizes the acquisition method of accounting in accordance with ASC Topic 805, Business Combinations. These standards require that the total cost of an acquisition be allocated to the tangible and intangible assets acquired and liabilities assumed based their respective fair values at the date of acquisition. The allocation of the purchase price is dependent upon certain valuations and other studies. Acquisition costs are expensed as incurred. The Company recognizes separately from goodwill the fair value of assets acquired and the liabilities assumed. Goodwill as of the acquisition date is measured as the excess of consideration transferred and the acquisition date fair values of the assets acquired and liabilities assumed. While the Company uses its best estimates and assumptions as a part of the purchase price allocation process to accurately value assets acquired and liabilities assumed at the acquisition date, the Company’s estimates are subject to refinement. As a result, during the measurement period, which may be up to one year from the acquisition date, the Company may retroactively record adjustments to the fair value of the assets

acquired and liabilities assumed, with the corresponding offset to goodwill. Upon the conclusion of the measurement period or final determination of the fair value of assets acquired or liabilities assumed, whichever comes first, any subsequent adjustments are recorded to the Company's consolidated statements of operations.

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 implied 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, 2014 and 2013.

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 table presents information about the Company's derivative liability as of December 31, 2013 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, 2013			
In thousands	Total	Level 1	Level 2	Level 3
Derivative liability:	$10.0	$ —	$ —	$ 10.0

The derivative liability ceased upon the conversion of the convertible promissory notes into common stock in July 2014. The carrying amounts of cash, cash equivalents, accounts payable and accrued liabilities approximate fair value because of their short-term nature.

Convertible Promissory Notes

The Company's convertible promissory notes at December 31, 2013 consisted of (i) $1.3 million face value convertible promissory notes, plus accrued interest of $15,671 and (ii) €518,519 face value convertible promissory notes, plus accrued interest of $8,605. The Euro denominated notes were acquired in conjunction with the merger with Sonkei (discussed further in Note 3 — Business Combinations), and recorded at their fair value of $680,000 on the date of the merger. At December 31, 2013, the fair market value of the convertible promissory notes was approximately $2.0 million. The carrying value of the convertible promissory notes at December 31, 2013 was $58,270, as a result of the beneficial conversion feature recorded at initial recognition as a debt discount.

Discount Purchase Option

The Company's 8% convertible promissory notes contained an embedded derivative related to the conversion option containing a discount purchase feature in a qualified financing, as defined. The derivative is carried at fair value and is classified as Level 3 in the fair value hierarchy due to the use of significant unobservable inputs. The initial fair value of the derivative liability at the date of issuance in November 2013 was determined to be $9,976 using a probability-weighted valuation model applying the following

assumptions: (i) discount rate of 8.0%, (ii) remaining term of approximately 7 months and (iii) the probabilities of conversion under various circumstances as at the date of measurement.

As of December 31, 2013, the fair value of the derivative liability was determined to be $10,093 using a probability-weighted valuation model applying the following assumptions: (i) discount rate of 8.0%, (ii) remaining term of approximately 6 months and (iii) the probabilities of conversion under various circumstances as at the date of measurement. The $117 increase in the fair value of the derivative liability was recognized in interest expense as a loss on change in fair value of derivative liability for the year ended December 31, 2013.

$3.50/€3.50 Conversion Option

The Company's 8% convertible promissory notes contained a beneficial conversion feature. The intrinsic value of the beneficial conversion feature was calculated by measuring the difference between the effective conversion price and the fair value of common stock at initial recognition. The Company recorded a debt discount for the fair value of the derivative, which was limited to the proceeds received of approximately $2.0 million, with an offsetting increase to additional paid-in capital. The beneficial conversion charge has been included in the balance sheet at December 31, 2013 as a discount to the related convertible promissory notes. The discount was accreted as non-cash interest expense over the expected term of the debt (June 30, 2014) using the effective interest method, which totaled $2.0 million and $36,231 for the years ended December 31, 2014 and 2013, respectively.

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.

Recent Accounting Pronouncements

In June 2014 the Financial Accounting Standards Board (FASB) issued Accounting Standards Update 2014-10 Development Stage Entities (Topic 915) Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities. The amendments in this Update 2014-10 removed the definition of a development stage entity from the Master Glossary of the Accounting Standards Codification, thereby removing the financial reporting distinction between development stage entities and other reporting entities from U.S. GAAP. In addition, the amendments eliminated the requirements for development stage entities to (1) present inception-to-date information in the statements of income, cash flows, and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. The Company adopted this pronouncement in 2014 and has eliminated the above mentioned disclosures.

From time to time, new accounting pronouncements are issued by FASB and are adopted by the Company as of the specified effective date. The Company believes that the impact of other recently issued but not yet adopted accounting pronouncements will not have a material impact on the consolidated financial position, consolidated results of operations, and consolidated cash flows, or do not apply to the Company.

NOTE 3 — BUSINESS COMBINATIONS

Mind-NRG

On February 11, 2014, the Company acquired Mind-NRG, a Swiss development stage biopharmaceutical company focused on the development and commercialization of an experimental drug for the treatment of Parkinson's Disease. This transaction was treated as a business combination by the Company. The purchase price was 1,481,583 shares of the Company's common stock with an estimated fair value of $11.17 per share, or approximately $16.5 million. The Company acquired 100% of the share capital of Mind-NRG largely to obtain the intellectual property estate which underpins Mind-NRG's lead product candidate NRG-101, renamed MIN-301.

The fair value of the Company's common stock issued was determined based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector, discounted cash flows and the likelihood of achieving a liquidity event, such as an IPO or a sale of the Company. The purchase price allocation was based upon an analysis of the fair value of the assets and liabilities acquired from Mind-NRG. Identifying the fair value of the tangible and intangible assets and liabilities acquired required the use of estimates by management, and were based upon currently available data, as noted below.

The fair value of current assets and liabilities approximated their book value.

The Company measured the value of the acquired IPR&D using the income approach — multi period excess earnings method and assembled workforce using the cost approach (for contributory asset charge calculations). The multi-period excess earning method measures the present value of the future earnings expected to be generated during the remaining lives of the subject assets.

The Company recorded a deferred tax liability for the difference in the book and tax basis of the IPR&D, multiplied by the effective income tax rate.

The establishment of the fair value of the consideration for an acquisition, and the allocation to identifiable tangible and intangible assets and liabilities requires the extensive use of accounting estimates and management judgment. The fair values assigned to the assets acquired and liabilities assumed are from estimates and assumptions based on data currently available.

The Company allocated the excess of purchase price over the identifiable intangible and net tangible assets to goodwill. The goodwill recorded recognizes the value of the overall development program, including both the current pre-clinical development program in process and the future clinical trial development strategy. Such goodwill is not deductible for tax purposes. The aggregate consideration of $16.5 million has been allocated to assets acquired and liabilities assumed based on estimated fair values at December 31, 2013 as follows:

Cash	$1,167,869
Other assets	71,130
Goodwill	7,076,412
In-process research and development	15,200,000
Deferred tax liability	(5,970,560)
Accrued expenses	(321,417)
ProteoSys milestone payable	(681,600)
	$16,541,834

IPR&D, an indefinite-lived asset, is included as an asset on the Company’s balance sheet until such time that: (i) a marketing approval to commercially sell the drug is received from a regulatory agency, in which case it will be amortized over its expected commercial life, or (ii) such time as the IPR&D is deemed to be impaired, in which case it will be expensed. The transaction is being treated as a stock purchase for income tax purposes and accordingly, the tax bases of Mind-NRG’s assets and liabilities are not adjusted for the effect of purchase accounting.

Sonkei

On November 12, 2013, Cyrenaic merged with Sonkei, with Cyrenaic being the survivor company. Each share of Sonkei common stock was converted into 0.383 shares of Cyrenaic common stock, resulting in the issuance of 2,423,368 shares. There were certain common stockholders between Sonkei and Cyrenaic, however, since the underlying investors in the venture funds were not “substantially similar”, the merger was accounted for as a business combination with Cyrenaic being treated as the acquirer. The results of Sonkei are included in the accompanying financial statements commencing November 12, 2013. The Company merged with Sonkei in order to acquire Sonkei’s lead product candidate, MIN-117.

At the date of the merger, a Sonkei non-employee held 1,112,500 shares of Sonkei common stock with a nonrecourse note due to Sonkei, which was being treated as a stock option for accounting purposes. In connection with the merger, the Company issued 426,176 shares to the holder with a nonrecourse note (discussed further in Note 8 — Stockholders’ Equity) in order to replace the holder’s stock options in Sonkei. Due to the nonrecourse note, these shares of the

Company are treated as stock options for accounting purposes and the holder of the option can only vest in the stock options if the holder continues to provide services to the Company through the time of a change in control, as defined. In summary, the Company issued replacement stock options of the Company for the old Sonkei stock options. As a change in control was not deemed probable as of the merger date, the options were not included as part of the consideration transferred in the merger accounting. Accordingly, the Company will recognize all of the compensation expense for these stock options in the statement of operations once achievement of the performance condition becomes probable. The merger accounting purchase price was therefore determined based upon the common stock shares issued of 1,997,192 at a valuation of $9.49 per common share for a total purchase price of approximately $18.9 million. Merger expenses of $14,000 were included in general and administrative expenses for the year ended December 31, 2013.

The fair value of the Company's common stock issued was determined based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector, discounted cash flows and the likelihood of achieving a liquidity event, such as an IPO or a sale of the Company. The purchase price allocation was based upon an analysis of the fair value of the assets and liabilities acquired from Sonkei. Identifying the fair value of the tangible and intangible assets and liabilities acquired required the use of estimates by management, and were based upon currently available data, as noted below.

- The fair value of current assets and liabilities approximated their book value.

The fair value of the convertible promissory notes was determined based upon a number of factors including (i) interest rate, (ii) creditworthiness of the Company, (iii) the applicable foreign exchange rate and (iv) the conversion features (described in Note 7 — Convertible Promissory Notes). The face amount of the note acquired is €518,519 (approximately $0.7 million at November 12, 2013).

The Company measured the value of the acquired IPR&D using the income approach — multi period excess earnings method and assembled workforce using the cost approach (for contributory asset charge calculations). The multi-period excess earning method measures the present value of the future earnings expected to be generated during the remaining lives of the subject assets.

The Company recorded a deferred tax liability for the difference in the book and tax basis of the IPR&D, multiplied by the effective income tax rate.

The Company allocated the excess of purchase price over the identifiable intangible and net tangible assets to goodwill. The goodwill recorded recognizes the synergies and value of the overall combined development programs, both the current pre-clinical development program in process and the future clinical trial development strategy. Such goodwill is not deductible for tax purposes. The aggregate consideration of $18.9 million has been allocated to assets acquired and liabilities assumed based on estimated fair values at the date of merger as follows:

Cash	$631,478
Goodwill	7,792,987
In-process research and development	19,000,000
Accrued expenses	(334,423)
Derivative liability	(3,476)
Deferred taxes	(7,463,200)
Convertible promissory notes (see Note 7)	(680,000)
	$18,943,366

The above cash was obtained by Sonkei in a November 6, 2013 financing and thus has been classified as a financing activity in the statements of cash flows. IPR&D, an indefinite-lived asset, is included as an asset on the Company's balance sheet until such time that: (i) a marketing approval to commercially sell the drug is received from a regulatory agency, in which case it will be amortized over its expected commercial life, or (ii) such time as the IPR&D is deemed to be impaired, in which case it will be expensed. The transaction is being treated as a stock purchase for income tax purposes and accordingly, the tax bases of Sonkei's assets and liabilities are not adjusted for the effect of purchase accounting. A deferred tax liability of $7.6 million has been recorded for the difference in the book and tax basis of the IPR&D, multiplied by the income tax rate. The acquired net operating losses of Sonkei of approximately $5.3 million had a full valuation allowance, however, will be not limited under Internal Revenue Code Section 382 as the amount that could be utilized after limitation exceeds the amount of the net operating loss carryforward. In 2014 the Company corrected the deferred tax rate used to record a deferred tax liability at the acquisition date by recording a $0.1 million reduction to deferred tax liability with a corresponding reduction to goodwill.

Pro Forma Results

The unaudited financial information in the table below summarizes the combined results of operations for the Company, Sonkei and Mind-NRG on a pro forma basis as though the companies had been acquired as of January 1, 2013. The unaudited pro forma financial information for the years ended December 31, 2014 and 2013 combines the Company's historical results for these years with the historical results for the comparable reporting periods for Sonkei and Mind-NRG. The unaudited pro forma financial information below is for informational purposes only and is not indicative of the results of operations or financial condition that would have been achieved if the acquisitions would have taken place at the beginning of each of the periods presented and should not be taken as indicative of the Company's future results of operations or financial condition.

	Years Ended December 31, 2014	2013
Operating loss	$(57,354,314)	$(5,541,476)
Loss per share	$(4.51)	$(0.74)

NOTE 4 — ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities consist of the following:

	December 31, 2014	December 31, 2013
Accrued severance	$ 636,033	$ -
Research and development costs	415,595	58,117
Accrued bonus	327,960	—
Primomed research funding (1)	127,209	—
Accrued excise and franchise taxes	76,885	—
Professional fees (2)	54,350	595,215
Deferred rent, current	7,226	—
Accrued payroll	—	126,910
Consulting and other costs	—	5,031
Vacation pay	—	5,690
Interest payable	—	24,276
	$ 1,645,258	$ 815,239

(1) Under the terms of a research agreement with Primomed, the Company received grant funds that will be used to offset

certain costs under the MIN-301 development program.

(2) Accounts payable and accrued professional fees at December 31, 2013 included $0.4 million incurred in

connection with the preparation of the Company’s IPO.

NOTE 5 — NET LOSS PER SHARE OF COMMON STOCK

Diluted loss per share is the same as basic loss per share for all periods presented as the effects of potentially dilutive items were anti-dilutive given the Company’s net loss. Basic loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding. The following table sets forth the computation of basic and diluted loss per share for common stockholders:

Year Ended December 31,

	2014	2013
Net loss	$(56,901,439)	$(3,262,005)
Weighted average shares of common stock outstanding	12,724,395	4,186,104
Net loss per share of common stock – basic and diluted	$(4.47)	$(0.78)

The following securities outstanding at December 31, 2014 and 2013 have been excluded from the calculation of weighted average shares outstanding as their effect on the calculation of loss per share is antidilutive:

	December 31, 2014	December 31, 2013
Non-vested stock issued (see Note 9 – Stockholders' Equity)	—	1,275,530
Common stock options	2,076,558	646,759

The above table does not include the potentially dilutive securities that would be issuable under the convertible promissory notes outstanding as described in Note 7 — Convertible Promissory Notes.

NOTE 6 — LICENSE AGREEMENTS

The Company has entered into a license agreement with Mitsubishi Tanabe Pharma Corporation ("Mitsubishi") dated as of August 30, 2007, as amended (the "License Agreement"). Under the terms of the License Agreement, the Company acquired an exclusive license to the compound known as CYR-101 (subsequently renamed MIN-101), and other compounds with a similar structure and intended purpose and other data included within the valid claims of certain patents licensed to the Company under the License Agreement. The license is for world-wide rights, excluding certain Asian countries such as China, Japan, India and South Korea. The Company will pay a tiered royalty for net sales of product by it or any of its affiliates or sub-licensees containing the licensed compound equal to a percentage ranging from the high single digit to the low teens depending on net sales of products under the License Agreement. The initial $1.0 million licensing fee paid in 2007 was expensed as research and development expense, as was an additional payment of $0.5 million in 2008 upon the onset of a Phase IIa study. The Company made a $0.5 million extension payment in 2010 which was expensed as part of research and development expense. The Company was also required to make milestone payments upon the achievement of certain development and commercial milestones, potentially up to $57.5 million for MIN-101 and up to $59.5 million for additional products.

In January 2014, the Company renegotiated the structure of the license for MIN-101 such that the Company is 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 addition, in the event that the Company sells the rights to the license, the licensor will be entitled to a percentage of milestone payments in the low teens and a percentage of royalties received by the Company in the low double digits.

In connection with the merger of Sonkei (see Note 3 — Business Combinations), the Company has a second license agreement with Mitsubishi dated September 1, 2008, as amended. Under the terms of the agreement, the Company has an exclusive license to the compound known as SON-117 (subsequently renamed MIN-117) and other data included within the valid claims of certain patents licensed to the Company under the agreement. The license is for world-wide rights other than certain countries in Asia, including China, Japan, India and South Korea. Under the agreement, the Company will pay a tiered royalty for net sales of product by it or any of its affiliates or sub-licensees containing the licensed compound ranging from the high single digits to the low teens depending on net sales of products. Through the date of the agreement, as amended, the Company was required to make payments up to $57.5 million upon the achievement of certain commercial milestones.

In January 2014, the Company renegotiated the structure of the license for MIN-117 such that the Company is required to make certain milestone payments upon the achievement of certain commercial milestones up to $47.5 million. In addition, in the event that the Company sells the rights to the license, the licensor will be entitled to a percentage of milestone payments in the low teens and a percentage of royalties received by the Company in the low double digits. Under the terms of the amended agreement, the Company is required to meet a certain diligence obligation to initiate either a Phase IIa or Phase IIb study with the licensed compound in patients suffering major mood disorders where initiation is defined as first patient enrolled in the study by the end of April 2015. If the Company fails to achieve this milestone, the Company may elect to extend the timeline to achieve the milestone by one year increments by making an extension payment of $0.5 million. The number of extension payments which may be made is unlimited. In addition, if the Company fails to achieve this development milestone by end April 2015 or make an extension payment, the licensor may elect to terminate the agreement.

The Company did not make any license payments under the agreements for the years ended December 31, 2014 or 2013.

NOTE 7 — DEBT

Loans Payable

In conjunction with the Mind-NRG acquisition on February 11, 2014 (discussed further in Note 3 — Business Combinations), working capital loans were executed between Mind-NRG and several stockholders or affiliates of stockholders for a maximum drawdown of $0.6 million. The loans bear interest at 8% and are repayable at the time the Company completes an IPO or December 1, 2015. The loans may be repaid at any time and contains standard terms of default, under which the interest rate would increase to 11%.

In April 2014, Mind-NRG repaid the working capital loans plus accrued interest, and certain stockholders and their affiliates subsequently executed new working capital loan agreements, with substantially identical terms, directly with the Company (the April Bridge Loan). The Company drew down the maximum $0.6 million available under the agreement in May 2014.

In May 2014, the Company entered into a new loan agreement (the May Bridge Loan) with certain stockholders and their affiliates. The Third Loan Agreement provides loan facilities to the Company up to a maximum of $1.0 million. The Third Loan Agreement bears interest at 8% per annum and is repayable at the time the Company completes an IPO or on December 1, 2015. The Third Loan

Agreement contains standard terms of default, under which the interest rate would increase to 11% per annum. The Third Loan Agreement provides that any amount outstanding may be repaid at any time without penalty.

The Company drew down $1.4 million under the April and May Bridge Loan Agreements. In conjunction with the closing of the Company's IPO on July 7, 2014, the Company repaid the outstanding principal balance under the April and May Bridge Loan agreements plus accrued interest of $11 thousand. Interest expense related to these loans during the year ended December 31, 2014 was $16 thousand and was included within interest expense (income), net.

Convertible Promissory Notes

On November 6, 2013, the Company issued $1.3 million 8% convertible promissory notes due June 30, 2014 to certain stockholders that are payable on demand at maturity. The notes contained certain terms of default, under which conditions the interest rate increases to 11% per annum.

In conjunction with the merger of Sonkei on November 12, 2013, the Company assumed convertible promissory notes held by certain stockholders with a principal amount of €518,519. These notes had a stated interest rate of 8% per annum and a maturity date of June 30, 2014. In conjunction with the IPO, the Company's 8% convertible promissory notes were converted on July 7, 2014 at the IPO price of $6.00 per share into 352,000 shares of the Company's common stock.

The notes issued by the Company on November 6, 2013 and the notes issued by Sonkei on November 6, 2013 and subsequently acquired by the Company on November 12, 2013 (collectively, the "Notes") contain identical terms and may be converted into common shares of the Company under the following conditions:

i) Discount Purchase Option. If the Company sells shares of its capital stock in the qualified financing, as defined, and the convertible promissory notes have not been paid in full, then the outstanding principal balance of these convertible promissory notes and accrued interest thereon shall convert into the common stock sold at the first closing of the qualified financing at a conversion price equal to the price per share paid by the Investors for each share of common stock multiplied by 80%.

ii) Initial Public Offering. If the Company conducts an IPO of its common shares before June 30, 2014, then the convertible promissory notes plus accrued interest will convert at the price per share issued in the IPO.

iii) $3.50/€3.50 Conversion Option. Subsequent to April 30, 2014, investors may elect to convert the Notes, and accrued interest into common stock of the Company at a conversion price of $3.50 per common share.

Discount Purchase Option

The Notes contained an embedded derivative related to the discount purchase feature. The initial fair value of the derivative liability at the date of initial recognition was determined to be $9,976 using a probability-weighted valuation model applying the following assumptions: (i) discount rate of 8.0%, (ii) remaining term of approximately 7 months and (iii) the probabilities of conversion under various circumstances as at the date of measurement. The

proceeds allocated to this conversion option of $9,976 were deducted from the initial fair value of the debt obligation. As of December 31, 2013, the fair value of the derivative liability was determined to be $10,093 using a probability-weighted valuation model applying the following assumptions: (i) discount rate of 8.0%, (ii) remaining term of approximately 6 months and (iii) the probabilities of conversion under various circumstances as at the date of measurement. Upon conversion of the Notes on July 7, 2014, the fair value of the derivative liability was determined to be $0 and the $10,093 decrease in the fair value of the derivative liability was included as a component of interest for the year ended December 31, 2014.

$3.50/€3.50 Conversion Option

The Notes contained a beneficial conversion feature. The intrinsic value of the beneficial conversion feature was calculated by measuring the difference between the effective conversion price and the fair value of the common stock at initial recognition. The Company recorded a debt discount for the intrinsic value of the beneficial conversion feature that was limited to the proceeds of the Notes received of approximately $2.0 million, with an offsetting increase to additional paid-in capital. The discount was amortized to interest expense using the effective interest method through the date of the Notes' conversion of July 7, 2014.

As of December 31, 2014 and 2013, the convertible promissory notes and debt discount are as follows:

	December 31, 2014	December 31, 2013
Convertible promissory notes	$ —	$ 1,973,500
Debt discount	—	(1,937,269)
Foreign exchange effect on Euro denominated notes	—	22,039
	$ —	$ 58,270

For the years ended December 31, 2014 and 2013, the Company recognized interest expense of $2.0 million and $59 thousand, respectively, related to the Notes which has been included within interest expense (income), net.

NOTE 8 — CO-DEVELOPMENT AND LICENSE AGREEMENT

On February 12, 2014, the Company signed a co-development and license agreement with Janssen Pharmaceutica N.V. (“Janssen”) and Janssen Research & Development, LLC (“JJDC”), subject to the completion of an IPO and the payment of a $22.0 million license fee. Under the agreement, the licensor granted the Company an exclusive license, with the right to sublicense, in the European Union, Switzerland, Liechtenstein, Iceland and Norway, referred to as 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) MIN-202 for any use in humans. In addition, upon regulatory approval in the Minerva Territory (and earlier if certain default events occur), the Company will have rights to manufacture MIN-202. The Company has granted to the licensor an exclusive license, with the right to sublicense, under all patent rights and know-how controlled by the Company related to MIN-202 to sell MIN-202 outside the Minerva Territory. In consideration of the licenses granted on July 7, 2014, the Company made a license fee payment of $22.0 million, which was included as a component of research and development expense in 2014. The Company will pay a quarterly royalty percentage in the high single digits on aggregate net sales for MIN-202 products sold by the Company, its affiliates and sublicensees in the European Union. The licensor will pay a quarterly royalty percentage to the Company in the high single digits on aggregate net sales for MIN-202 products sold by the licensor outside the European Union. In accordance with the development agreement, the Company will pay 40% of MIN-202 development costs related to the joint development of any MIN-202 products. However, the Company’s share of aggregate development costs shall not exceed (i) $5.0 million for the period beginning from the effective date of the license and ending following the completion of certain Phase Ib clinical trials and animal toxicology studies, and (ii) $24.0 million for the period beginning from the effective date of the license and ending following the completion of certain Phase II clinical trials. The licensor has a right to opt out at the end of certain development milestones, with the first milestone being the completion of a single day Phase I clinical trial in patients with Major Depressive Disorder (“MDD”). Upon opt out, the licensor will not have to fund further development of MIN-202 and the Minerva Territory will be expanded to also include all of North America. The Company would then owe the licensor a reduced royalty in the mid-single digits for all sales in the Minerva Territory. The Company has the right to terminate the license following certain development milestones the first being completion of a certain Phase Ib clinical trial in patients with insomnia and certain toxicology studies in animals. If the Company terminates the license within 45 days of this milestone, the Company must pay a termination fee equal to $3.0 million. If the Company terminates the license at any time following the last development milestone involving a certain Phase IIb clinical trial, the Company will be entitled to a royalty in the mid-single digits from sales of MIN-202 by the licensor. The licensor may also terminate the agreement for the Company’s material breach or certain insolvency events, including if the Company is unable to fund its portion of the development costs.

The Company included the $22.0 million license fee payment as a component of research and development expense since the licensed rights were not deemed to have an alternative future use. The Company accounts for the co-development and license agreement as a joint risk-sharing collaboration in accordance with ASC 808, Collaboration Arrangements. Payments between the Company and the licensor with respect to each party's share of MIN-202 development costs that have been incurred pursuant to the joint development plan are recorded within research and development expense or general and administrative expense, as applicable, in the accompanying consolidated statements of operations due to the joint risk-sharing nature of the activities. The Company has included $1.2 million in accrued collaborative expenses as of December 31, 2014 and paid $1.2 million during the year ended December 31, 2014 related to this agreement.

The Company entered into a common stock purchase agreement with an affiliate of the above mentioned licensor, dated as of February 12, 2014, pursuant to which, among other things, the affiliate agreed to purchase from the Company up to $26.0 million of common stock in a private placement concurrent with the closing of the IPO at a price equal to the IPO price. This investment was consummated simultaneously with the closing of an IPO in July 2014 with the purchase by the affiliate of 3,284,353 shares of common stock resulting in net proceeds to the Company of $19.7 million.

NOTE 9 — STOCKHOLDERS' EQUITY

Reverse Stock Split

The Company's board of directors and holders of the requisite number of outstanding shares of the Company's common stock approved an amendment to the Company's restated certificate of incorporation to effect a 3.5-to-1 reverse stock split of the Company's outstanding common stock (the "reverse stock split") that became effective on June 9, 2014 upon the filing of its Certificate of Amendment of the Restated Certificate of Incorporation with the Delaware Secretary of State. The reverse stock split did not result in an adjustment to par value. All issued and outstanding common stock, warrants for common stock, options to purchase common stock, share transactions, and related per share amounts contained in the consolidated financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented. On June 9, 2014, the Company amended its Amended and Restated Certificate of Incorporation to increase the total number of authorized shares to 225,000,000 shares, consisting of 125,000,000 shares of common stock, par value $0.0001 per share and 100,000,000 shares of preferred stock, par value $0.0001 per share.

Initial Public Offering and Concurrent Private Placements

On July 7, 2014, the Company closed the sale of 5,454,545 shares of its common stock at a price to the public of $6.00 per share, or an aggregate of approximately $32.7 million. On July 29, 2014, the Company closed the sale of an over-allotment of 160,993 shares of its common stock at a price of $6.00 per share. Net proceeds to the Company from the offering and the over allotment were approximately $28.2 million, after deducting the underwriting discount and expenses of approximately $3.1 million. In addition, the Company closed the sale in a private placement of 666,666 shares of its common stock at a price of $6.00 per share, or an aggregate of approximately $4.0 million. Net proceeds to the Company were approximately $3.7 million, after deducting the underwriting discount. JJDC purchased 3,284,353 shares of the Company's common stock in a private placement resulting in net proceeds to the Company of approximately $19.7 million.

Common Stock Issued for Nonrecourse Notes

On April 26, 2012, the Company issued 821,429 shares of its common stock in exchange for a nonrecourse note of $3,058,026 (or approximately $3.71 per share, the "Original Price"). The note payable was due in a single installment on February 28, 2014, and was amended to extend the maturity date to September 30, 2014. The note bears interest at the rate of 0.19% per annum and is secured solely by the underlying stock. The stock purchase agreement contains i) a right of first refusal held by the Company, whereby if a third party buyer offers to buy the holder's stock at a certain price, then the Company has the right to purchase the stock at that same price; and ii) a standard drag-along in case of a sale of the Company. In lieu of payment, the holder is entitled to offset amounts owed under the nonrecourse note in connection with the Company repurchasing common stock from the holder. The Company has the option (a call option) to repurchase the shares if the holder ceases to provide services to the Company or after September 30, 2014, at the Original Price. The holder has the option (a put option) to require the Company to repurchase the shares at any time at the Original Price.

In accordance with ASC 718-10-25, the purchase of stock in exchange for a nonrecourse note effectively is the same as granting a stock option. If the value of the underlying shares falls below the note amount, the stockholder will relinquish the stock in lieu of repaying the note and would be in the same position as if he or she never purchased the stock. Further, as the shares sold subject to the nonrecourse note are considered an option for accounting purposes, the Company did not record a nonrecourse note or shares outstanding on the balance sheet. The Company also did not recognize interest income on the note as that interest is included in the exercise price of the option. The ultimate holder of the option can only benefit from the instrument if he continues to provide services to the Company through the time of a change in control, as defined. As a change in control was not deemed probable, stock-based compensation expense was not recorded for the year ended December 31, 2013.

In December 2013, the Company issued 27,925 shares of common stock to the holder, subject to a $97,737 nonrecourse note payable by the holder. The accounting for the additional share issuance is consistent with the 821,429 shares discussed above.

Sonkei had a similar arrangement with the consultant, whereby Sonkei issued 1,112,500 shares of its common stock in exchange for a nonrecourse note of €1,119,017 (approximately $1.5 million at December 31, 2013). The note payable was due in a single installment on April 30, 2015. The note bears interest at the rate of 0.19% per annum and is secured solely by the underlying stock. As the shares sold subject to the nonrecourse note are considered an option for accounting purposes, the Company did not record a note or shares outstanding on the balance sheet. The Company also did not recognize interest income on the note as that interest is included in the exercise price of the option. The ultimate holder of the option can only benefit from the instrument if he continues to provide services to the Company through the time of a change in control, as defined. Until a change in control is deemed probable, stock-based compensation expense will not be recorded until a change in control occurs at the then fair value of the option. The Company assumed this agreement upon the merger with Sonkei, and the Sonkei shares were converted into the Company’s common shares in accordance with the terms of the merger agreement (see Note 3 — Business Combinations). On March 31, 2014, the issuer of the $4.7 million

nonrecourse notes, which includes accrued interest, remitted to the Company 348,926 shares of common stock with a fair value of $13.51 per share in full settlement of the outstanding note due in a cashless transaction. Additionally, the Company further modified the awards by cancelling the put option and adding a term whereby upon an IPO the award will vest. The remittance of the shares in exchange for settling the outstanding note, the cancellation of the put option, and the addition of the IPO performance condition, represents a modification of the original terms of the stock options. The effect of these changes is that the Company has modified the awards and has converted approximately 1.3 million stock options with an exercise price of $4.7 million to 926,604 shares of non-vested stock (with no exercise price). The non-vested stock remained subject to the above mentioned vesting conditions of a change in control and IPO, which are not deemed probable until they occur. As described in the preceding sentence, the effect of the modification was to replace stock options that were improbable of vesting with non-vested stock that is improbable of vesting and accordingly, the Company did not recognize stock-based compensation expense for the non-vested stock at the time that the vesting conditions are deemed probable of occurrence. The following is a summary of common shares issued in exchange for nonrecourse notes for the years December 31, 2014 and 2013:

	Common Shares
Outstanding December 31, 2012	821,429
Assumed in Sonkei merger	426,176
Issued	27,925
Outstanding December 31, 2013	1,275,530
Repurchased	(348,926)
Shares vested June 30, 2014	926,604

The 926,604 shares of non-vested common stock held by the consultant became probable of vesting upon the effectiveness of the Company's IPO registration statement on June 30, 2014, resulting in a charge for stock-based compensation of approximately $10.5 million, representing the 926,604 shares multiplied by the fair value per share on May 1, 2014, the date the consultant became an employee, less previous compensation expense recorded.

Common Stock Issued to Consultant

On December 20, 2013, the Company sold 24,516 shares of common stock to the consultant for an aggregate purchase price of $8.58. The Company recognized the fair value of the shares less the par value as an administrative expense of $232,534.

NOTE 10 — STOCK OPTION PLAN

The Company adopted the 2013 Equity Incentive Plan ("Plan") in December 2013, which provides for the issuance of options, stock appreciation rights, stock awards and stock units. On April 30, 2014, the Company increased the number of shares of common stock reserved for issuance over the term of the Plan to 3,543,754 shares. The exercise price per share shall not be less than the fair value of the Company's underlying common stock on the grant date and no option may have a term in excess of ten years. Stock option activity under the Plan for the years ended December 31, 2014 and 2013 is as follows:

	Stock Options	Weighted-Average Exercise Price
Outstanding January 1, 2013	—	—
Granted	646,759	$ 9.49
Outstanding December 31, 2013	646,759	$ 9.49
Granted	1,975,151	$ 6.05
Forfeited	(545,352)	$ 7.89
Outstanding December 31, 2014	2,076,558	$ 6.64
Exercisable December 31, 2014	1,286,890	$ 6.91

The fair value of each stock option to purchase common stock of the Company granted on December 20, 2013 was estimated by management using the Black-Scholes option pricing model applying the following assumptions: (i) expected term of 5.8 to 10 years, (ii) risk free interest rate of 1.9 to 2.9%, (iii) volatility of 102 to 107%, (iv) no dividend yield and (v) a grant date fair value of common stock of $9.49 per share. The Company recognized stock-based compensation expense for the year ended December 31, 2014 and 2013 related to these options of $2.1 million and $0.4 million, respectively, which is included in general and administrative expense.

The table above includes stock options granted on December 20, 2013 to purchase an aggregate of 20,089 shares of the Company's common stock which became fully vested and exercisable on June 30, 2014, the effective date of the Company's IPO registration statement. The Company recognized stock-based compensation expense for the year ended December 31, 2014 related to these options of $0.2 million, which is included in general and administrative expense.

The Company entered into two employment agreements effective May 1, 2014. In accordance with the employment agreements, on June 30, 2014, the Company granted 539,116 fully vested stock options to purchase shares of the Company's common shares at an exercise price of $6.00 per share and recognized stock based compensation expense of approximately $2.7 million related to these grants on the grant date. The fair value of each such option was estimated by management using the Black Scholes option pricing model applying the following assumptions: (i) expected term of 6.25 years, (ii) risk free interest rate of 1.9%, (iii) volatility of 113%, (iv) no dividend yield and (v) a grant date fair value of common stock of $6.00 per share.

Under the terms of three employment agreements, the Company issued 955,932 stock options upon the effective date of the Company's IPO registration statement, which vest over a four-year period beginning from November 12, 2013, the date of the Sonkei Merger. The Company recognized stock-based compensation expense related to these options of approximately $1.9 million for the year ended December 31, 2014. The fair value of each such option was estimated by management using the Black Scholes option pricing model applying the following assumptions: (i) expected term of 6.25 years, (ii) risk free interest rate of 1.9%, (iii) volatility of 113%, (iv) no dividend yield and (v) a grant date fair value of common stock of $6.00 per share.

An additional 480,103 options were granted to employees and directors at and following the IPO of which 352,590 options vest over a four year period and 127,513 options vest over a three year period beginning with the date each recipient began providing service. The Company recognized stock-based compensation expense related to these options of approximately $0.5 million for the year ended December 31, 2014. The fair value of each of these options to purchase common stock of the Company granted was estimated by management using the Black Scholes option pricing model applying the following assumptions: (i) expected term of 6-6.25 years, (ii) risk free interest rate of 1.9%, (iii) volatility of 113%, (iv) no dividend yield.

The weighted average grant-date fair value of stock options outstanding on December 31, 2014 was $5.63 per share. Total unrecognized compensation costs related to non-vested awards at December 31, 2014 was approximately $4.0 million and is expected to be recognized within future operating results over a period of 3.75 years. At December 31, 2014, the weighted average contractual term of the options outstanding is approximately 9.4 years. The intrinsic value of outstanding stock options at December 31, 2014 was $37 thousand.

The expected term of the employee-related options was estimated using the "simplified" method as defined by the Securities and Exchange Commission'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 any trading history for its common stock. The risk-free interest rate assumption is based on the U.S. Treasury instruments whose term 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.

NOTE 11 — INCOME TAXES

Net deferred tax assets (liabilities) as of December 31, 2014 and 2013 consist of the following:

	2014	2013
Deferred tax assets:		
Net operating loss carryforwards	$11,384,959	$5,886,683
Research and development tax credits	145,115	141,231
Capitalized research and development costs	3,067,414	—
Stock-based compensation	2,961,324	88,368
Deferred start-up and license costs	11,991,001	2,705,248
Net deferred tax assets	29,549,813	8,821,530
Valuation allowance	(29,549,813)	(8,821,530)
Net deferred tax assets	$—	$—
Deferred tax liabilities:		
In-process research and development	(13,433,760)	(7,588,600)
Net deferred tax liabilities	$(13,433,760)	$(7,588,600)

A reconciliation between the Company’s effective tax rate and the federal statutory rate for the years ended December 31, 2014 and 2013 are as follows:

	2014	2013
Federal statutory rate	(34.00%)	(34.00%)
Permanent differences	4.27 %	(2.49 %)
State income taxes	(4.62 %)	(5.94 %)
Valuation allowance	34.35 %	42.43 %
Effective tax rate	0.0 %	0.0 %

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 increased by approximately $20.7 million and $3.3 million during the years ended December 31, 2014 and 2013, respectively.

As of December 31, 2014, the Company had approximately $26.4 million of Federal net operating losses that will begin to expire in 2027. As of December 31, 2014, the Company's wholly owned subsidiary had approximately $4.9 million of operating losses in Switzerland that will begin to expire in 2018. As of December 31, 2014, the Company had approximately $10.4 million of New Jersey and $11.0 million of Massachusetts operating losses that will begin to expire in 2015 and 2024, respectively. As of December 31, 2014, the Company had approximately $0.1 million of

federal research and development credits that will begin to expire in 2028. The Internal Revenue Code ("IRC") limits the amounts of net operating loss carryforwards that a company may use in any one year in the event of certain cumulative changes in ownership over a three-year period as described in Section 382 of the IRC. The Company has not performed a detailed analysis to determine whether an ownership change has occurred as of December 31, 2014.

Deferred tax liabilities related to indefinite-lived assets typically are not used as a source of income to support realization of deferred tax assets in jurisdictions where tax attributes expire (e.g., jurisdictions where net operating loss carryforwards expire) unless the deferred tax liability is expected to reverse prior to the expiration date of the tax attribute. Therefore, the net operating losses of Sonkei cannot be used to offset the deferred tax liability resulting from the IPR&D due to the fact that the IPR&D currently has an indefinite life while the NOLs have a maximum life of 20 years.

NOTE 12 — COMMITMENTS

In September 2014, the Company entered into a lease agreement for 4,043 square feet of office space in Waltham, MA. The term of the lease is approximately 2 years, and the Company is required to make monthly rental payments commencing December 2014. Estimated annual rent payable under this operating lease is approximately $0.1 million per year in each of the two years.

NOTE 13 — RELATED PARTY TRANSACTIONS

The Company reimbursed certain expenses paid by its investors incurred on behalf of the Company. For the years ended December 31, 2014 and 2013, these reimbursements were $268,990 and $111,351, respectively.

An investor provided accounting and other services to the Company for $60,000 per year. An additional $5,000 was charged for maintaining the Sonkei records in 2013. For the years ended December 31, 2014 and 2013, the total expense recognized in operating results in connection with services provided was $35,000 and $65,000, respectively.

For the years ended December 31, 2014 and 2013, the Company retained the services of certain consultants who were also stockholders of the Company (see Note 9 – Stockholders' Equity). The total expense recognized by the Company in connection with these consulting services was $247,400 and $538,996 for the years ended December 31, 2014 and 2013, respectively.

The Company's convertible promissory notes were held by certain stockholders. Accrued interest payable listed in Note 4 as of December 31, 2013 relates to these convertible promissory notes. Also refer to Note 8 – Co-Development and License agreement and Note 9 – Stockholder's Equity for additional related party transactions.

NOTE 14 — QUARTERLY RESULTS (Unaudited)

	Three Months Ended			
	March 31, 2014	June 30, 2014	September 30, 2014	December 31, 2014
	(in thousands, except per share data)			
Total revenues	$-	$-	$-	$-
Operating loss	(2,623)	(17,650)	(27,151)	(7,446)
Net loss	(2,938)	(19,366)	(27,155)	(7,442)
Loss per share, basic and diluted	$(0.43)	$(2.55)	$(1.53)	$(0.40)

	Three Months Ended			
	March 31, 2013	June 30, 2013	September 30, 2013	December 31, 2013

	(in thousands, except per share data)			
Total revenues	$-	$-	$-	$-
Operating loss	(271)	(379)	(482)	(2,043)
Net loss	(271)	(376)	(488)	(2,127)
Loss per share, basic and diluted	$(0.08)	$(0.10)	$(0.12)	$(0.41)

NOTE 15 — SUBSEQUENT EVENTS

The Company evaluated subsequent events for financial reporting purposes through the date which the financial statements were issued to determine whether any events occurred that required disclosure in the accompanying consolidated financial statements.

Stock Option Plan

On January 1, 2015, in accordance with the terms of the Company's 2013 Equity Incentive Plan, the total shares authorized for issuance under the plan increased by 737,579 to 4,281,333. This increase represents 4% of the total shares outstanding calculated as of the end of the most recent fiscal year. On January 2, 2015, the Company granted 10,000 stock options to purchase common shares to a newly hired employee at an exercise price of $6.11 and on February 2, 2015 granted a total of 15,000 stock options to purchase common shares to two members of the Board of Directors at an exercise price of $4.34.

Loan and Security Agreement

On January 16, 2015, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Oxford Finance LLC ("Oxford") and Silicon Valley Bank ("SVB" and, together with Oxford, the "Lenders"), providing for term loans to the Company in an aggregate principal amount of up to $15 million, in two tranches.

The Company drew down the initial term loans in the aggregate principal amount of $10 million (the "Term A Loans") on January 16, 2015. The Term A Loans bear interest at a fixed rate of 7.05% per annum. On or prior to March 31, 2016, the Company may borrow additional term loans (the "Term B Loans" and, together with the Term A Loans, the "Term Loans") in the aggregate principal amount up to $5 million, subject to the satisfaction of certain borrowing conditions, including its achievement of primary endpoints on its Phase IIa trials for its MIN-117 and MIN-202 programs. The Term B Loans will bear interest at a fixed rate per annum of the greater of (i) 7.05% or (ii) the sum of (a) the prime rate reported in The Wall Street Journal three (3) business days prior to the funding date of the Term B Loans, plus (b) 3.80%.

The Company paid a facility fee of $75,000 for access to the Term Loans and will be required to pay a final payment of 4.45% (or, if the interest-only period is extended as described below, 5.10%) of the total amount borrowed. Through February 1, 2016, the Company is obligated only to make monthly interest payments on the outstanding principal balance on the Term A Loans, followed by thirty (30) months of equal principal and interest payments. If the Company raises at least $30,000,000 in capital (including at least $20,000,000 from the sale of equity securities) and completes the first dosing of its Phase I/II clinical trial for MIN-117 prior to December 31, 2015, the interest-only period will be extended an additional six (6) months and the repayment period will be reduced by six (6) months. The Term Loans mature on August 1, 2018. The Company may prepay all, but not less than all, of the loaned amount upon thirty (30) days' advance notice to the Lenders, provided that the Company will be obligated to pay a prepayment fee equal to (i) 3% of the outstanding balance, if the loan is prepaid within twenty-four (24) months of the funding date, (ii), 2% of the outstanding balance, if the loan is prepaid between twenty-four (24) and thirty-six (36) months of the funding date and (iii) 1% of the outstanding balance, if the loan is prepaid thereafter (each, a "Prepayment Fee").

While any amounts are outstanding under the loan agreement, the Company is subject to a number of affirmative and restrictive covenants, including covenants regarding delivery of financial statements, maintenance of inventory, payment of taxes, maintenance of insurance, dispositions of property, business combinations or acquisitions, incurrence of additional indebtedness and transactions with affiliates, among other customary covenants. The Company is also restricted from paying dividends or making other distributions or payments on its capital stock, subject to limited exceptions.

The Company's obligations under the Loan Agreement are secured by a first priority security interest in substantially all of its assets, other than its intellectual property. The Company has also agreed not to pledge or otherwise encumber its intellectual property assets, except that it may grant certain exclusive and non-exclusive licenses of its intellectual property as set forth in the Loan Agreement. In addition, the Company pledged all of its equity interests in Minerva Neurosciences Securities Corporation and 65% of its equity interests in Mind-NRG, SA as security for its obligations under the Loan Agreement.

Upon the occurrence of certain events, including but not limited to the Company's failure to satisfy its payment obligations under the Loan Agreement, the breach of certain of its other covenants under the Loan Agreement, or the occurrence of a material adverse change, the Lenders will have the right, among other remedies, to declare all principal and interest immediately due and payable, and will have the right to receive the final payment fee and, if the payment of principal and interest is due prior to maturity, the applicable Prepayment Fee.

Under the Loan Agreement, the Company agreed to issue the Lenders warrants (the "Warrants") to purchase shares of its common stock, $0.0001 par value per share ("Common Stock"), upon its draw of each tranche of the Term Loans. The aggregate number of shares of Common Stock issuable upon exercise of the Warrants is equal to 2.25% of the amount drawn of such tranche,

divided by the average closing price per share of Common Stock reported on the NASDAQ Global Market for the ten (10) consecutive trading days prior to the applicable draw.

On January 16, 2015, upon the draw of the Term A Loans, 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.

Private Placement

On March 18, 2015, pursuant to a securities purchase agreement with certain accredited investors dated March 13, 2015, the Company sold in a private placement 6,281,661 shares of the Company's common stock at a price per share of $4.81 and warrants to purchase up to an aggregate of 6,281,661 shares of common stock at a purchase price of $0.125 per warrant share, with an initial exercise price of $5.772 per share. The Company received net proceeds of approximately $28.8 million, after deducting placement agent fees. The warrants will expire on March 18, 2017, two years after the date on which they were initially issued.

In connection with the private placement, the Company also entered into a Registration Rights Agreement, dated March 13, 2015 (the "Registration Rights Agreement") with certain accredited investors. Pursuant to the terms of the Registration Rights Agreement, the Company is obligated to prepare and file with the SEC a registration statement to register for resale the shares of its common stock issued in the private placement and the shares of its common stock issuable upon exercise of the warrants on or prior to May 2, 2015. If registration statements are not filed timely or are not maintained effective, the Company could be subject to penalties of up to 10% of proceeds received in the private placement.

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.

At December 31, 2013, we concluded that there were material weaknesses and significant deficiencies in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses that we identified related to (1) lack of segregation of duties, (2) lack of personnel competent to perform complex accounting, including stock-based compensation, the convertible promissory notes beneficial conversion features and income tax disclosures, (3) lack of financial statement disclosure controls, and (4) not performing a risk assessment.

To address the control issues, during 2014 we hired experienced accounting staff and established procedures to enable the proper segregation of duties. We adopted the COSO Internal Control – Integrated Framework in 2014 and designed and implemented an effective system of internal control. We created and documented procedures for all accounting functions and for the review and release of financial statements and other information. In addition, we performed a detailed risk assessment for all related financial reporting and control activities.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2014. Based on the evaluation of our disclosure controls and procedures as of December 31, 2014, 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.

Changes in Internal Control over Financial Reporting

Other than the adoption of COSO Internal Control – Integrated Framework and the corrective actions noted above related to the remediation of the material weaknesses, there were no other changes in internal control over financial reporting during the Company's fourth quarter that would have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Management Report on Internal Control over Financial Reporting

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's registered independent public accounting firm due to a transition period established by rules of the SEC for newly public companies.

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 2015 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 2015 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 2015 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 2015 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 2015 Annual Meeting of Stockholders and is incorporated by reference herein.

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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

Consolidated Statements of Operations

Consolidated Statements of Stockholders' Equity

Consolidated Statements of Cash Flows

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 Exhibits listed in the Exhibit Index are filed as a part of this Form 10-K.

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.
President and Chief Executive Officer

Date: March 26, 2015

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Remy Luthringer, Ph.D. and Geoff 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.	President, Chief Executive Officer and Member of the Board of Directors (Principal Executive Officer)	March 26, 2015
/s/ Geoff Race Geoff Race	Chief Financial Officer (Principal Financial Officer)	March 26, 2015
/s/ Frederick Ahlholm Frederick Ahlholm	Chief Accounting Officer (Principal Accounting Officer)	March 26, 2015
/s/ Marc D. Beer Marc D. Beer	Chairman of the Board of Directors	March 26, 2015
	Member of the Board of Directors	

/s/ Francesco de Rubertis, Ph.D. Francesco de Rubertis, Ph.D.		March 26, 2015
/s/ Michèle Ollier, MD Michèle Ollier, MD	Member of the Board of Directors	March 26, 2015
/s/ Nico Vandervelpen Nico Vandervelpen	Member of the Board of Directors	March 26, 2015
/s/ Jan van Heek Jan van Heek	Member of the Board of Directors	March 26, 2015

EXHIBIT INDEX

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	S-1/A	333-195169	3.2	June 10, 2014	
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	4.2	June 10, 2014	
10.1	Assignment Agreement between ProteoSys AG, Mind-NRG SA and Pentavest S.à.r.l. dated as of September 6, 2010	S-1	333-195169	10.12	April 9, 2014	
10.2	Share Purchase Agreement between the Registrant, Mind-NRG SA and Various Shareholders dated as of	S-1	333-195169	10.13	April 9, 2014	

	February 11, 2014				
10.3	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
10.4†	Consulting Agreement between Remy Luthringer and the Registrant, f/k/a Cyrenaic Pharmaceuticals, Inc., dated as of January 11, 2011	S-1	333-195169	10.15	April 9, 2014
10.5†	Amendment No. 1 to the Consulting Agreement between Remy Luthringer and the Registrant, f/k/a Cyrenaic Pharmaceuticals, Inc., dated as of September 1, 2011	S-1	333-195169	10.16	April 9, 2014
10.6†	Consulting Agreement between Geoff Race and the Registrant, f/k/a Cyrenaic Pharmaceuticals, Inc., dated as of September 1, 2011	S-1	333-195169	10.17	April 9, 2014
10.7†	Consulting Agreement between Geoff Race and the Registrant as successor in interest to Sonkei Pharmaceuticals, Inc., dated as of October 1, 2011	S-1	333-195169	10.18	April 9, 2014
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Exhibit No.	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith
10.8	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	
10.9	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	
10.10	Stock Repurchase Agreement between Wint2felden Holding SA and the Registrant, dated as of March 31, 2014	S-1	333-195169	10.21	April 9, 2014	
10.11†	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	
10.12†	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	
10.13†	Letter Agreement between Jan van Heek and the Registrant, dated as of December 11, 2013	S-1	333-195169	10.25	April 9, 2014	
10.14†	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	
10.15*	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	
10.16*	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	
10.17*	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	

10.18*	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
10.19*	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
10.20*	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
10.21†	Employment Agreement between Joseph Reilly and the Registrant, dated as of December 23, 2013	S-1/A	333-195169	10.9	June 10, 2014

Exhibit No.	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith
10.22†	Letter Agreement between Marc D. Beer and the Registrant f/k/a Cyrenaic Pharmaceuticals, Inc., dated as of October 16, 2013	S-1/A	333-195169	10.10	June 10, 2014	
10.23†	Amended and Restated 2013 Equity Incentive Plan of the Registrant	S-1/A	333-195169	10.24	June 10, 2014	
10.24	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	
10.25	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	
10.26	Loan and Security Agreement by and among Oxford Finance LLC, Silicon Valley Bank and the Registrant, dated as of January 16, 2015	8-K	001-36517	10.1	January 20, 2015	
10.27	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	
10.28	Form of Warrant to Purchase Common Stock of the Registrant	8-K	001-36517	10.2	March 18, 2015	
10.29	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	
						X
10.30	Separation and Release Agreement between Rogerio Vivaldi Coelho and the Registrant, dated as of November 30, 2014					
						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	XBRL Instance Document		X
101.SCH	XBRL Taxonomy Extension Schema Document		X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document		X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document		
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Exhibit No.	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith
						X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					

† Indicates management contract or compensatory plan or arrangement.

* Confidential treatment has been requested from 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.

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