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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

OR

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

Commission File Number 001-36517

Minerva Neurosciences, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**26-0784194**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1500 District Avenue Burlington, MA	**01803**
(Address of principal executive offices)	**(Zip Code)**

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

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

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

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

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

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

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

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

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

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

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

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate value of the Company's Common Stock held by non-affiliates of the Company was approximately $12.9 million as of June 30, 2024, when the last reported sales price was $3.19 per share.

The number of shares of Registrant's Common Stock outstanding as of February 20, 2025 was 6,993,406.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement relating to the 2025 Annual Meeting of Stockholders to be filed pursuant to Regulation 14A with the Securities and Exchange Commission are incorporated by reference into Part III of this Report. Such proxy statement will be filed with the Securities and Exchange Commission not later than 120 days following the end of the Registrant's fiscal year ended December 31, 2024.

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," "projects," "should," "would" and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Because of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not transpire. These risks and uncertainties include, but are not limited to, the risks included in this Annual Report on Form 10-K under Part I, Item IA, "Risk Factors."

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

Summary of Risks Associated with Our Business

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

- We have incurred significant losses since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability;
- We will require additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations;
- Raising additional funds by issuing equity securities will cause dilution to existing stockholders. Raising additional funds through debt financings may involve restrictive covenants and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights;
- Changes in estimates regarding fair value of intangible assets may result in an adverse impact on our results of operations;
- We cannot give any assurance that any of our product candidates will receive regulatory approval in a timely manner or at all. The results of clinical trials conducted at sites outside the U.S. may not be accepted by the FDA and the results of clinical trials conducted at sites in the U.S. may not be accepted by comparable foreign regulatory authorities;
- If we experience delays in clinical testing, we will be delayed in commercializing our product candidates, our costs may increase, and our business may be harmed. If we are unable to enroll subjects in clinical trials, we will be unable to complete these trials on a timely basis or at all. Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which could prevent or delay regulatory approval and commercialization, and also increase costs;
- Disruptions at the FDA and other government agencies or comparable foreign regulatory authorities caused by funding shortages or global health concerns could negatively impact our business;
- We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success;
- Even if we complete the necessary clinical trials, we cannot predict when or if we will obtain regulatory approval to commercialize a product candidate or the approval may be for a narrower indication than we expect. We have no experience in advancing product candidates beyond Phase 3 clinical trials, which makes it difficult to assess our ability to develop and commercialize our product candidates;
- Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties, including ongoing regulatory obligations and continued regulatory review. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to administrative sanctions or penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products;

- The regulatory pathway for our product candidate, MIN-301, has not yet been determined. Depending on the pathway, we may be subject to different regulatory requirements;
- If the market opportunities for any product that we or our collaborators develop are smaller than we believe, our revenue may be adversely affected and our business may suffer;
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than us;
- Even if any of our drug candidates receives regulatory 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;
- We currently have a limited marketing and sales organization. If we are unable to establish greater marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to effectively market and sell our product candidates, if approved, or generate product revenues. 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;
- Recently enacted and future legislation may increase the difficulty and cost for us to commercialize our product candidates and affect the prices we may obtain;
- Our business and operations would suffer in the event of system failures. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud;
- We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets.
- We are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, policies, industry standards, and other obligations related to data privacy and security.
- If our information technology systems, or those of third parties with whom we work, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.
- We currently rely and continue to expect to rely on third parties to conduct our future clinical trials. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business;
- We contract with third parties for the manufacturing of our product candidates for pre-clinical and clinical testing and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products, or such quantities at an acceptable cost;
- We depend on collaborations with certain of our licensing partners, and could be seriously harmed if our license agreements are terminated or breached;
- Substantial potential future milestone payments to the Company depend on the development and commercialization of seltorexant, and we may be obligated to make related payments to certain of our contractual partners even if certain of our other contractual partners breach their obligations to pay us;
- We may not be successful in establishing new collaborations, which could adversely affect our ability to develop future product candidates and commercialize future products;
- One or more of our owned or licensed patents directed to our proprietary products or technologies may expire or have limited commercial life before the proprietary product or technology is approved for marketing in a relevant jurisdiction;
- We have in-licensed or acquired a portion of our intellectual property necessary to develop our product candidates, and if we fail to comply with our obligations under any of these arrangements, we could lose such intellectual property rights;
- We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful;

- We cannot predict what the market price of our common stock will be and, as a result, it may be difficult for you to sell your shares of our common stock;
- Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval;
- Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall;
- Securities litigation could result in substantial damages and may divert management's time and attention from our business;
- 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; and
- Our common stock may be delisted from The Nasdaq Capital Market which could negatively impact the price of our common stock, liquidity and our ability to access the capital markets.

Part I

ITEM 1. Business

Overview

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

We are developing roluperidone for the treatment of negative symptoms in patients with schizophrenia and have exclusive rights to develop and commercialize MIN-301 for the treatment of Parkinson's disease. In addition, we previously co-developed seltorexant with Janssen Pharmaceutica NV, one of the Janssen Pharmaceutical Companies of Johnson & Johnson ("Janssen"), for the treatment of insomnia disorder and adjunctive treatment of Major Depressive Disorder ("MDD"). In June 2020, we exercised our right to opt out of our agreement with Janssen for the Phase 3 development of seltorexant and as a result, we were entitled to collect royalties in the mid-single digits on potential future worldwide sales of seltorexant in certain indications, with no further financial obligations to Janssen. In January 2021, we sold our rights to these potential royalties to Royalty Pharma plc ("Royalty Pharma") for a $60 million cash payment and up to an additional $95 million in potential future milestone payments, subject to completion of Phase 3 trials by Janssen and regulatory approvals.

In August 2022, we submitted a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") for our lead product candidate, roluperidone, for the treatment of negative symptoms in schizophrenia. On February 26, 2024, the FDA issued a Complete Response Letter ("CRL") regarding our NDA for roluperidone. Since receiving the CRL, we have continued to have interactions with the FDA with the goal of addressing the questions raised in the CRL.

We have not received any regulatory approvals to commercialize any of our product candidates, and we have not generated any revenue from the sales or license of our product candidates. We routinely evaluate the status of our drug development programs as well as potential strategic options. We have incurred significant operating losses since inception and expect to continue to incur net losses and negative cash flows from operating activities for the foreseeable future in connection with the clinical and regulatory activities associated with advancing our product candidates. As of December 31, 2024 and 2023, we had an accumulated deficit of $395.4 million and $396.8 million, respectively. For the years ended December 31, 2024 and 2023, we recorded net income of $1.4 million and a net loss of $30.0 million, respectively. We believe our product candidates have potential to improve the lives of a large number of affected patients and their families who are currently not well-served by available therapies. According to Datamonitor, an independent market research firm, in 2024 approximately 2.9 million people suffered from schizophrenia in the United States ("U.S."), Japan, the United Kingdom ("UK"), and the four major European Union ("EU") markets of France, Germany, Italy, and Spain. There is no approved treatment to address negative symptoms in patients with schizophrenia in the U.S., which is a significant driver of the cost burden of that disease. An estimated 69% of treated patients with schizophrenia have predominant/persistent negative symptoms. Negative symptoms also exist in other CNS diseases beyond schizophrenia, the existing treatments for which we believe are poorly addressed in a broad range of indications such as Alzheimer's disease, Parkinson's disease and depression.

Our Strategy

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

- Identify, acquire and develop differentiated products with innovative mechanisms of action based on biological and clinical insights into the unmet needs of patients;
- Leverage the randomized, double-blind, placebo-controlled data from completed trials to advance the clinical development of our product candidates in multiple regulatory jurisdictions;
- Advance our lead product, roluperidone, which, if approved, will potentially be the first product approved to treat negative symptoms in patients with schizophrenia in the U.S. and, in the longer term as a potential treatment for other brain disorders in which negative symptoms represent a significant debilitating, unmet need;

- Selectively explore collaborations with leading pharmaceutical companies to maximize the value of our current product candidate portfolio, particularly in connection with pivotal clinical trials and subsequent regulatory review, approval and commercialization; and
- Apply our management team's expertise and current intellectual property portfolio to identify and explore additional indications to investigate with our current portfolio of compounds and to acquire additional product candidates.

Our History

Minerva Neurosciences, Inc. was formed in November 2013 from the merger of Cyrenaic Pharmaceuticals, Inc. and Sonkei Pharmaceuticals, Inc. These two predecessor companies had exclusively licensed roluperidone and another compound from Mitsubishi Tanabe Pharma Corporation ("MTPC"). In February 2014 we acquired Mind-NRG Sarl ("Mind-NRG"), which owns exclusive rights to develop and commercialize MIN-301 globally.

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

Our Clinical-Stage Programs

Roluperidone (MIN-101)

Introduction

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

We believe the scientifically supported and innovative mechanisms of action of roluperidone may potentially address the unmet needs of schizophrenic patients, which include treatment of negative symptoms and cognitive impairment, without the side effects of existing therapies. Negative symptoms are lifelong debilitating symptoms and include: asociality, or the lack of motivation to engage in social interactions; anhedonia, or the inability to experience positive emotions; alogia, or failure to engage in normal conversation; avolition, or loss of energy and interest in activities; and blunted affect, or diminished emotional expression. We plan to seek approval of roluperidone initially as a first line treatment of negative symptoms in patients diagnosed with schizophrenia, and we also may study its use to treat all aspects of the disease, including positive symptoms and relapse prevention. We believe that roluperidone, if approved, could treat the majority of patients diagnosed with schizophrenia. An estimated 69% of patients diagnosed with schizophrenia have negative symptoms, with at least 42% of patients diagnosed with schizophrenia having prominent negative symptoms.

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

Clinical and Regulatory Updates

Complete Response Letter (CRL)

On February 26, 2024, the FDA issued a CRL to our NDA for roluperidone for the treatment of negative symptoms in patients with schizophrenia. In the CRL, the FDA cited the following clinical deficiencies:

- Although one study (MIN-101C03) demonstrated statistical significance on the primary efficacy endpoint, it is insufficient on its own to establish substantial evidence of effectiveness.
- The NDA submission lacks data on concomitant antipsychotic administration.
- The NDA submission lacks data needed to establish that the change in negative symptoms of schizophrenia with roluperidone treatment was clinically meaningful.
- The submitted safety database included an inadequate number of subjects exposed to roluperidone at the proposed dose (64 mg) for at least 12 months.

To address these deficiencies, the FDA stated that we must submit at least one additional positive, adequate, and well-controlled study to support the safety and effectiveness of roluperidone for the treatment of negative symptoms. We must also provide additional data to demonstrate the safety and efficacy of roluperidone co-administered with antipsychotic medications, to support the observed effect on negative symptoms with roluperidone treatment corresponds to a clinically meaningful change, and to demonstrate the long-term safety of the proposed dose.

In addition to the clinical deficiencies described above, the FDA also provided comments on, among other items, clinical pharmacology, product quality, biopharmaceutics, and nonclinical issues.

Phase 1b Clinical Trial (MIN-101C18)

In the first quarter of 2024, we completed a clinical trial initiated in October 2023 to evaluate the safety, tolerability, pharmacodynamics and pharmacokinetics of the co-administration of roluperidone and olanzapine in adult subjects with moderate to severe negative symptoms of schizophrenia. This clinical trial (NCT06107803) was designed to investigate the pharmacodynamic and pharmacokinetic effects and safety of the concomitant therapy of roluperidone with an established and widely used antipsychotic.

We enrolled 17 male and female subjects with moderate to severe negative symptoms of schizophrenia for this study. Out of the 17 enrolled subjects, 13 completed all 17 days of daily dosing with roluperidone 64 mg (for 7 days) and roluperidone with olanzapine 10 mg (for 10 additional days). Two subjects withdrew consent after enrollment, one patient was discontinued due to a major protocol deviation, and one was discontinued due to a treatment-unrelated serious adverse event. Roluperidone administered concomitantly with olanzapine was generally well tolerated and no unexpected safety signals were detected, with few treatment-emergent adverse events (TEAEs) reported, most of which were mild, and all resolved without sequelae. We observed no emergent clinically significant electrocardiogram or laboratory abnormalities during the study. We observed no symptomatic worsening during the administration of roluperidone alone (7 days) or when administered in combination with olanzapine at 10 mg (10 days). The study demonstrated that pharmacokinetic interactions between the two drugs were not relevant.

New Drug Application Filed

On April 27, 2023, the FDA filed our NDA for roluperidone for the treatment of negative symptoms in patients with schizophrenia. The decision to file the NDA followed our request for formal dispute resolution and appeal of the RTF. The issues cited in the RTF decision included those discussed at the Type C meeting in March 2022. In granting the appeal, the FDA deciding official agreed with us that the issues cited in the RTF decision should be considered during the FDA's review of the NDA.

On May 8, 2023, we received confirmation from the FDA that the NDA for roluperidone has been filed in accordance with the Appeal Granted letter dated April 27, 2023 and assigned a standard review classification and a Prescription Drug User Fee Act ("PDUFA") goal date of February 26, 2024. The FDA advised that it identified potential review issues that had been previously cited in the RTF decision letter, which included those discussed at a Type C meeting in March 2022, described further below.

New Drug Application Submission

In August 2022, we submitted an NDA to the FDA for roluperidone for the treatment of negative symptoms in patients with schizophrenia. The NDA submission is supported by results from two late-stage, well-controlled studies in patients with moderate to severe negative symptoms and stable positive symptoms of schizophrenia, referred to as Study MIN-101C03 (the Phase 2b trial) and Study MIN-101C07 (the Phase 3 trial). Both studies were planned to constitute the bulk of evidence of roluperidone's effectiveness for the indication of treating negative symptoms of schizophrenia. This plan relied on both studies having the same overall study design: both were multicenter, multinational, randomized, double-blind, placebo-controlled, parallel-group studies in which patients received either 32 mg or 64 mg doses of roluperidone. In both studies, if patients were taking antipsychotic treatments, they were discontinued and a washout period of at minimum two days was implemented before beginning the assigned study treatment. Both studies capture comparative placebo-controlled data through their 12-week double-blind period. Both studies also provide long-term

exposure data regarding the safety and tolerability of roluperidone, as well as efficacy based on blinded doses of roluperidone, specifically intended to demonstrate the maintenance of improvement in negative symptoms and the low rate of worsening of positive symptoms following 24-week (Study MIN-101C03) and 40-week (Study MIN-101C07) Open Label ("OL") periods. With the exception of the duration of the OL period, these two studies were nearly identical with respect to patient population and main assessment tools (namely, Positive and Negative Syndrome Scale ("PANSS"), Personal and Social Performance Scale ("PSP"), and Clinical Global Impression ("CGI")). As such, the data from these studies are the basis for the decision to submit the application at this stage of development as we believe they provide data to support the long-term safety and efficacy in adults in an area of high unmet medical need.

We are seeking approval for the 64 mg dose of roluperidone, and results described hereafter are for the 64 mg dose only.

Results of Study MIN-101C03 supported the primary hypothesis that after 12 weeks of treatment, roluperidone is superior to placebo in reducing negative symptoms of schizophrenia. In the primary efficacy analysis, 64 mg roluperidone resulted in a statistically significant reduction of negative symptoms of schizophrenia as measured by PANSS Pentagonal Structured Model Negative score ("PSM") ($p \leq 0.0036$). A post hoc analysis of the change from Baseline to Week 12 in the PANSS Marder's Negative Symptoms Factor Score ("NSFS") also demonstrated a statistically significant difference for 64 mg roluperidone compared with placebo ($p \leq 0.001$). Statistically significant improvements with 64 mg roluperidone compared with placebo after 12 weeks of the Double Blind ("DB") period were also seen for multiple secondary/exploratory efficacy analyses. Further improvements in the NSFS were also seen during the 24-week OL period.

The superiority of roluperidone over placebo was also demonstrated in Study MIN-101C07. Although the primary analysis (intent-to-treat ("ITT")) of change from Baseline in the NSFS to Week 12 for roluperidone compared to placebo marginally missed statistical significance ($p \leq 0.064$), the results were quantitatively superior for 64 mg roluperidone treatment. Furthermore, the analysis of the modified intent-to-treat ("mITT") population (mITT data set excludes data from one clinical site with implausible results for the 17 patients recruited at this site) demonstrated a nominal statistically significant improvement in the NSFS for 64 mg roluperidone compared to placebo ($p \leq 0.044$). In addition, statistically significant improvements (unadjusted) in the NSFS from Baseline were seen as early as Weeks 4 and 8 for 64 mg roluperidone compared to placebo for both the ITT and the mITT populations. PSP Total score (sole key secondary endpoint measuring vocational and social skills) reached statistical significance for both ITT and mITT populations ($p \leq 0.022$ and $p \leq 0.017$, respectively). Further improvements in the NSFS and PSP Total score were also seen during the 40-week OL period.

Type C Meeting

In April 2022, we received the official meeting minutes from the Type C meeting with the FDA held on March 2, 2022, in which the development of roluperidone for the treatment of negative symptoms in schizophrenia was discussed. Four main topics (listed below) were highlighted by the FDA for which they requested input and further clarification from us. Following the meeting, we provided additional data to address:

1. The potential impact of roluperidone administration on the efficacy and safety of antipsychotic drugs. More specifically, the psychiatric division (the "Division") wanted reassurance that those patients administered roluperidone who manifest worsening of schizophrenia symptoms and in the opinion of the clinician/investigators need treatment with antipsychotics, do not experience a diminished benefit of the antipsychotic treatment or unexpected adverse effects.
2. The comparability of US and non-US schizophrenia patients. More specifically, the Division wanted to be reassured that data collected in MIN-101C03 in non-US patients is applicable to US patients.
3. Supporting statistical evidence of efficacy of roluperidone on negative symptoms.
4. The ability of clinicians to identify patients who might benefit from roluperidone.

Chemistry, Manufacturing and Controls program

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

In September 2019 we entered into a long-term commercial supply agreement for roluperidone with Catalent, Inc. ("Catalent"), a leading global provider of advanced delivery technologies, development, and manufacturing solutions for drugs, biologics, gene therapies, and consumer health products. Under the terms of the agreement, Catalent manufactures and packages the finished dose form of roluperidone at its facility in Schorndorf, Germany. To date, Catalent has worked with us to enable the transfer from pilot to

commercial-scale production. This has included analytical methods transfer and validation, process optimization, stability studies, and registration batch manufacturing, as well as packaging studies and the assessment of the influence of formulation factors on the product's critical quality attributes as required by Quality by Design process.

Drug-Drug Interaction Studies

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

Dose Escalation Study with formulation employed in Phase 3 clinical trial

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

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

We believe the findings from the trial suggest an expanded therapeutic window and a significantly improved safety margin for roluperidone. Furthermore, we believe these data suggest the potential for future testing of roluperidone in schizophrenic patients with an exacerbation of psychosis at higher doses than those used in the Phase 3 trial.

Brain-Derived Neurotrophic Factor ("BDNF") Findings

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

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

Roluperidone License Agreement with MTPC

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

In January 2014 we renegotiated the structure of the license for roluperidone such that we are required to make milestone payments upon the achievement of one development milestone totaling $0.5 million and certain commercial milestones, which could total up to $47.5 million, in the aggregate, as well as the tiered royalty payments described above. In addition, in the event that we sell the rights to the license, MTPC will be entitled to a percentage of milestone payments in the low teens and a percentage of royalties received by us in the low double digits. This license agreement expires upon 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 12 year anniversary from the launch of the product in each country in our territory.

Seltorexant (MIN-202)

Introduction of Seltorexant and the Royalty Pharma Arrangement

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

In June 2020 we exercised our right to opt out of our agreement with Janssen for the future Phase 3 development and commercialization of seltorexant. Under the terms of the opt-out agreement, we were entitled to collect royalties in the mid-single digits on potential future worldwide sales of seltorexant in certain indications, with no further financial obligations to Janssen. In January 2021 we sold our rights to these potential royalties to Royalty Pharma for a $60 million cash payment and up to an additional $95 million in potential milestone payments, subject to completion of Phase 3 trials by Janssen and regulatory approvals.

Historical Clinical Developments

In October 2019 we announced top-line results from a Phase 2b clinical trial in which flexibly dosed seltorexant (20 mg or 40 mg) was compared to flexibly dosed quetiapine XR (150 mg or 300 mg) for adjunctive treatment of patients with MDD. There were 102 patients enrolled, each with MDD not responding adequately to SSRIs and SNRIs. The primary endpoint was all cause discontinuation of therapy over 6 months. Mood improvement, measured using the MADRS, and safety and tolerability were evaluated. The primary intent of this exploratory trial was to generate data to assist with the planning of Phase 3 studies; it was not powered to detect statistical significance. Quetiapine XR was used as a comparator, because it is the only medication approved for the adjunctive treatment of MDD in both the U.S. and the European Union.

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

MIN-301

Introduction of MIN-301 and Strategic Development Deferral

As a result of our acquisition of Mind-NRG in February 2014, we have exclusive rights to develop and commercialize MIN-301, a soluble recombinant form of the Neuregulin-1b1 ("NRG-1b1"), protein, for the treatment of Parkinson's disease and potentially for other neurodegenerative disorders. We believe MIN-301 may have the potential to slow the onset of, and restore the brain tissue damage caused by, the disease. MIN-301 is produced by recombinant technology, which is a type of process that modifies the genetics of a biological organism to cause it to produce a particular product. MIN-301 is a peptide that contains the extracellular domain of the human neureglin-1 beta 1 protein and is produced using an Escherichia coli organism that is genetically engineered to express this peptide. Once administrated, this peptide binds to a particular receptor, ErbB4, which produces certain biological effects. For instance, binding to ErbB4 modulates the levels of certain neurotransmitters such as Gamma-Aminobutyric Acid ("GABA") and glutamate in the brain, which are often unbalanced in individuals with Parkinson's disease. Further, ErbB4 promotes oxygenation and metabolism of neurons and it is involved in the control of brain inflammation, which may indicate that MIN-301 could have the potential to reverse the damage caused by Parkinson's disease.

Current treatments for Parkinson's disease improve the symptoms of patients, but none have been proven to delay the onset of the disease, slow or prevent the progression of the disease or reverse its effects. Due to MIN-301's novel mechanism of action that targets neurological deficits, we believe MIN-301 may have 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 2021, we made the strategic decision to focus our limited resources on moving forward our lead drug candidate, roluperidone, and deferred the development of MIN-301 until additional resources become available.

Non-clinical Development

Results from a non-human primate study showed that treatment with an analog of MIN-301 resulted in improvements in a range of symptoms associated with a Parkinson's disease model in primates. The results confirmed the beneficial effects of MIN-301 in non-primate pre-clinical models. We believe these data provide support for advancing MIN-301 into clinical trials for the treatment of Parkinson's disease in humans.

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

Competition

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

Current drug therapies for the treatment of schizophrenia mainly target the positive symptoms of the disease. When patients present positive symptoms and require treatment, they are typically given either conventional "first-generation" antipsychotic medication, such as GlaxoSmithKline's Thorazine Sanofi-Aventis' Largactil (chlorpromazine) and Janssen's Haldol (haloperidol), or second-generation "atypical antipsychotics," such as Novartis' Clozaril (clozapine), Janssen's Risperdal (risperidone), AstraZeneca's Seroquel (quetiapine), Eli Lilly's Zyprexa (olanzapine) and Bristol-Myers Squibb's Abilify (aripiprazole). More recently, in February 2020, Intra-Cellular Therapies launched Caplyta (lumateperone) for the treatment of schizophrenia. It has since demonstrated efficacy in bipolar depression and received FDA approval in December 2021. In September 2024, FDA approved a new type of treatment for schizophrenia from Bristol Meyers Squibb which works differently from "atypical antipsychotics". Cobenfy (previously known as KarXT and developed by Karuna Therapeutics) targets proteins in the brain called muscarinic receptors, which may indirectly impact dopamine.

Both first and second generation antipsychotics as well as more recent entrants to the market have not shown any benefit on negative symptoms and cognitive symptoms in a monotherapy clinical study. In addition, certain older therapies have extensive side effects such as weight gain, metabolic syndrome, sedation, nausea, movement disorders, restlessness, insomnia, impairment of cognitive skills, and prolactin increase. More recent entrants into the market have made claims that they have an improved side effect profile compared to antipsychotics. Since schizophrenia has a wide range of symptoms, multiple therapeutics are often prescribed in an attempt to address all aspects of the disease, compounding these side effects.

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

Specific compounds under late-stage development that include negative symptoms as a target include Acadia Pharmaceuticals' pimavanserin, a selective serotonin $5HT_{2A}$ inverse agonist ("SSIA") that is approved for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis. During 2019, Acadia initiated a second Phase 3 pivotal study, ADVANCE-2. The Phase 3 program evaluated the efficacy of pimavanserin in patients with predominantly negative symptoms of schizophrenia who have achieved adequate control of positive symptoms with their existing antipsychotic treatment. On March 11th 2024, Acadia announced that the study did not meet the primary endpoint. There have been no further clinical studies initiated with pimavanserin in negative symptoms of schizophrenia. In January 2019, Lundbeck indicated they would begin proof-of-concept studies for Lu AF11167, a PDE-10 inhibitor for the treatment of persistent negative symptoms in schizophrenia. In August 2020, Lundbeck announced they were discontinuing the trial based on the results of a futility interim analysis, which concluded that the trial was unlikely to achieve statistical significance on its primary endpoint, mean change from baseline to week 12 on the Brief Negative Symptom Scale ("BNSS").

Other products in clinical development, as a monotherapy or as an adjunctive treatment, whose targets include negative symptoms, (although not necessarily defined as a primary outcome of their clinical trials) are SyneuRx's NaBen, Neurocrine NBI-568 and NBI-570, and products being developed by Luye Pharma Group and Denovo Biopharma. In addition, a number of academic groups are conducting studies with existing compounds for the treatment of negative symptoms of schizophrenia.

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

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

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

Intellectual Property

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

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

Roluperidone

Compound

We own numerous granted patents and patent applications worldwide that provide strong protection for roluperidone. These include patents and applications directed to pharmaceutical compositions comprising roluperidone and methods of using roluperidone.

Pharmaceutical Compositions

We own four granted U.S. patents, U.S. Patent Nos. 9,458,130, 9,730,920, 10,258,614 and 10,799,493, and patents in Australia, Brazil, Chile, Colombia, Eurasia, Europe, Israel, Mexico, New Zealand, Peru, South Africa, and Ukraine, as well as pending applications in the U.S., Australia, Canada, Europe, Israel, Ukraine, and South Africa that cover a novel formulation comprising roluperidone. This novel formulation provides improved therapeutic response and minimizes the potential for transient QTc increases – and thus safety issues – when compared to previous formulations. Because of this improved safety profile, it is this formulation of roluperidone that is being used in Phase 3 clinical trials, and it is this formulation that we expect will be the basis for approval in the US and EU. The granted U.S. patents, as well as any other U.S. or foreign patents that may grant from these applications, will expire no earlier than November 30, 2035. The U.S. patents are listable in the FDA's Orange Book and would, we believe, bar generic competition during their terms. In addition to the patent terms referenced above, a patent term extension of up to 5 years may also be available.

We also own two granted U.S. Patents, U.S. Patent Nos. 11,464,744 and 12,048,768, patents in Australia, Colombia, Israel, Mexico, Russian, and Ukraine, as well as pending applications in the U.S., Australia, Brazil, Canada, Chile, Europe, Israel, Mexico, New Zealand, Peru, Russia, Ukraine, and South Africa that cover gastro-resistant, controlled release dosage formulations of roluperidone. The terms of any future granted patents in this patent family would expire no earlier than June 21, 2038. U.S. patents in this family may be listable in the FDA's Orange Book. In addition to the patent terms referenced above, a patent term extension of up to 5 years may also be available.

Methods of Use

We own U.S. Patent No. 9,732,059, three granted patents in Russia, three granted patents in Canada, and four granted patents in a number of European territories (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Norway, Poland, Portugal, Spain, Sweden, Switzerland, Turkey, United Kingdom, Anguilla, Bermuda, Cayman Islands, Gibraltar, Jersey, Turks & Caicos Islands, and British Virgin Islands), as well as pending applications in United States, Canada,

Europe, and Russia across two patent families that are directed to methods of use of roluperidone to treat negative and other symptoms of schizophrenia, sleep disorders, depression, and other sigma-2 disorders or conditions. U.S. Patent No. 9,732,059 covers the use of roluperidone to treat one or more negative symptoms of schizophrenia and will not expire until 2033, including 558 days of Patent Term Adjustment. This patent is listable in the FDA's Orange Book and would, we believe, bar generic competition during its term. A patent term extension of up to 5 years may also be available. The foreign patents, as well as any future U.S. or foreign patents granting in these families, are scheduled to expire no earlier than July 20, 2031.

In addition, we own patents in the U.S. Mexico, and Russia, as well as pending applications in the U.S., Australia, Brazil, Canada, Chile, Europe, Israel, Mexico, New Zealand, Russia, Ukraine, and South Africa directed to the use of roluperidone to treat negative symptoms, various disorders (including autism disorders, amblyopia, personality disorders, traumatic brain injury), as well as increasing neuroplasticity and promoting neuroprotection in subjects in need thereof. The U.S. Patent and any future U.S. or foreign patents granting from these applications would expire no earlier than August 21, 2039.

We also own patent applications in the U.S., Australia, Brazil, Canada, Chile, China, Eurasia, Europe, Israel, Japan, South Korea, Mexico, New Zealand, Ukraine, and South Africa directed to methods of preventing relapse in a schizophrenia patient comprising administering roluperidone to the patient. Any future U.S. or foreign patents granting from these applications would expire no earlier than February 13, 2043.

We also own an international (PCT) application directed to methods of treating lysosomal storage disorders or a symptom of a lysosomal storage disorder comprising administering roluperidone. Any patents granting from national phase applications that may be filed based upon this PCT application would expire no earlier than October 23, 2044.

MIN-301

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

Sigma Ligands

We own a U.S. patent and patent applications in the U.S., Australia, Canada, China, Europe, Japan, and Hong Kong directed to sigma ligand compounds and their potential use in treating a variety of diseases and disorders, including pain disorders, CNS disorders (e.g., Parkinson's disease and Alzheimer's disease), viruses, and cancer. The U.S. Patent, as well as any future US or foreign patents granting from these applications would expire no earlier than August 12, 2041.

We also own a PCT application directed to the use of sigma ligand compounds in treating lysosomal storage disorders, including Niemann-Pick disease. Any patents granting from national phase applications that may be filed based upon this PCT application would expire no earlier than February 15, 2044. A patent term extension of up to five years may be available in the United States.

Data and Marketing Exclusivity

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

For small molecules, such as roluperidone, the data and marketing exclusivity period in the U.S. is generally four and five years, respectively, measured from the FDA approval date. If MIN-301 is approved as a biologic product, it may be eligible for a data and marketing exclusivity period of twelve years in the U.S. The data and marketing exclusivity periods in the U.S. may be extended by an additional 6 months of pediatric exclusivity if a qualifying pediatric study is performed. Similar data and market exclusivity opportunities are available in the EU; for more information, see the section titled "—Government Regulation and Product Approval—*Data and Marketing Exclusivity in the EU"* below.

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 regulatory approval. Our product candidates are manufactured in reliable and reproducible synthetic processes from readily available starting materials. The chemistry does not require unusual equipment in the manufacturing process. We expect to continue to develop product candidates that can be produced cost-effectively at contract manufacturing facilities.

Commercialization

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

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

Government Regulation and Product Approval

Regulation of Medicinal Products in the European Union

Clinical Trials in the EU

In the EU, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014 ("CTR"), which entered into application on January 31, 2022, repealing and replacing the former Clinical Trials Directive 2001/20 ("CTD") and related national implementing legislation of EU Member States.

The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increasing their transparency. Specifically, the Regulation, which is directly applicable in all EU Member States, introduces a streamlined application procedure through a single-entry point, the "EU portal," the Clinical Trials Information System ("CTIS"); a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each concerned EU Member State. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory. The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR.

In all cases, the clinical trials must be conducted in accordance with EU and national requirements governing clinical trials, including the Good Clinical Practice Directive 2005/28 and ethical principles that have their origin in the Declaration of Helsinki. Studies should also be conducted in accordance with all applicable European Medicines Agency ("EMA"), European Commission and national guidelines and investigational medicinal products used in clinical trials must be manufactured in accordance with Good Manufacturing Practices and in a GMP licensed facility, which can be subject to GMP inspections.

Marketing Authorization in the EU

In the EU, medicinal products can only be commercialized after a related marketing authorization ("MA") has been granted. A company may submit a marketing authorization application ("MAA"), either on the basis of the centralized, or decentralized procedure or mutual recognition procedure.

To obtain a MA for a product in the EEA (which is comprised of the 27 Member States of the European Union plus Norway, Iceland and Liechtenstein), an applicant must submit an MAA either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in the EU Member States (decentralized procedure, national procedure or mutual recognition procedure). An MA may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single MA by the European Commission that is valid for all EU Member States. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii)products designated as orphan medicinal products, (iii) advanced therapy medicinal products ("ATMPs") and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, authorization through the centralized procedure is optional on related approval.

Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use ("CHMP") conducts the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA.

Under the centralized procedure in the EU, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (excluding clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Unlike the centralized authorization procedure, the decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralized Procedures – Human ("CMDh") for review. The subsequent decision of the European Commission is binding on all EU Member States.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU Member State to apply for this authorization to be recognized by the competent authorities in other EU Member States. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU Member States of the MA of a medicinal product by the competent authorities of other EU Member States. The holder of a national MA may submit an application to the competent authority of an EU Member State requesting that this authority recognize the MA delivered by the competent authority of another EU Member State.

An MA has, in principle, an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the eCTD (Common Technical Document) providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide on justified grounds relating to pharmacovigilance, to proceed with one further five-year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized MA) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines ("PRIME") scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical

need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

In the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional MA for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the MA will cease to be renewed.

An MA may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA will be withdrawn if the risk-benefit ratio is no longer favorable.

Pediatric Development

In the EU, Regulation (EC) No 1901/2006 provides that all marketing authorization applications for new medicinal products must include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan ("PIP"), agreed with the EMA's Pediatric Committee ("PDCO"). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which marketing authorization is being sought. The PDCO may grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Furthermore, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the marketing authorization is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate ("SPC"), if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

Manufacturing Regulation in the EU

Various requirements apply to the manufacturing and placing on the EU market of medicinal products. The manufacturing of medicinal products in the EU requires a manufacturing authorization and import of medicinal products into the EU requires a manufacturing authorization allowing for import. The manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance, including EU cGMP standards. Similarly, the distribution of medicinal products within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of EU Member States. Marketing authorization holders and/or manufacturing and import authorization, or MA holders and/or distribution authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU Member States' requirements applicable to the manufacturing of medicinal products.

Data and Marketing Exclusivity in the EU

The EU provides opportunities for data and market exclusivity related to MAs. Upon receiving an MA, innovative medicinal products are generally entitled to receive eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar MAA can be submitted,

and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for marketing authorization. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

Post-approval Requirements

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EU Member States. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk- minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, which may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU.

Clinical Trial Data Disclosure

Many jurisdictions have mandatory clinical trial information obligations incumbent on sponsors. In the EU, transparency requirements relating to clinical trial information are established in the CTR. The CTR establishes a general principle according to which information contained in CTIS shall be made publicly accessible unless confidentiality is justified on grounds of protecting personal data, or commercially confidential information, necessary to protect confidential communications between EU Member States in relation to the preparation of an assessment report, or necessary to ensure effective supervision of the conduct of a clinical trial by EU Member States. This confidentiality exception may be overruled if there is an overriding public interest in disclosure. The publication of data and documents in relation to the conduct of a clinical trial will take place in accordance with specific timelines. The timelines are established by the EMA and are determined based on the documents and the categorization of the clinical trial.

In addition, Regulation No. 1049/2001 on access to documents, or the ATD Regulation, and the related EMA policy 0043 on access to documents, provide for a wide right for EU-based interested parties to submit an access to documents request to the EMA to access certain information held by the EMA. Only very limited information is exempted from disclosure (i.e., commercially confidential information, which is construed increasingly narrowly and protected personal data). It is possible for competitors to access and use this data in their own research and development programs anywhere in the world, once these data are in the public domain.

U.S. FDA Approval Process

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

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

Pre-clinical tests include laboratory evaluation of product chemistry, pharmacology, stability, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices. The results of pre-clinical testing are submitted to the FDA as part of an IND along with other information including information about product chemistry, manufacturing and controls, any available clinical data or literature, and a proposed clinical trial protocol, among other items. Certain pre-clinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may be conducted after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not placed a clinical hold on the IND within this 30-day period, the clinical trial proposed in the IND may begin. Should FDA place a clinical hold on the IND, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial may begin.

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations, good clinical practices ("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 ("IRB"). Clinical trials must also be conducted under protocols detailing the objectives of the trial, trial procedures, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated, and a statistical analysis plan. Each protocol involving testing in U.S. subjects and subsequent protocol amendments must be submitted to the FDA as part of the IND. The study protocol and informed consent information for subjects in clinical trials, along with all amendments, must also be submitted to an IRB for approval.

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

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

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

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

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

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

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

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

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

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

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

Post-Approval Requirements

Drugs manufactured or distributed pursuant to approvals from the FDA or comparable foreign regulatory authorities are subject to pervasive and continuing regulation by the FDA, or comparable foreign regulatory authorities 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 review and approval by the FDA or comparable foreign regulatory authorities.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are subject to periodic announced and unannounced inspections by the FDA, state agencies, as well as comparable foreign regulatory authorities for compliance with cGMP and other regulatory requirements. Changes to the manufacturing process are strictly regulated and may require prior approval from or notification to the FDA or comparable foreign regulatory authorities before being implemented. FDA and comparable foreign regulatory authorities 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.

The FDA and comparable foreign regulatory authorities strictly regulate 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 regulatory authorities 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. Equivalent limitations and penalties are provided in the EU both at the EU and at national level in individual EU Member States.

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

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EU Member States. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports.

All new MAAs in the European Union must include a risk management plan ("RMP"), describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. RMPs and PSURs can be made available to third parties requesting access, subject to limited redactions and related conditions. In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each EU Member State and can differ from one country to another. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Direct-to-consumer advertising of prescription only medicines is also prohibited in the European Union.

Brexit

The United Kingdom's, or UK, withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has changed the regulatory relationship between the UK and the EU. The Medicines and Healthcare products Regulatory Agency, or MHRA, is now the UK's standalone regulator for medicinal products and medical devices. The United Kingdom is no longer subject to EU regulations ((Northern Ireland continues to follow certain limited EU regulatory rules, including in relation to medical devices, but not in relation to medicinal products).

The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from the CTD, as implemented into UK national law through secondary legislation. On January 17, 2022, the UK Medicines and Healthcare products Regulatory Agency, or MHRA, launched an eight-week consultation on reframing the UK legislation for clinical trials. The UK Government published its response to the consultation on March 21, 2023 confirming that it would bring forward changes to the legislation and such changes were laid in parliament on December 12, 2024. These resulting legislative amendments will, if implemented in their current form, bring the UK into closer alignment with the EU CTR. In October 2023, the MHRA announced a new Notification Scheme for clinical trials which enables a more streamlined and risk-proportionate approach to initial clinical trial applications for Phase 4 and low-risk Phase 3 clinical trial applications.

Marketing authorizations in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. Since January 1, 2021, an applicant for the EU centralized procedure marketing authorization can no longer be established in the UK. As a result, since this date, companies established in the UK cannot use the EU centralized procedure and instead must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain a marketing authorization to market products in the UK. All existing EU marketing authorizations for centrally authorized products were automatically converted or grandfathered into UK marketing authorization, effective in Great Britain only, free of charge on January 1, 2021, unless the marketing authorization holder opted-out of this possibility. Northern Ireland remained within the scope of EU authorizations in relation to centrally authorized medicinal products until January 1, 2025. However, on January 1, 2025, a new arrangement as part of the so-called "Windsor Framework" came into effect and reintegrated Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products. The Windsor Framework removes EU licensing processes and EU labelling and serialization requirements in relation to Northern Ireland and introduces a UK-wide licensing process for medicines.

The MHRA has also introduced changes to national marketing authorization procedures. This includes introduction of procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment route, a rolling review procedure and the International Recognition Procedures which entered into application on January 1, 2024. Since January 1, 2024, the MHRA may rely on the International Recognition Procedure, or IRP, when reviewing certain types of marketing authorization applications. This procedure is available for applicants for marketing authorization who have already received an authorization for the same product from a reference regulator. These include the FDA, the EMA, and national competent authorities of individual EEA countries. A positive opinion from the EMA and CHMP, or a positive end of procedure outcome from the mutual recognition or decentralized procedures are considered to be authorizations for the purposes of the IRP.

There is no pre-marketing authorization orphan designation for medicinal products in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding marketing authorization application. The criteria are essentially the same as those in the EU, but have been tailored for the market. This includes the criterion that prevalence of the condition in the United Kingdom, rather than the EU, must not be more than five in 10,000. Upon the grant of a marketing authorization with orphan

status, the medicinal product will benefit from up to 10 years of market exclusivity from similar products in the approved orphan indication. The start of this market exclusivity period will be set from the date of first approval of the product in the United Kingdom.

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

In addition to FDA restrictions on marketing and promotion of pharmaceutical products, other federal and state healthcare laws restrict business practices in the biopharmaceutical industry. These laws include, without limitation, state and federal anti-kickback and false claims laws, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers.

The federal Anti-Kickback Statute prohibits, among other things, individuals and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the referral of an individual for the furnishing or arranging for the furnishing of any item or service, or the purchase, lease, order, arrangement for, or recommendation of the purchase, lease, or order of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, "ACA"), to a stricter standard such that a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Further, the ACA codified case law 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 civil False Claims Act.

The federal false claims laws, including the civil False Claims Act, which can be enforced through civil whistleblower or qui tam actions, impose civil and criminal penalties on 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. Further, the civil monetary penalties statute, 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.

In addition, the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Moreover, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their respective business associates and covered subcontractors that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements.

The federal Physician Payments Sunshine Act and its implementing regulations requires manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services ("CMS") information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

Most states and foreign countries also have statutes or regulations similar to the fraud and abuse laws described above, including certain state laws which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. We may also be subject to state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by the HIPAA, thus complicating compliance efforts. In addition, we may be subject to reporting requirements under state transparency laws, as well as

state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government that otherwise restricts certain payments that may be made to healthcare providers and entities.

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

Coverage and Reimbursement

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

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

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

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

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. presidential executive orders, congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, on August 16, 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law which, among other things, (1) directs the U.S. Department of Health and Human Services ("HHS") to negotiate the price of certain single-source drugs covered under Medicare that have been on the market for at least 7 years and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon price of the first ten drugs that were subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become

subject to the Medicare drug price negotiation program. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry.

Further, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. On December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, legislatures are passing increasing amounts of legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, on January 5, 2024, the FDA approved Florida's Section 804 Importation Program (SIP) proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA.

In the EU, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Other EU Member States may approve a specific price for a product, or they may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions.

In addition, some EEA countries may require the completion of additional studies that compare the cost-effectiveness of a particular medicinal product candidate to currently available therapies. This Health Technology Assessment ("HTA") process is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States.

Healthcare Reform

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

In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, including the ACA, which substantially changed healthcare financing and delivery by both governmental and private insurers, and significantly impacted the pharmaceutical industry. The ACA contains provisions that may potentially reduce the profitability of products, including, for example, increased rebates for products sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. There have been executive, judicial and congressional challenges and amendments to the ACA, as well as to repeal or replace certain aspects of the ACA. For example, the IRA, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear how any such challenges and additional healthcare reform measures of the second Trump administration will impact the ACA and our business.

In December 2021, Regulation No 2021/2282 on Health Technology Assessment ("HTA") amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and will apply as of January 2025, is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation foresees a three-year transitional period and will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas.

Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act ("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.

Employees and Human Capital Resources

Employees

As of December 31, 2024, we had 8 full-time employees. In addition, we are or have engaged with a number of consultants and companies, including Pharma Partnering in Research & Strategy SAS ("PPRS"), that provide expertise in the key functions involved with the development of our products. None of our employees is subject to a collective bargaining agreement and we consider our relationship with our employees to be good.

Talent Acquisition and Development

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

Available Information

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

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

ITEM 1A. Risk Factors

This Annual Report on Form 10-K contains forward-looking information based on our current expectations. Because our actual results may differ materially from any forward-looking statements that we make or that are made on our behalf, this section includes a discussion of important factors that could affect our actual future results, including, but not limited to, our capital resources, the progress and timing of our clinical programs, the safety and efficacy of our product candidates, risks associated with regulatory filings, risks associated with determinations made by regulatory authorities, 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. ("Sonkei"), and, in February 2014, we acquired Mind-NRG Sarl ("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. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we may never generate product revenue or achieve profitability. Our net income was $1.4 million and our net loss was $30.0 million for the fiscal years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of approximately $395.4 million.

In August 2022, we submitted a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") for our lead product candidate, roluperidone, for the treatment of negative symptoms in schizophrenia. The FDA subsequently notified us that they would not accept the file for review, issuing a refusal to file letter ("RTF") in October 2022. In December 2022, following a Type A meeting held on November 30, 2022, the FDA confirmed the RTF remained in effect with respect to our NDA for roluperidone. On May 1, 2023, we announced that the FDA filed our NDA for roluperidone on April 27, 2023. The decision to file the NDA followed our request for formal dispute resolution and appeal of the October 2022 RTF. On May 8, 2023, we received confirmation from the FDA that the NDA for roluperidone has been assigned a standard review classification, and that the FDA has assigned a Prescription Drug User Fee Act ("PDUFA") goal date of February 26, 2024. The FDA advised that it identified potential review issues that had been previously cited in the RTF decision letter, which included those discussed at the Type C meeting in March 2022.

On February 26, 2024, the FDA issued a Complete Response Letter (the "CRL") to our NDA for roluperidone for the treatment of negative symptoms in schizophrenia. The CRL provided that the FDA had completed its review of the NDA and had determined that it could not approve the NDA in its present form. Specifically, the FDA cited the following clinical deficiencies: (i) although one study (MIN-101C03) demonstrated statistical significance on the primary efficacy endpoint, it is insufficient on its own to establish substantial evidence of effectiveness; (ii) the NDA submission lacks data on concomitant antipsychotic administration; (iii) the NDA submission lacks data needed to establish that the change in negative symptoms of schizophrenia with roluperidone treatment was clinically meaningful; and (iv) the submitted safety database included an inadequate number of subjects exposed to roluperidone at the proposed dose (64 mg) for at least 12 months. To address these deficiencies, the FDA stated that we must submit at least one additional positive, adequate, and well-controlled study to support the safety and effectiveness of roluperidone for the treatment of negative symptoms. We must also provide additional data to demonstrate the safety and efficacy of roluperidone co-administered with antipsychotic medications, to support that observed effect on negative symptoms with roluperidone treatment corresponds to a clinically meaningful change, and to demonstrate the long-term safety of the proposed dose. See the section titled "Item 1. Business—Our Clinical-Stage Programs—Clinical and Regulatory Updates—Complete Response Letter" for more information. While we have continued to have interactions with the FDA since receiving the CRL, with the goal of addressing questions raised in the CRL, there can be no assurances that we will obtain approval for roluperidone in a timely manner, on favorable terms, or at all. As a result, the regulatory approval process for roluperidone in the United States is highly uncertain. If we do not obtain approval of roluperidone in the United States, or if the approval is delayed, it would have a material adverse impact on our business. Even if we are able to obtain approval, the expense and time to do so could adversely impact our ability to successfully commercialize roluperidone or conduct our other business operations and our financial condition could be materially harmed.

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/or seek regulatory approvals for, roluperidone and other potential product candidates. If any of our product candidates fail in clinical trials or do not obtain 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. Failure to become and remain profitable may adversely affect the

market price of shares of our common stock and our ability to raise capital and continue operations. 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 results of operations, financial position 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. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

Our operations and the historic operations of Sonkei and Mind-NRG have consumed substantial amounts of cash since inception. As of December 31, 2024, we had cash, cash equivalents, and restricted cash of $21.5 million. We believe that our existing cash, cash equivalents, and restricted cash will be sufficient to meet our cash commitments for at least the next 12 months after the date that the year-end condensed financial statements are issued. The process of drug development can be costly, and the timing and outcomes of clinical trials are uncertain. The assumptions upon which we have based our estimates are routinely evaluated and may be subject to change. The actual amount of our expenditures will vary depending upon a number of factors, including, but not limited to, the design, timing and duration of future clinical trials, the progress of our research and development programs, the infrastructure to support a commercial enterprise, the cost of a commercial product launch, and the level of financial resources available.

We will require additional capital in the short-term to continue advancing the development and regulatory approval process of roluperidone. We will also require additional capital in the long-term to advance the development, regulatory approval process and potential commercialization of roluperidone and other potential product candidates that we may develop in the future. Because the length of time and activities associated with successful development of product candidates are highly uncertain, we are unable to estimate with certainty the actual funds we will require for development and any approved marketing and commercialization activities. Additional capital may not be available in sufficient amounts, on the requisite timing or on reasonable terms, if at all, and our ability to raise additional capital may be adversely impacted by global economic conditions, geopolitical conflicts, such as the war in Ukraine and hostilities in the Middle East, and other factors. Our future funding requirements, both short and long-term, will depend on many factors, including:

- the initiation, progress, timing, costs and results of pre-clinical studies and clinical trials for our product candidates and future product candidates we may develop;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the European Commission, 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.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to delay, limit or terminate the development or commercialization of one or more of our product candidates or other operations, including exploring strategic alternatives and partnership opportunities and potentially discontinue operations altogether. In addition, 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. Any of these events could significantly harm our business, financial condition and prospects, and our stockholders could lose all or part of their investment in our company.

Raising additional funds by issuing equity securities will cause dilution to existing stockholders. Raising additional funds through debt financings may involve restrictive covenants and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

We expect that significant additional capital will be needed in the future to continue our planned operations. Until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt

financings, strategic alliances and license and development agreements or other collaborations. 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, the terms of these securities may include liquidation or other preferences that could adversely affect the rights of a common stockholder, 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 or limit our ability to take specific actions, such as incurring additional indebtedness, making capital expenditures or declaring dividends, and other restrictive covenants that could adversely impact our ability to conduct our business. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our future revenue streams, research programs or any future product candidate or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

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.

As a result of our limited resources and development deferral combined with the overall market conditions, we recognized a non-cash charge of $15.2 million as of December 31, 2021 related to the impairment of the intangible asset for MIN-301. We had previously recognized in-process research and development for MIN-301 in conjunction with the acquisition of MIN-301 during 2014. No updates were made in respect of the development of MIN-301 during 2024.

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

Our ability to use our federal and state NOL carryforwards to offset potential future taxable income is dependent upon our generation of future taxable income before the expiration dates of the NOL carryforwards, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOL carryforwards. Under current law, federal NOL carryforwards generated in taxable years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such NOL carryforwards is limited to 80% of taxable income. Many states have similar laws. As of December 31, 2024, we had approximately $156.8 million of federal net operating losses that will begin to expire in 2036, if not utilized. Of the total federal net operating loss, approximately $135.4 million has an unlimited carryforward and therefore will not expire. As of December 31, 2024, we had approximately $7.7 million of New Jersey and approximately $148.1 million of Massachusetts operating losses that will begin to expire in 2029 and 2037, respectively, if not utilized. Accordingly, certain of our federal and state NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities.

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

Changes in tax laws or tax rulings could materially affect our financial position, results of operations, and cash flows.

The tax regimes we are subject to or operate under, including income and non-income taxes, are unsettled and may be subject to significant change. Changes in tax laws, regulations, or rulings, or changes in interpretations of existing laws and regulations, could

materially affect our financial position and results of operations. For example, the Tax Cuts and Jobs Act Tax Act enacted in 2017 (the "Tax Act") made broad and complex changes to the U.S. tax code, including changes to U.S. federal tax rates, additional limitations on the deductibility of interest, both positive and negative changes to the utilization of future NOL carryforwards, allowing for the expensing of certain capital expenditures, and putting into effect the migration from a "worldwide" system of taxation to a territorial system. Moreover, the IRA provides for a minimum tax equal to 15% of the adjusted financial statement income of certain large corporations, as well as a 1% excise tax on certain share buybacks by public corporations that would be imposed on such corporations. The issuance of additional regulatory or accounting guidance related to the Tax Act or the IRA could materially affect our tax obligations and effective tax rate. In addition, our tax position could be adversely impacted by changes in tax laws applicable to corporate multinationals which have been proposed, and, in some cases, enacted by various countries, and by other international tax developments including the implementation of the base erosion and profit shifting project led by the Organization for Economic Cooperation and Development and certain tax initiatives proposed by the European Commission. These changes and developments include changes to the existing framework in respect of income taxes, as well as the imposition of new types of non-income taxes (such as taxes based on a percentage of revenue) which could apply to our business. These types of changes to the taxation of our activities could increase our worldwide effective tax rate, increase the amount of taxes imposed on our business and our compliance costs, and harm our financial position. Such changes may also apply retroactively to our historical operations and result in taxes greater than the amounts estimated and recorded in our financial statements.

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 European Commission (following the opinion of the Committee of Medicinal Products for Human Use of the European Medicines Agency ("EMA")), FDA or other comparable regulatory authorities in other jurisdictions to sell any product is uncertain and may take years.

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

If, following submission, our application is not accepted for substantive review or approved, 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. On October 14, 2022, we received a refusal-to-file communication from the FDA for our NDA submission for roluperidone, our lead product candidate, which decision was confirmed by the FDA in a subsequent Type A meeting. On April 27, 2023, the FDA filed our NDA for roluperidone following our request for formal dispute resolution and appeal of the refusal-to-file letter. On May 8, 2023, we received confirmation from the FDA that our NDA for roluperidone had been assigned a standard review classification and a PDUFA goal date of February 26, 2024. The FDA also advised that it identified potential review issues that had been previously cited in the RTF decision letter, which included those discussed at the Type C meeting in March 2022. See the section titled "Item 1. Business— Our Clinical-Stage Programs—Clinical and Regulatory Updates—Type C Meeting" for more information. On February 26, 2024, the FDA issued a CRL to our NDA for roluperidone. See the section titled "Item 1. Business—Our Clinical-Stage Programs—Clinical and Regulatory Updates—Complete Response Letter" for more information. See also the risk factor above titled "*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.*" As a result of the CRL, we potentially need additional studies. Additional studies and data would impose increased costs and delays in the regulatory approval process, which may require us to expend more resources than we have available. In addition, the EMA, FDA or other comparable foreign regulatory authorities may not consider any additional required trials, data or information that we perform or provide to be sufficient, or we may decide, or be required, to abandon the program.

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

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

- The EMA, FDA or other regulatory authorities may disagree with the design or implementation of our clinical trials.

- We may be unable to demonstrate to the satisfaction of the EMA, the European Commission, the FDA or other comparable 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, the European Commission, 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, the European Commission, the 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 national competent authorities of EU Member States, 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 European Commission, 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 boxed 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 ("REMS") or comparable foreign strategies, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product. Any of the foregoing could materially harm the commercial prospects for our product candidates.

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

The results of pre-clinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Interpretation of results from early, usually smaller, trials that suggest positive trends in some subjects require caution. Results from later stages of clinical trials enrolling more subjects may fail to show the desired safety and efficacy results or otherwise fail to be consistent with the results of earlier trials of the same product candidate. For example, our Phase 3 trial of roluperidone for the treatment of negative symptoms of schizophrenia failed to meet its primary endpoint despite our Phase 2b trial of the same design achieving statistical significance on the same endpoint. Inconsistencies such as this may occur for a variety of reasons, including differences in trial design, trial endpoints (or lack of trial endpoints in exploratory studies), subject population, number of subjects, subject selection criteria, trial duration, drug dosage and formulation or due to the lack of statistical power in the earlier trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding positive 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 comparable foreign regulatory authorities.

We may conduct our future 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 study population must 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 an application for regulatory approval, and it is not unusual for the FDA to require some Phase 3 clinical trial data to be generated in the United States. If the FDA does not accept the data from our international clinical trials, it would likely result in the need for additional trials in the United States, which would be costly and time-consuming and could delay or permanently halt the development of one or more of our product candidates. Similar requirements and consequences apply outside the United States in relation to acceptance by for foreign regulatory authorities of data from clinical trials conducted outside their territory.

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 approval or Ethics Committee positive opinions as part of the decision on the authorization of the clinical trial issued by EU Member States including input from the national competent authorities and Ethics Committee to conduct a trial at a prospective site, or complying with conditions imposed by IRBs, Ethics Committees or comparable foreign regulatory authorities;
- challenges recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including competition from other programs for the treatment of similar conditions;
- severe or unexpected drug-related adverse events experienced by subjects in a clinical trial;
- difficulty retaining subjects who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, which are common among schizophrenia and MDD subjects who we require for our clinical trials of our product candidate roluperidone;
- delays in adding new investigators and clinical sites;
- withdrawal of clinical trial sites from clinical trials;
- lack of adequate funding; and
- clinical holds or termination imposed by competent authorities, including national regulatory authorities of EU Member States, 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 national competent authorities of EU Member States or the FDA due to a number of factors, including:

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

Failure to conduct a clinical trial in accordance with regulatory requirements, the trial protocols and applicable laws may also result in the inability to use the data from such trial to support product approval. Additionally, changes in regulatory requirements and guidance may occur, and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to the national competent authorities of EU Member States, 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.

Disruptions at the FDA and other government agencies or foreign regulatory authorities caused by funding shortages or global health concerns could negatively impact our business.

The ability of the FDA to review and approve proposed clinical trials or new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Similar considerations are applicable to foreign regulatory authorities.

Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies or comparable foreign regulatory authorities may also slow the time necessary for new product candidates to be reviewed and/or approved, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities.

If a prolonged government shutdown occurs or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

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

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

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

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

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

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

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive pre-clinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication, and failures can occur at any stage of testing. Clinical trials often fail to demonstrate safety and statistically significant efficacy of the product candidate studied for the target indication in later stages of clinical development. For example, a Phase 2b trial in MDD with respect to a drug that we were previously developing, MIN-117, failed to achieve its primary endpoint, and we decided to discontinue development of MIN-117 for MDD. Regulatory authorities may find that our studies do not support, in combination with other studies, approval of our product candidates for the target indication. In addition, our product candidates may

be associated with undesirable side effects or have characteristics that are unexpected, which may result in abandoning their development or regulatory authorities restricting or denying regulatory approval. For instance, prior clinical studies indicated that roluperidone and MIN-117 may cause adverse events, including, but not limited to, dizziness, vital sign changes, central nervous system events, cardiac events, including prolongation of the QT/QTc interval, and gastrointestinal events. Most product candidates that commence clinical trials are never approved by the applicable regulatory authorities.

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

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

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

Because we have limited financial and management resources, we focus on a limited number of research programs and product candidates. For instance, at the present time we are prioritizing the development of the most advanced of our product candidates, roluperidone. As a result, we have suspended further development of MIN-301, and may forego or delay pursuit of opportunities with other product candidates, 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 regulatory approval to commercialize a product candidate or the approval may be for a narrower indication than we expect.

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our product candidates demonstrate safety and efficacy in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval from the relevant regulatory authorities. 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 authority 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 or comparable foreign strategies, additional safety monitoring, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. For instance, in 2007, the FDA requested that makers of all antidepressant medications update existing black box warnings about increased risk of suicidal thoughts and behavior in young adults, ages 18 to 24, during initial treatment. If approved for marketing, our drugs may be required to carry warnings similar to this and other class-wide warnings.

Any approved products would further be subject to ongoing requirements imposed by the 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. These requirements include submissions of safety and other post-marketing information and reports, registration, as well

as continued compliance with cGMP, regulations and GCPs, for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products.

In addition, 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, marketing authorization application or comparable foreign application, post-implementation notification, application for a variation or an existing marketing authorization, or other reporting may be required or requested, which may require additional data or additional pre-clinical studies and clinical trials.

Clinical trials of our product candidates are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. 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 restrict or suspend marketing of such product or the manufacturing process for any component thereof, or withdraw, recall or seize, such product;
- regulatory authorities may withdraw, vary, or suspend approvals of such product;
- regulatory authorities may require additional warnings or otherwise restrict the product's indicated use, label, or marketing;
- the FDA or other comparable foreign regulatory authorities 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 issue a conditional approval and we may fail to fulfill the requirements of the conditional approval;
- regulatory authorities may require that we conduct post-marketing studies or surveillance;
- initiation of regulatory investigations and government enforcement actions;
- 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 competent authorities of EU Member States, the FDA and other comparable foreign regulatory authorities for compliance with current Good Manufacturing Practices ("cGMP"), regulations and standards. The European Union cGMP guidelines are as set forth in Commission Directive 2017/1572 of October 15, 2017. Despite our efforts to audit and verify regulatory compliance, third-party manufacturing vendors may be found on regulatory inspection by the FDA or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations. This may result in shutdown of the third-party vendor or invalidation of drug product lots or processes. In some cases, a product recall may be warranted or required, which would materially affect our ability to supply and market our drug products. If we or a regulatory 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 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 regulatory approval, a regulatory authority may, depending on the stage of product development and approval:

- issue adverse inspectional findings;
- issue Warning Letters or Untitled Letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- amend and update labels or package inserts;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil, criminal and/or administrative penalties, damages or monetary fines or imprisonment;
- suspend, vary or withdraw regulatory approval;
- suspend, vary or terminate any ongoing clinical studies;
- bar us from submitting or assisting in the submission of new regulatory applications;

- refuse to approve or delay approval of 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 authorities. Additionally, comparable foreign regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval outside of the United States. In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Although general requirements for advertising and promotion of medicinal products are established under EU legislation, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities in connection with a marketing authorization. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Direct-to-consumer advertising of prescription medicinal products is also prohibited in the EU. Enforcement of advertising and promotional requirements relating to medicinal products in the EU is carried out at the national level by the national competent authorities of EU Member States. Furthermore, national or industry codes of conduct or practice, such as the Association of the British Pharmaceutical Industry (the United Kingdom innovative pharmaceutical industry trade association) code of practice, may established additional, stricter requirements than applicable legislative requirements.

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.

Failure to comply with EU and EU Member State laws that apply to the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and marketing of such products, both before and after grant of the marketing authorization, or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

The policies of the FDA, the competent authorities of the EU Member States, the European Commission and other comparable regulatory authorities with respect to drugs or clinical trials may change and additional government regulations may be enacted. As an example, the regulatory landscape related to clinical trials in the EU has evolved. The EU Clinical Trials Regulation ("CTR"), which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR permits trial sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment of some elements of the application by all EU Member States in which the trial is to be conducted, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State's decision is communicated to the sponsor through a centralized EU portal. The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR. Our compliance with the CTR requirements and that of our third-party service providers, such as CROs, may impact our developments plans.

On April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation and on 10 April 2024, the Parliament adopted its related position. The proposed revisions remain to be agreed and adopted by the European Council. Moreover, on December 1, 2024, a new European Commission took office. The proposal could, therefore, still be subject to revisions. If adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of drugs may result in a decrease in data and market exclusivity for our product candidates in the EU.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

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

MIN-301 is a peptide, and, as a peptide, may be subject to the Public Health Service Act ("PHSA"), and the Food, Drug, and Cosmetic Act ("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 BLA, for product approval. Moreover, based on an FDA intercenter agreement, we believe that MIN-301 will be regulated by the FDA's Center for Drug Evaluation and Research. However, we intend to discuss jurisdiction with the FDA to determine the appropriate regulatory pathway and corresponding requirements. Depending on the pathway, we may be subject to different regulatory requirements, including different regulatory and testing requirements, shorter or longer periods of market exclusivity, and different approval processes for generic drug and biosimilar competitors.

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

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

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

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

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

We plan to seek regulatory approval to commercialize our product candidates in the European Union and the United States. We also expect to seek regulatory approval in additional foreign countries. To market and sell our products in other jurisdictions, we must obtain separate regulatory 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 European Commission or FDA approval. The regulatory approval process outside the European Union and United States generally includes risks substantially similar to those associated with obtaining European Commission 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 regulatory 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 regulatory 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 authority. 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, or comparable foreign regulatory authorities, standards for interchangeability, the structure of government and commercial managed care formularies, and applicable 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 regulatory 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 regulatory approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant revenue from drug sales and we may not become profitable. Our commercial success also depends on coverage and adequate reimbursement of our products by third-party payors, including government payors, which may be difficult or time-consuming to obtain, may be limited in scope or may not be obtained in all jurisdictions in which we may seek to market our products. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

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

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

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

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

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

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

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

We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we enter into arrangements with third parties to perform sales, marketing and distribution services for our products, the resulting revenues or the profitability from

these revenues to us are likely to be lower than if we had sold, marketed and distributed our products ourselves. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval. Depending on the nature of the third party relationship, we may have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell, market and distribute our products effectively.

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

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

The laws that govern regulatory 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 regulatory 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 regulatory approval.

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 the European Union ("EU"), the pricing and reimbursement schemes of drugs is governed by the national legislation of each EU Member State and also vary widely from country to country. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of regulatory approval for a product. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval.

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 the European Union. There is very limited harmonization between EU Member States regarding pricing and reimbursement practices.

Legislators, policymakers and healthcare insurance funds in the EU may continue to propose and implement cost-containing measures to keep healthcare costs down; particularly due to the financial strain that the COVID-19 pandemic has placed on national healthcare systems of the EU Member States. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of EU and other foreign countries use prices for drugs established in other countries as "reference prices" to help determine the price of the product in their own territory. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced EU 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. Consequently, a downward trend in prices of drugs in some countries could contribute to similar downward trends elsewhere.

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 ability to commercialize any products successfully will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities and other third-party payors, such as private health insurers and health maintenance organizations. Government authorities and other third-party payors determine which medications they will cover and establish reimbursement levels. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients

are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

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

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

We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain regulatory 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 regulatory 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 European Commission, 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.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Presidential executive orders, Congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, on August 16, 2022, the Inflation Reduction Act of 2022 (“IRA”) was signed into law which, among other things, (1) directs U.S. Department of Health and Human Services (“HHS”) to negotiate the price of certain single-source drugs covered under Medicare that have been on the market for at least 7 years and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. These provisions began to take effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon price of the first ten drugs that were subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price

Negotiation Program. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, legislatures are passing increasing amounts of legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, on January 5, 2024, the FDA approved Florida's Section 804 Importation Program (SIP) proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA.

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 regulatory 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 regulatory approval.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, "ACA") broadened access to health insurance, reduced or constrained the growth of healthcare spending, enhanced remedies against healthcare fraud and abuse, add imposed new transparency requirements for healthcare and health insurance industries, imposed new taxes and fees on pharmaceutical manufacturers and imposed additional health policy reforms. Since the ACA's enactment, there have been executive, judicial and Congressional challenges and amendments to certain aspects of the ACA. For example, the IRA, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and additional healthcare reform measures of the second Trump administration will impact the ACA and our business.

Further, Congress is considering additional health reform measures. We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that may be charged for any of our product candidates, if approved.

Many EU Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the EU Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down.

Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States.

In December 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and began to apply on January 12, 2025, through a phased implementation. The Regulation is intended to boost cooperation among EU Member States in assessing health technologies,

including new medicinal products, and provides the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation permits EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for drug candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected. In light of the fact that the United Kingdom has left the EU, Regulation No 2021/2282 on HTA does not apply in the United Kingdom. However, the UK Medicines and Healthcare products Regulation Agency ("MHRA") is working with UK HTA bodies and other national organizations, such as the Scottish Medicines Consortium ("SMC"), the National Institute for Health and Care Excellence ("NICE"), and the All-Wales Medicines Strategy Group, to introduce new pathways supporting innovative approaches to the safe, timely and efficient development of medicinal products, including relaunching the Innovative Licensing and Access Pathway with more predicable timelines and closer involvement of the National Health Service.

Legislators, policymakers and healthcare insurance funds in the EU may continue to propose and implement cost-containing measures to keep healthcare costs down; particularly due to the financial strain that the COVID-19 pandemic has placed on national healthcare systems of the EU Member States. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of EU and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

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

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

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

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

- different regulatory requirements for conduct of clinical trials of investigational drugs and obtaining and maintaining approval of drugs in foreign countries;
- reduced protection for contractual and intellectual property rights in certain countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, political instability in particular foreign economies and markets, such as the instability caused by geopolitical conflicts including the war in Ukraine and hostilities in the Middle East, or public health issues or pandemics;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- compliance with tax laws of various jurisdictions, including with respect to intercompany transfer pricing arrangements and taxable nexus;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in North America;
- increasing obligations and tighter restrictions on privacy and the collection, use, and other processing of personal data, including patient data; and

- business interruptions resulting from geopolitical actions, including political instability, hostilities, war and terrorism, such as the war in Ukraine and hostilities in the Middle East, or natural disasters including pandemics, earthquakes, typhoons, floods and fires.

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

The United Kingdom's withdrawal from the EU may have a negative effect on global economic conditions, financial markets and our business, which could reduce the price of our common stock.

Following Brexit, the UK and the EU signed a EU-UK Trade and Cooperation Agreement, or TCA, which became provisionally applicable on January 1, 2021 and entered into force on May 1, 2021. This agreement provides details on how some aspects of the UK and EU's relationship will operate going forwards however there are still uncertainties. The TCA primarily focuses on ensuring free trade between the EU and the UK in relation to goods, including medicinal products. Among the changes that have occurred are that the UK is treated as a "third country", a country that is not a member of the EU and whose citizens do not enjoy the EU right to free movement (Northern Ireland continues to follow certain limited EU regulatory rules, including in relation to medical devices, but not in relation to medicinal products) . As part of the TCA, the EU and the UK recognize GMP inspections carried out by the other party and the acceptance of official GMP documents issued by the other party. The TCA also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The UK has unilaterally agreed to accept EU batch testing and batch release. However, the EU continues to apply EU laws that require batch testing and batch release to take place in the EU territory. This means that medicinal products that are tested and released in the UK must be retested and re-released when entering the EU market for commercial use.

On February 27, 2023, the UK Government and the European Commission reached a political agreement on the so-called "Windsor Framework". The Windsor Framework is intended to revise the Northern Ireland Protocol to address some of the perceived shortcomings in its operation. The agreement was adopted at the Withdrawal Agreement Joint Committee on March 24, 2023 and the arrangements under the Windsor Framework relating to medicinal products took effect on January 1, 2025. As it relates to marketing authorizations, the United Kingdom has a separate regulatory submission process, approval process and a separate national marketing authorization. Northern Ireland continued, until January 1, to be covered by the marketing authorizations granted by the European Commission but the Windsor Framework provides that the UK MHRA is the sole regulatory body responsible for granting marketing authorizations for Northern Ireland as of January 1, 2025.

A significant proportion of the regulatory framework in the UK applicable to medicinal products is currently derived from EU Directives and Regulations. The potential for UK legislation to diverge from EU legislation following Brexit could materially impact the regulatory regime with respect to the development, manufacture, import, approval, and commercialization of our product candidates in the UK or the EU. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

All of these changes could increase our costs and otherwise adversely affect our business. Any delay in obtaining, or an inability to obtain, any regulatory approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the UK or the EU and restrict our ability to generate revenue and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of our product candidates into the EU. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the UK or the EU for our product candidates, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the UK. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU.

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 and performance-based restricted stock units. The value to employees of such equity grants

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. In addition, if performance conditions in these awards, to the extent applicable, are not met or if our stock-based compensation otherwise ceases to be viewed as a valuable benefit, our ability to attract, retain and motivate personnel could be weakened, which could harm our business.

Despite our efforts to retain valuable employees, members of our management, scientific and development teams generally may terminate their employment with us, with or without good reason, upon written notice to us. Pursuant to their employment arrangements, some 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, 2024, we had 8 full-time employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including:

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

As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, collaborators, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

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

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

- disruption in our relationships with collaborators or suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- retention of key employees;
- diversion of management time and focus from operating our business to management of strategic alliances or joint ventures or acquisition integration challenges;

- increases in our expenses and reductions in our cash available for operations and other uses; and
- possible write-offs or impairment charges relating to acquired businesses.

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

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

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

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

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

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

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

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

disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

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

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

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

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

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

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

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

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees and independent contractors, such as principal investigators, CROs, manufacturers, consultants, commercial partners and vendors, could include failures to comply with regulations of the FDA or comparable foreign regulatory authorities, to provide accurate information to the FDA or comparable foreign regulatory authorities to comply with manufacturing standards we have established, to comply with US federal and state healthcare fraud and abuse laws and comparable foreign regulatory requirements, to report financial information or data accurately or to disclose unauthorized activities to us. For example, in our Phase 3 trial of roluperidone for the treatment of negative symptoms of schizophrenia, one clinical site that recruited 17 patients reported implausible behavioral (schizophrenia symptoms) and physiological (blood pressure) data. As a result, these 17 patients were excluded and made part of an mITT analysis set. Sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and

other abusive practices. These laws may restrict or prohibit a wide range of business activities, including, but not limited to certain activities related to research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee and independent contractor misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in sanctions, monetary penalties, and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct.

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

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

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

- The federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the referral of an individual for the furnishing or arranging for the furnishing of any item or service, or the purchase, lease, order, arrangement for, or recommendation of the purchase, lease, or order of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs.
- The federal civil False Claims Act, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; conspiring to defraud the government by getting a false or fraudulent claim paid or approved by the government; or knowingly making, using or causing to be made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government.
- The federal criminal False Claims Act, which imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false, fictitious or fraudulent.
- The civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.
- The Veterans Health Care Act of 1992 that requires manufacturers of "covered drugs" to offer them for sale to certain federal agencies, including but not limited to, the Department of Veterans Affairs, on the Federal Supply Schedule, which requires compliance with applicable federal procurement laws and regulations and subjects manufacturers to contractual remedies as well as administrative, civil and criminal sanctions.
- The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor

(e.g., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("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 and covered subcontractors that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements.
- The federal Physician Payments Sunshine Act and its implementing regulations requires manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace and other activities that potentially harm consumers.
- State law equivalents of each of the above federal laws, such as anti-kickback, false claims, consumer protection and unfair competition laws which may apply to our business practices, including but not limited to our research, distribution, sales and marketing arrangements and our practices for submitting claims involving healthcare items or services reimbursed by any third-party payors, including commercial insurers. State laws may also (1) require that pharmaceutical companies comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restrict the payments that may be made to healthcare providers, (2) require that drug manufacturers file reports with states regarding marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on a pharmaceutical company's business and/or increase enforcement scrutiny of its activities), (3) require the reporting of information related to drug pricing, ,and (4) govern the privacy and security of health information in certain circumstances. State laws are not uniform, may differ from each other in significant ways and may be applied with differing effects.

In addition, any sales of our products or product candidates once commercialized outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above. Outside the United States, interactions between pharmaceutical companies and health care professionals are governed by strict laws such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. These laws may include, for instance, the UK Bribery Act 2010 other national anti-corruption legislation related to EU Member States' adherence to the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, European Union consumer laws protecting against defective products, including the Product Liability Directive 85/374/EEC, the UK ABPI Code of Practice as well as the French "Bertrand Law" and related Decrees and Ordinances Imposing Transparency requirements on manufacturers in their interactions with French healthcare actors, and comparable requirements in other EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

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, significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs or comparable foreign programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

We are subject to the Foreign Corrupt Practices Act.

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

We are subject to stringent and evolving U.S. and foreign laws, regulations and rules, contractual obligations, policies, industry standards, and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive data, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, sensitive third-party data, and employee data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act). For example, the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 as amended by the California Privacy Rights Act of 2020 ("CPRA") (collectively, "CCPA") applies to personal data of consumers, business representatives, and employees who are California residents, requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights, such as those noted below. The CCPA provides for fines for intentional violations and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA and other state laws exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts and increase legal risk and compliance costs for us and the third parties with whom we work.

In addition, data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts, and we expect more states to pass similar laws in the future.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security, including the European Union's General Data Protection Regulation ("EU GDPR") and the United Kingdom's GDPR ("UK GDPR") (collectively, "GDPR"), which impose strict requirements for processing personal data. Violators of these laws face significant penalties. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under EU GDPR / 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

The Swiss Federal Act on Data Protection, or the FADP, also applies to the collection and processing of personal data, including health-related information, by companies located in Switzerland, or in certain circumstances, by companies located outside of Switzerland. Compliance with the FADP and its revised ordinances may result in an increase of costs of compliance, risks of noncompliance and penalties for noncompliance.

In the ordinary course of business, we transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions have adopted and may adopt stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data, as well as other adverse consequences. In particular we may be unable to import personal data to the United States, which could significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties that are subject to such cross-border data transfer or localization laws; or requiring us to increase our personal data processing capabilities and infrastructure in foreign countries at significant expense. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

In addition to data privacy and security laws, we are contractually subject to data privacy and security obligations, including industry standards adopted by industry groups and may become subject to new data privacy and security obligations in the future. For example, certain privacy laws require our customers to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. Regulators in the United States have scrutinized and are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources. These obligations may, and certain cases have, necessitate changes to our information technologies, systems, and data processing practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including proceedings against us by governmental entities or others.

If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. The Foreign Corrupt Practices Act ("FCPA"), prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and debarment from government contracts.

We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

If our information technology systems, or those of third parties with whom we work, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

In the ordinary course of our business, we and the third parties with whom we work process proprietary, confidential, and sensitive data, including personal data (such as health-related data and data related to clinical trials), intellectual property, and trade secrets (collectively, sensitive information).

Cyberattacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties with whom we work. Such threats are prevalent, continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. We and the third parties with whom we work may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, attacks enhanced or facilitated by AI, and other similar threats.

In particular, ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, ability to provide our products or services, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such

acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program. Remote work has increased risks to our information technology systems and data, as our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

We rely upon third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email, content delivery to customers, and other functions. We also share or receive sensitive information with or from third parties. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. While we may be entitled to damages if our third-party service providers or the third parties with whom we work fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or that of the third parties with whom we work have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures, or those of the third parties with whom we work, will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work), but we may not be able to detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our services or conduct our operations. For example, a cyber-attack on one of our external contractors during the summer of 2019 resulted in a disruption to patient recruitment in our Phase 3 clinical trial of roluperidone. We expend significant resources and may have to modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to implement other requirements, such as providing credit monitoring. Such disclosures and compliance with such requirements are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may negatively impact our ability to grow and operate our business or disrupt our ability to develop and provide our products and services. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, our sensitive information could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

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 national competent authorities of EEA countries and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCPs through periodic unannounced 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 FDA or comparable foreign 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 regulatory 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 regulatory 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 comparable foreign regulatory authorities have comparable requirements and powers. We, our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA or other comparable foreign regulatory authorities, to monitor and ensure compliance with cGMP. Despite our efforts to audit and verify regulatory compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA, competent authorities of EU Member States or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations. 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 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 comparable 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 limited 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 regulatory 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 authorities. 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. If on regulatory inspection by the FDA or other comparable foreign regulatory authorities, one or more of our third-party manufacturing vendors are found to be to be noncompliant with cGMP regulation, this may result in shutdown of the third-party vendor or invalidation of drug product lots or processes. In some cases, a product recall may be warranted or required, which would materially affect our ability to supply and market our drug products.

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 regulatory 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 regulatory 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 supranational, national, federal, state and local laws in the United States and in Europe governing the use, manufacture, storage, handling and disposal of medical, radioactive and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical, radioactive or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state, federal authorities or other equivalent national authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical radioactive or hazardous

materials. Compliance with applicable environmental laws is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

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

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

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

We exclusively license roluperidone, our lead product candidate, from MTPC, with the rights to develop, sell and import roluperidone globally, excluding most of Asia. If our license agreement with MTPC was terminated, it could have a material impact on our operations.

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

On January 19, 2021, we entered into an agreement with Royalty Pharma under which Royalty Pharma acquired our royalty interest in seltorexant for an upfront payment of $60 million and up to $95 million in future milestone payments that are contingent upon the achievement of certain clinical, regulatory and commercial milestones for seltorexant by Janssen Pharmaceutica NV, one of the Janssen Pharmaceutical Companies of Johnson & Johnson ("Janssen"), or any other party in the event that Janssen sells seltorexant. For more information regarding this arrangement, see the sections titled "Item 1. Business—Overview" and "Item 1. Business—Our Clinical-Stage Programs—Seltorexant (MIN-202)" in this Annual Report on Form 10-K.

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

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

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

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

Risks Related to Intellectual Property

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

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

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

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

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

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after our product candidates obtain regulatory approval, which may subject us to increased competition and reduce or eliminate our ability to recover our development costs. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Finally, any patent that grants from our U.S. patent applications relating to methods of using MIN-301 to treat neurologic and psychiatric diseases is expected to expire as early as 2028. Although we expect to seek extensions of patent terms where available, including in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, which permits a patent term extension of up to five years beyond the expiration of the patent, we cannot be certain that an extension will be granted, or if granted, what the applicable time period or the scope of patent protection afforded during any extended period will be. The applicable authorities, including the 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 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 ("USPTO"). Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our products. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Under certain circumstances, we could be forced, including by court order, to cease commercializing our products. In addition, in any such proceeding or litigation, we could be found liable for monetary damages. Regardless of the outcome, such claims or litigation may be time-consuming and costly to defend, divert management resources and have other adverse effects on our business.

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

Our success will depend, in part, on our ability to obtain and maintain patent protection for our product candidates, preserve our trade secrets, prevent third parties from infringing upon our proprietary rights and operate without infringing upon the proprietary rights of others. Composition-of-matter patents on the biological or chemical active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to

any method of use. We have filed and in-licensed composition-of-matter patent applications for all of our product candidates. However, we cannot be certain that the claims in our patent applications to inventions covering our product candidates will be considered patentable by the USPTO and courts in the United States or by the patent offices and courts in foreign countries.

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

Patent applications in the United States and most other countries are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months or more. As a result, we cannot be certain that we and the inventors of the issued patents and applications that we may in-license were the first to conceive of the inventions covered by such patents and pending patent applications or that we and those inventors were the first to file patent applications covering such inventions. Also, we have a number of issued patents and numerous patent applications pending before the USPTO and foreign patent offices and the patent protection may lapse before we manage to obtain commercial value from them, which might result in increased competition and materially affect our position in the market.

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

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

Depending on decisions by the United States Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors' or collaborators' ability to obtain new patents or to enforce existing and future patents.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Ownership of Our Common Stock

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

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

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

The trading price of our common stock is likely to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. As a result of this volatility, investors may not be able to sell their securities at a profit. The market price of our securities could be subject to wide fluctuations in response to a variety of factors, including but not limited to:

- the success of competitive products or technologies;
- adverse results or delays in our preclinical or clinical trials or those of our competitors;
- regulatory actions, including adverse regulatory decision, with respect to our products or our competitors' products;
- failure to successfully develop or commercialize any of our product candidates;
- the perception of limited market sizes or pricing for any of our product candidates;
- the results of our efforts to in-license or acquire additional product candidates or products;
- failure to maintain our existing strategic collaborations or enter into new collaborations;
- 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;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- 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, or any inability to obtain additional funding;
- sales of our common stock by us, our insiders or our other stockholders;
- changes in laws or regulations applicable to our products, including changes in the structure of healthcare payment systems, including coverage and reimbursement;
- significant lawsuits, including stockholder litigation and litigation filed by us or filed against us pertaining to patent infringement or other violations of intellectual property rights;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies, including in connection with the war in Ukraine, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Biopharmaceutical 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, including potentially worsening economic conditions, increased inflation and other adverse effects or developments, including political, regulatory and other market conditions, may negatively affect the market price of shares of our common stock, regardless of our actual operating performance. The market price of shares of our common stock may decline, and you may lose some or all of your investment.

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 42.2% of our voting stock as of December 31, 2024, including 19.3% held by funds affiliated with Federated Hermes, Inc. ("Federated") and 18.2% held by BI (as defined below). Accordingly, Federated and BI will have significant influence in determining the outcome of any corporate transaction or other matter submitted to the stockholders for approval, including mergers, consolidations, and the sale of all or substantially all of our assets and other significant corporate actions. Unless full participation of all stockholders takes place in such stockholder meetings, Federated and/or BI may be able to approve such matters itself. This concentration of ownership may (i) delay or deter a change of control of our Company; (ii) deprive stockholders of an opportunity to receive a premium for their common stock as part of a sale of our Company; and (iii) affect the market price and liquidity of our common stock. In conjunction with the Private Placement (as defined below), we provided BI with the right to designate an observer at all meetings of our board of directors and any committee thereof so long as BI holds not less than 10% of shares of our common stock (including shares of common stock issuable upon exercise of pre-funded warrants), unless a change of control of the Company occurs sooner. The interests of our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates 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. The effect of these rights and these principal stockholders' influence may impact the price that investors are willing to pay for our securities. If these principal stockholders sell a substantial number of shares of our common stock in the public market, the market price of our common stock could be adversely impacted. The perception among the public that these sales will occur could also contribute to a decline in the market price of 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. These sales, or the possibility that these sales may occur, might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate. See also the risk factor above titled "*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*."

In addition, in the future, we may issue shares of common stock, or other equity or debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement or otherwise. Any such issuance, including pursuant to any at-the-market agreements, such as the at-the-market offering program that we entered into with Jefferies LLC in September 2022, could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

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

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

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

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

Pursuant to our Amended and Restated 2013 Equity Incentive Plan, our management is authorized to grant stock options and other equity-based awards of up to 2,078,917 shares to our employees, directors and consultants. To the extent that new awards are granted and exercised or settled, or we issue additional shares of common stock in the future, our stockholders may experience additional dilution, which could cause our stock price to fall.

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

As a public company listed in the United States, we incur significant additional legal, accounting and other costs. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the Securities and Exchange Commission ("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 ("Nasdaq"), 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 are a "smaller reporting company" and, because we have opted to use the reduced reporting requirements available to us, certain investors may find investing in our securities less attractive.

We are a "smaller reporting company" under the SEC's disclosure rules, meaning that we have either: (i) a public float of less than $250 million; or (ii) annual revenues of less than $100 million during the most recently completed fiscal year; and no public float; or a public float of less than $700 million.

As a smaller reporting company, we are permitted to comply with scaled-back disclosure obligations in our SEC filings compared to other issuers, including with respect to disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We have elected to adopt the accommodations available to smaller reporting companies. Until we cease to be a smaller reporting company, the scaled-back disclosure in our SEC filings will result in less information about our company being available than for other public companies. If investors consider our common shares less attractive as a result of our election to use the scaled-back disclosure permitted for smaller reporting companies, there may be a less active trading market for our common shares and our share price may be more volatile.

We are also a non-accelerated filer under the Exchange Act of 1934, and we are not required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002. Therefore, our internal controls over financial reporting will not receive the level of review provided by the process relating to the auditor attestation included in annual reports of issuers that are subject to the auditor attestation requirements. In addition, we cannot predict if investors will find our common shares less attractive because we are not required to comply with the auditor attestation requirements. We cannot predict if investors will find our securities less attractive because we rely on these available exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities and the market price of our securities may be more volatile.

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

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. We have and may become the target of securities litigation in the future. The outcome of litigation is necessarily uncertain, and we could be forced to expend significant resources in the defense of such suits, and we may not prevail. Monitoring and defending against legal actions is time-consuming for our management and detracts from management's ability to fully focus our internal resources on our business activities. In addition, we may incur substantial legal fees and costs in connection with any such litigation. We have not established any reserves for any potential liability relating to any such potential lawsuits. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages. We currently maintain insurance coverage for some of these potential liabilities. Other potential liabilities may not be covered by insurance, insurers may dispute coverage or the amount of insurance may not be enough to cover damages awarded. In addition, certain types of damages may not be covered by insurance, and insurance coverage for all or certain forms of liability may become unavailable or prohibitively

expensive in the future. A decision adverse to our interests on one or more legal matters or litigation could result in the payment of substantial damages, or possibly fines, and could have a material adverse effect on our reputation, financial condition and results of operations.

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

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

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

- establishing a classified board of directors such that not all members of the board are elected at one time;
- allowing the authorized number of directors to be changed only by resolution of our board of directors;
- limiting the removal of directors by the stockholders;
- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders;
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters than can be acted upon at stockholder meetings; and
- requiring the approval of the holders of at least 66 2/3% of the votes that all of our stockholders would be entitled to cast to amend or repeal our bylaws.

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

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation, as amended, or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business and financial condition.

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.

Our common stock may be delisted from The Nasdaq Capital Market which could negatively impact the price of our common stock, liquidity and our ability to access the capital markets.

Our common stock is currently listed on The Nasdaq Capital Market under the symbol "NERV." The listing standards of The Nasdaq Capital Market provide that a company, in order to qualify for continued listing, must maintain a minimum stock price of $1.00 and satisfy standards relative to minimum stockholders' equity, minimum market value of publicly held shares and various additional requirements. If Nasdaq delists our securities from trading on its exchange for failure to meet the listing standards, we and our stockholders could face significant negative consequences including:

- limited availability of market quotations for our securities;
- a determination that the common stock is a "penny stock" which would require brokers trading in the common stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for shares of common stock;
- a limited amount of analyst coverage, if any; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

Delisting from The Nasdaq Capital Market could also result in other negative consequences, including the potential loss of confidence by suppliers, customers and employees, the loss of institutional investor interest, fewer business development opportunities and potential liabilities arising from stockholder litigation or other disputes.

On April 10, 2024, we received written notice from Nasdaq notifying us that for the last 31 consecutive business days, our minimum Market Value of Listed Securities was below the minimum of $35 million required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(b)(2) (the "MVLS Rule").

On January 10, 2025, we received a notice from Nasdaq indicating that following our hearing before the Nasdaq Hearings Panel (the "Panel") on December 10, 2024, the Panel has granted our request for continued listing on Nasdaq, subject to the following: (1) on or before March 31, 2025, we will have filed a public disclosure describing the transactions undertaken by us to achieve compliance and demonstrate long-term compliance with Nasdaq Listing Rule 5550(b)(1) (the "Equity Rule"), which requires issuers listed on The Nasdaq Capital Market to maintain minimum stockholders' equity of $2.5 million, and will have provided an indication of our equity following those transactions; and (2) on or before March 31, 2025, we must have provided the Panel with income projections for the next 12 months, with all underlying assumptions clearly stated, and evidence compliance with all applicable criteria for continued listing on The Nasdaq Capital Market.

We are working to prepare and file, as applicable, the documents described above by March 31, 2025 to enable us to regain compliance with Nasdaq's listing standards. Notwithstanding, there can be no assurance that we will be able to regain compliance with Nasdaq's listing standards, including the continued listing requirements under the Equity Rule or the MVLS Rule, that we will be able to maintain compliance with the other continued listing requirements set forth in Nasdaq's listing standards or that we will be able to continue our listing on Nasdaq.

In particular, our share price may continue to decline for a number of reasons, including many that are beyond our control. See the risk factor captioned "*The market price of our stock may be volatile, and you could lose all or part of your investment.*"

If we fail to comply with the continued listing standards of The Nasdaq Capital Market, we may seek to list our common stock on the NYSE American or on a regional stock exchange or, if one or more broker-dealer market makers comply with applicable requirements, the over-the-counter ("OTC") market. Listing on such other market or exchange could reduce the liquidity of our common stock. If our common stock were to trade in the OTC market, an investor would find it more difficult to dispose of, or to obtain accurate quotations for the price of, the common stock. Delisting of the common stock could depress our stock price, substantially limit liquidity of our common stock and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Further, delisting of the common stock would likely result in the common stock becoming a "penny stock" under the Exchange Act.

ITEM 1B. Unresolved Staff Comments

None.

ITEM 1C. Cybersecurity

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, patient data, and data related to our clinical trials ("Information Systems and Data").

The Company's information security function and third-party service providers help identify, assess and manage the Company's cybersecurity threats and risks, including through the use of the Company's risk assessment process. The Company's information security function and third-party service providers identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment and risk profile using various methods including, for example:

- automated tools;
- subscribing to reports and services that identify cybersecurity threats;
- analyzing reports of threats and actors;
- conducting scans of the threat environment;
- evaluating our and our industry's risk profile;
- evaluating threats reported to us;
- conducting audits;
- conducting threat assessments for internal and external threats;
- conducting vulnerability assessments to identify vulnerabilities; and
- using external intelligence feeds.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards, and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example:

- our incident response plan;
- incident detection and response processes;
- a disaster recovery/business continuity plan;
- encryption of certain data;
- network security controls;
- access controls;
- asset management, tracking and disposal;
- systems monitoring;
- employee training;
- penetration testing;
- cybersecurity insurance; and
- outsourced cybersecurity staff.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, the Company's information security function works with management, including our Chief Operating Officer ("COO") to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example:

- our external IT service provider;
- professional services firms, including legal counsel;
- cybersecurity consultants;
- managed cybersecurity service providers; and
- penetration testing firms.

We use third-party service providers to perform a variety of functions throughout our business, such as application providers, contract research organizations and contract manufacturing organizations. As part of our vendor security due diligence and to manage cybersecurity risks associated with our use of certain vendors, we perform risk assessments on vendors and may include cybersecurity obligations in our contracts with them. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor due diligence involves different levels of assessment designed to help identify cybersecurity risks associated with a provider. For example, we may impose contractual obligations related to cybersecurity on the provider.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including:

- *If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.*

Governance

Our board of directors addresses the Company's cybersecurity risk management as part of its general oversight function. The board of directors' audit committee is responsible for overseeing Company's cybersecurity risk management processes, including oversight of mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including our COO.

The COO is responsible for managing our information security function and overseeing our third-party information technology service providers. The COO is also responsible for helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy, communicating key priorities to relevant personnel, and approving budgets. Our outsourced Chief Technology Officer, who has over 20 years in executive-level IT and cybersecurity roles, is responsible for developing and implementing our technology environment and cybersecurity framework, helping the Company prepare for cybersecurity incidents, approving and implementing certain cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response plan is designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including the COO and Chief Financial Officer ("CFO"). The COO and CFO work with the other members of the Company's incident response team to help the Company mitigate and remediate cybersecurity incidents of which they are notified. In addition, the Company will report to the audit committee of the board of directors for certain cybersecurity incidents.

The audit committee receives periodic updates from the CFO and finance department concerning the Company's significant cybersecurity threats and risk and the processes the Company has implemented to address them. The audit committee also receives various updates, summaries or presentations related to cybersecurity threats, risk and mitigation.

ITEM 2. Properties

Our principal executive offices are located at 1500 District Avenue, Burlington, MA 01803. We lease this facility, which consists of approximately 491 square feet of office space. The lease is on a month-to-month basis commencing on February 1, 2025, with a monthly payment of $9,106. The term of the previous lease agreements for this space was from July 15, 2022 through January 31, 2025. 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

Market Information

Our common stock was traded on the Nasdaq Global Market under the symbol "NERV" from our initial public offering on July 1, 2014 until September 11, 2022. Effective September 12, 2022, our common stock began trading on The Nasdaq Capital Market under the symbol "NERV."

Holders of Record

As of the close of business on February 20, 2025, there were approximately 35 holders of record of our common stock, including Cede & Co., a nominee for The Depository Trust Company ("DTC"), which holds shares of our common stock on behalf of an indeterminate number of beneficial owners. All of the shares of common stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are considered to be held of record by Cede & Co. as one stockholder. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Securities Authorized for Issuance Under Equity Compensation Plans

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.

ITEM 6. [Reserved]

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

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

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

Overview

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

We are developing roluperidone for the treatment of negative symptoms in patients with schizophrenia and have exclusive rights to develop and commercialize MIN-301 for the treatment of Parkinson's disease. In addition, we previously co-developed seltorexant with Janssen Pharmaceutica NV, one of the Janssen Pharmaceutical Companies of Johnson & Johnson ("Janssen"), for the treatment of insomnia disorder and adjunctive treatment of Major Depressive Disorder ("MDD"). In June 2020, we exercised our right to opt out of our agreement with Janssen for the Phase 3 development of seltorexant and as a result, we were entitled to collect royalties in the mid-single digits on potential future worldwide sales of seltorexant in certain indications, with no further financial obligations to Janssen. In January 2021, we sold our rights to these potential royalties to Royalty Pharma plc ("Royalty Pharma") for a $60 million cash payment and up to an additional $95 million in potential future milestone payments, subject to completion of Phase 3 trials by Janssen and regulatory approvals.

In August 2022, we submitted a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") for our lead product candidate, roluperidone, for the treatment of negative symptoms in schizophrenia. On February 26, 2024, the FDA issued a Complete Response Letter ("CRL") regarding our NDA for roluperidone. Since receiving the CRL, we have continued to have interactions with the FDA with the goal of addressing the questions raised in the CRL.

We have not received any regulatory approvals to commercialize any of our product candidates, and we have not generated any revenue from the sales or license of our product candidates. We routinely evaluate the status of our drug development programs as well as potential strategic options. We have incurred significant operating losses since inception and expect to continue to incur net losses and negative cash flows from operating activities for the foreseeable future in connection with the clinical and regulatory activities associated with advancing our product candidates. As of December 31, 2024 and 2023, we had an accumulated deficit of $395.4 million and $396.8 million, respectively. For the years ended December 31, 2024 and 2023, we recorded net income of $1.4 million and a net loss of $30.0 million, respectively.

Clinical and Regulatory Updates

Roluperidone (MIN-101)

Complete Response Letter (CRL)

On February 26, 2024, the FDA issued a CRL to our NDA for roluperidone for the treatment of negative symptoms in patients with schizophrenia. In the CRL, the FDA cited the following clinical deficiencies:

- Although one study (MIN-101C03) demonstrated statistical significance on the primary efficacy endpoint, it is insufficient on its own to establish substantial evidence of effectiveness.
- The NDA submission lacks data on concomitant antipsychotic administration.
- The NDA submission lacks data needed to establish that the change in negative symptoms of schizophrenia with roluperidone treatment was clinically meaningful.

- The submitted safety database included an inadequate number of subjects exposed to roluperidone at the proposed dose (64 mg) for at least 12 months.

To address these deficiencies, the FDA stated that we must submit at least one additional positive, adequate, and well-controlled study to support the safety and effectiveness of roluperidone for the treatment of negative symptoms. We must also provide additional data to demonstrate the safety and efficacy of roluperidone co-administered with antipsychotic medications, to support the observed effect on negative symptoms with roluperidone treatment corresponds to a clinically meaningful change, and to demonstrate the long-term safety of the proposed dose.

In addition to the clinical deficiencies described above, the FDA also provided comments on, among other items, clinical pharmacology, product quality, biopharmaceutics, and nonclinical issues.

Phase 1b Clinical Trial (MIN-101C18)

In the first quarter of 2024, we completed a clinical trial initiated in October 2023 to evaluate the safety, tolerability, pharmacodynamics and pharmacokinetics of the co-administration of roluperidone and olanzapine in adult subjects with moderate to severe negative symptoms of schizophrenia. This clinical trial (NCT06107803) was designed to investigate the pharmacodynamic and pharmacokinetic effects and safety of the concomitant therapy of roluperidone with an established and widely used antipsychotic.

We enrolled 17 male and female subjects with moderate to severe negative symptoms of schizophrenia for this study. Out of the 17 enrolled subjects, 13 completed all 17 days of daily dosing with roluperidone 64 mg (for 7 days) and roluperidone with olanzapine 10 mg (for 10 additional days). Two subjects withdrew consent after enrollment, one patient was discontinued due to a major protocol deviation, and one was discontinued due to a treatment-unrelated serious adverse event. Roluperidone administered concomitantly with olanzapine was generally well tolerated and no unexpected safety signals were detected, with few treatment-emergent adverse events (TEAEs) reported, most of which were mild, and all resolved without sequelae. We observed no emergent clinically significant electrocardiogram or laboratory abnormalities during the study. We observed no symptomatic worsening during the administration of roluperidone alone (7 days) or when administered in combination with olanzapine at 10 mg (10 days). The study demonstrated that pharmacokinetic interactions between the two drugs were not relevant.

New Drug Application Filed

On April 27, 2023, the FDA filed our NDA for roluperidone for the treatment of negative symptoms in patients with schizophrenia. The decision to file the NDA followed our request for formal dispute resolution and appeal of the RTF. The issues cited in the RTF decision included those discussed at the Type C meeting in March 2022. In granting the appeal, the FDA deciding official agreed with us that the issues cited in the RTF decision should be considered during the FDA's review of the NDA.

On May 8, 2023, we received confirmation from the FDA that the NDA for roluperidone has been filed in accordance with the Appeal Granted letter dated April 27, 2023 and assigned a standard review classification and a Prescription Drug User Fee Act ("PDUFA") goal date of February 26, 2024. The FDA advised that it identified potential review issues that had been previously cited in the RTF decision letter, which included those discussed at a Type C meeting in March 2022, described further below.

New Drug Application Submission

In August 2022, we submitted an NDA to the FDA for roluperidone for the treatment of negative symptoms in patients with schizophrenia. The NDA submission is supported by results from two late-stage, well-controlled studies in patients with moderate to severe negative symptoms and stable positive symptoms of schizophrenia, referred to as Study MIN-101C03 (the Phase 2b trial) and Study MIN-101C07 (the Phase 3 trial). Both studies were planned to constitute the bulk of evidence of roluperidone's effectiveness for the indication of treating negative symptoms of schizophrenia. This plan relied on both studies having the same overall study design: both were multicenter, multinational, randomized, double-blind, placebo-controlled, parallel-group studies in which patients received either 32 mg or 64 mg doses of roluperidone. In both studies, if patients were taking antipsychotic treatments, they were discontinued and a washout period of at minimum two days was implemented before beginning the assigned study treatment. Both studies capture comparative placebo-controlled data through their 12-week double-blind period. Both studies also provide long-term exposure data regarding the safety and tolerability of roluperidone, as well as efficacy based on blinded doses of roluperidone, specifically intended to demonstrate the maintenance of improvement in negative symptoms and the low rate of worsening of positive symptoms following 24-week (Study MIN-101C03) and 40-week (Study MIN-101C07) Open Label ("OL") periods. With the exception of the duration of the OL period, these two studies were nearly identical with respect to patient population and main assessment tools (namely, Positive and Negative Syndrome Scale ("PANSS"), Personal and Social Performance Scale ("PSP"), and Clinical Global Impression ("CGI")). As such, the data from these studies are the basis for the decision to submit the application at

this stage of development as we believe they provide data to support the long-term safety and efficacy in adults in an area of high unmet medical need.

We are seeking approval for the 64 mg dose of roluperidone, and results described hereafter are for the 64 mg dose only.

Results of Study MIN-101C03 supported the primary hypothesis that after 12 weeks of treatment, roluperidone is superior to placebo in reducing negative symptoms of schizophrenia. In the primary efficacy analysis, 64 mg roluperidone resulted in a statistically significant reduction of negative symptoms of schizophrenia as measured by PANSS Pentagonal Structured Model Negative score ("PSM") ($p \leq 0.0036$). A post hoc analysis of the change from Baseline to Week 12 in the PANSS Marder's Negative Symptoms Factor Score ("NSFS") also demonstrated a statistically significant difference for 64 mg roluperidone compared with placebo ($p \leq 0.001$). Statistically significant improvements with 64 mg roluperidone compared with placebo after 12 weeks of the Double Blind ("DB") period were also seen for multiple secondary/exploratory efficacy analyses. Further improvements in the NSFS were also seen during the 24-week OL period.

The superiority of roluperidone over placebo was also demonstrated in Study MIN-101C07. Although the primary analysis (intent-to-treat ("ITT")) of change from Baseline in the NSFS to Week 12 for roluperidone compared to placebo marginally missed statistical significance ($p \leq 0.064$), the results were quantitatively superior for 64 mg roluperidone treatment. Furthermore, the analysis of the modified intent-to-treat ("mITT") population (mITT data set excludes data from one clinical site with implausible results for the 17 patients recruited at this site) demonstrated a nominal statistically significant improvement in the NSFS for 64 mg roluperidone compared to placebo ($p \leq 0.044$). In addition, statistically significant improvements (unadjusted) in the NSFS from Baseline were seen as early as Weeks 4 and 8 for 64 mg roluperidone compared to placebo for both the ITT and the mITT populations. PSP Total score (sole key secondary endpoint measuring vocational and social skills) reached statistical significance for both ITT and mITT populations ($p \leq 0.022$ and $p \leq 0.017$, respectively). Further improvements in the NSFS and PSP Total score were also seen during the 40-week OL period.

Type C Meeting

In April 2022, we received the official meeting minutes from the Type C meeting with the FDA held on March 2, 2022, in which the development of roluperidone for the treatment of negative symptoms in schizophrenia was discussed. Four main topics (listed below) were highlighted by the FDA for which they requested input and further clarification from us. Following the meeting, we provided additional data to address:

1. The potential impact of roluperidone administration on the efficacy and safety of antipsychotic drugs. More specifically, the psychiatric division (the "Division") wanted reassurance that those patients administered roluperidone who manifest worsening of schizophrenia symptoms and in the opinion of the clinician/investigators need treatment with antipsychotics, do not experience a diminished benefit of the antipsychotic treatment or unexpected adverse effects.
2. The comparability of US and non-US schizophrenia patients. More specifically, the Division wanted to be reassured that data collected in MIN-101C03 in non-US patients is applicable to US patients.
3. Supporting statistical evidence of efficacy of roluperidone on negative symptoms.
4. The ability of clinicians to identify patients who might benefit from roluperidone.

Seltorexant

In June 2020 we exercised our right to opt out of our agreement with Janssen for the future Phase 3 development and commercialization of seltorexant. Under the terms of the opt-out agreement, we were entitled to collect royalties in the mid-single digits on potential future worldwide sales of seltorexant in certain indications, with no further financial obligations to Janssen. In January 2021 we sold our rights to these potential royalties to Royalty Pharma for a $60 million cash payment and up to an additional $95 million in potential milestone payments, subject to completion of Phase 3 trials by Janssen and regulatory approvals. The $60 million payment received from Royalty Pharma has been included on our balance sheet under liability related to the sale of future royalties.

For further discussion of the sale of future royalties, please refer to Note 5, Sale of Future Royalties, to our financial statements appearing elsewhere in this Form 10-K.

MIN-301

In 2021, we made the strategic decision to focus our limited resources on moving forward our lead drug candidate, roluperidone, and deferred the development of MIN-301 until additional resources become available. As a result of our limited resources and development deferral combined with the overall market conditions, we recognized a non-cash charge of $15.2 million as of December 31, 2021 related to the impairment of the intangible asset for MIN-301. We had previously recognized in-process research and development for MIN-301 in conjunction with the acquisition of MIN-301 during 2014. No updates were made in respect of the development of MIN-301 during 2024.

Financial Overview

Revenue

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

Research and Development Expenses

Research and development costs are expensed as they are incurred and consist principally of costs incurred in connection with the development of our product candidates including: fees paid to consultants and clinical research organizations ("CROs"), investigator grants, patient screening, laboratory work, database management, material management, statistical analysis, license fees, regulatory compliance, and costs related to salaries, benefits, bonuses and stock-based compensation granted to employees in research and development functions.

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

	Year Ended December 31,	
	2024	2023
Roluperidone	$ 11,448	$ 11,795
MIN-117	—	—
MIN-301	—	—
Total	$ 11,448	$ 11,795

Completion dates and costs can vary significantly by product candidate and are difficult to predict. We anticipate making determinations as to which programs to pursue and the level of 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 of each product candidate's commercial potential. We will need to raise additional capital or may seek additional product collaborations in the future to complete the development and commercialization of our product candidates.

General and Administrative Expenses

General and administrative costs are expensed as they are incurred and consist principally of costs for facility and information systems, professional fees for auditing, consulting and legal services and costs related to salaries, benefits, bonuses and stock-based compensation granted to employees in administrative functions. General and administrative costs also include costs for maintaining a publicly listed company including increased audit and legal fees, compliance with securities laws, corporate governance and investor relations.

Foreign Exchange Gains (Losses)

Foreign exchange gains (losses) are comprised primarily of gains and (losses) on foreign currency transactions primarily related to research and development expenses. We incur certain expenses, primarily in Euros, and record these expenses in United States Dollars at the time the liability is incurred. Changes in the applicable foreign currency rate between the date that an expense is recorded and the payment date is recorded as a foreign currency gain or (loss).

Investment Income

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

Non-Cash Interest Expense for the Sale of Future Royalties

Non-cash interest expense for the sale of future royalties consists of the non-cash interest expense associated with the Royalty Pharma agreement.

Other Income

Other income consists of the gain associated with the adjustment to the carrying amount of the liability related to the sale of future royalties.

Net Operating Losses Carryforwards

As of December 31, 2024, we had approximately $156.8 million of federal net operating losses that will begin to expire in 2036, if not utilized. Of the total federal net operating loss, approximately $135.4 million has an unlimited carryforward and therefore will not expire. As of December 31, 2024, we had approximately $7.7 million of New Jersey and approximately $148.1 million of Massachusetts operating losses that will begin to expire in 2029 and 2037, respectively, if not utilized.

Results of Operations

Comparison of the Years Ended December 31, 2024 and December 31, 2023 (in thousands):

	Year Ended December 31,	
	2024	2023
Expenses		
Research and development	$ 11,898	$ 12,705
General and administrative	9,950	10,414
Total expenses	21,848	23,119
Loss from operations	(21,848)	(23,119)
Foreign exchange losses	(2)	(40)
Investment income	1,272	1,437
Non-cash interest expense for the sale of future royalties	(4,562)	(8,283)
Other income	26,579	—
Net income (loss)	$ 1,439	$ (30,005)

Research and Development Expenses

Research and development expenses were $11.9 million and $12.7 million for the years ended December 31, 2024 and 2023, respectively, a decrease of $0.8 million. The decrease in research and development expenses was primarily due to costs associated with the C18 study and lower compensation expenses, partially offset by higher costs associated with our drug substance validation campaign. Non-cash stock compensation costs included in research and development expenses were $0.5 million and $0.9 million for the years ended December 31, 2024 and 2023, respectively.

General and Administrative Expenses

General and administrative expenses were $9.9 million and $10.4 million for the years ended December 31, 2024 and 2023, respectively, a decrease of $0.5 million. The decrease in general and administrative expenses was primarily due to lower compensation expenses, partially offset by higher professional service fees. Non-cash stock compensation costs included in general and administrative expenses were $0.9 million and $1.1 million for the years ended December 31, 2024 and 2023, respectively.

Foreign Exchange Losses

Foreign exchange losses were $2 thousand and $40 thousand for the years ended December 31, 2024 and 2023, respectively, a decrease of $38 thousand, primarily due to currency movements.

Investment Income

Investment income was $1.3 million and $1.4 million for the years ended December 31, 2024 and 2023, respectively, a decrease of approximately $0.1 million, primarily due to cash and cash equivalents balances and interest rates.

Non-Cash Interest Expense for the Sale of Future Royalties

Non-cash interest expense for the sale of future royalties was $4.6 million and $8.3 million for the years ended December 31, 2024 and 2023, respectively, a decrease of $3.7 million. The decrease in non-cash interest expense for the sale of future royalties was due to revising our estimates for the timing and amount of future royalty payments to be received under the royalty arrangement. During the third quarter of 2024, we adjusted the carrying amount of our liability related to the sale of future royalties to the initial payment of $60 million. This adjustment resulted in the recognition of $26.6 million in other income during the third quarter of 2024, representing the amount of non-cash interest expense amortized through June 30, 2024.

Other Income

Other income was $26.6 million and zero for the years ended December 31, 2024 and 2023, respectively, an increase of $26.6 million, due to recognizing other income in the third quarter of 2024 as a result of the adjustment to the carrying amount of the liability related to the sale of future royalties.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2024, we had an accumulated deficit of approximately $395.4 million. We anticipate that we will continue to incur net losses for the foreseeable future as we continue the development and potential commercialization of our product candidates and to support our operations as a public company. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we may never generate product revenue or achieve profitability. As of December 31, 2024, we had approximately $21.5 million in cash, cash equivalents, and restricted cash, which we believe will be sufficient to meet our operating commitments for the next 12 months from the date our financial statements are issued. Our cash requirements primarily relate to expenditures to support the development of roluperidone, which includes advancing the program through the regulatory process.

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

Private Placement of Common Stock and Warrants

On June 27, 2023, we entered into a securities purchase agreement with certain institutional accredited investors, pursuant to which we agreed to issue and sell in a private placement (i) an aggregate of 1,425,000 shares of our common stock at a purchase price of $10.00 per share, and (ii) in lieu of additional shares of common stock, pre-funded warrants to purchase an aggregate of 575,575 shares of common stock at a purchase price of $9.99 per pre-funded warrant. The price per pre-funded warrant represents the price of $10.00 per share sold in the private placement, minus the $0.01 per share exercise price of each such pre-funded warrant. The pre-funded warrants are exercisable at any time after their original issuance and will not expire until exercised in full.

On June 30, 2023, we received aggregate gross proceeds under the private placement of $20.0 million and incurred approximately $0.4 million in offering expenses. Pursuant to the securities purchase agreement, we filed a registration statement on Form S-3 (File No. 333-273686), which was declared effective by the SEC on August 9, 2023, covering the resale of the Registrable Securities (as defined in the securities purchase agreement). In connection with the private placement, on August 29, 2023, Boehringer Ingelheim International GmbH, an investor in the private placement, designated an observer to attend, subject to certain exceptions, meetings of our board of directors and our committees, until the earlier of (i) the occurrence of a Change of Control and (ii) the date that it and its affiliates collectively hold less than 10% of our Common Stock.

At-the-Market Equity Offering Program

In September 2022, we entered into an Open Market Sale Agreement (the "Sales Agreement") with Jefferies LLC ("Jefferies") pursuant to which we may offer and sell, from time to time, through Jefferies, shares of our common stock, by any method permitted by law deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. During the twelve months ended December 31, 2024, no shares of our common stock were issued or sold under the Sales Agreement. As of December 31, 2024, an aggregate of $22.6 million was eligible for sale pursuant to the Sales Agreement under our effective registration statement on Form S-3 (File No. 333-267424).

Seltorexant Royalties

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

On January 19, 2021, we sold our royalty interest in seltorexant to Royalty Pharma for an upfront payment of $60 million and up to an additional $95 million in potential future milestone payments, contingent upon the achievement of certain clinical, regulatory and commercial milestones for seltorexant by Janssen.

Uses of Funds

To date, we have not generated any revenue from sales of products. We have only generated collaborative revenue due to opting out of our license and co-development agreement with Janssen. Furthermore, the $60 million payment received from Royalty Pharma for the sale of our royalty interests in seltorexant has been included on our balance sheet under liability related to the sale of future royalties. We do not know when, or if, we will generate any revenue from sales of our products, or from the potential future non-cash royalty revenue associated with the sale of our royalty interests in seltorexant to Royalty Pharma. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize any of our product candidates. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates. We also expect to continue to incur costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution.

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

Cash Flows

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

	Year Ended December 31,	
	2024	2023
	(dollars in millions)	
Net cash (used in) provided by:		
Operating activities	$ (19.6)	$ (14.8)
Investing activities	—	—
Financing activities	—	19.6
Net (decrease) increase in cash	$ (19.6)	$ 4.8

Net Cash Used in Operating Activities

Net cash used in operating activities of approximately $19.6 million during the year ended December 31, 2024 was primarily due to our net income of $1.4 million, non-cash interest expense for the sale of future royalties of $4.6 million and stock-based compensation expense of $1.3 million, offset by the adjustment to the carrying amount of the liability related to the sale of future royalties of $26.6 million and an approximately $0.3 million decrease in accrued expenses.

Net cash used in operating activities of approximately $14.8 million during the year ended December 31, 2023 was primarily due to our net loss of $30.0 million, partially offset by non-cash interest expense for the sale of future royalties of $8.3 million, a $3.1 million decrease in refundable regulatory fees, and stock-based compensation expense of $2.0 million.

Net Cash Provided by Investing Activities

Net cash provided by investing activities was zero during the years ended December 31, 2024 and 2023.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was zero during the twelve months ended December 31, 2024.

Net cash provided by financing activities of approximately $19.6 million during the year ended December 31, 2023 was primarily due to the net proceeds from the Private Placement closed in June 2023.

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 ("GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

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

Research and Development Costs

Costs incurred in connection with research and development activities are expensed as incurred. These costs include licensing fees to use certain technology in our research and development projects as well as fees paid to consultants and various entities that perform certain research and testing on our behalf and costs related to salaries, benefits, bonuses and stock-based compensation granted to employees in research and development functions. We determine our expenses related to clinical studies based on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the

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

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

Goodwill

We test our goodwill for impairment annually, or whenever events or changes in circumstances indicate an impairment may have occurred, by comparing our reporting unit's carrying value to its fair value. Impairment may result from, among other things, deterioration in the performance of the acquired business, adverse market conditions, adverse changes in applicable laws or regulations and a variety of other circumstances. If we determine that an impairment has occurred, we are required to record a write-down of the carrying value and charge the impairment as an operating expense in the period the determination is made. In evaluating the recoverability of the carrying value of goodwill, we must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the acquired assets. Changes in strategy or market conditions could significantly impact those judgments in the future and require an adjustment to the recorded balances. We have a single reporting unit, which is the level that the goodwill impairment test is performed. There was no impairment of goodwill for the years ended December 31, 2024 and 2023. As of December 31, 2024, $14.9 million of goodwill was associated with a reporting unit with zero or negative carrying value. As the reporting unit had a positive fair value, there was no impairment associated with this reporting unit.

Liability related to the sale of future royalties

We treat the sale of future royalties to Royalty Pharma as a debt financing, as we have significant continuing involvement in facilitating the transfer of royalties to Royalty Pharma and Royalty Pharma has recourse against us relating to the payments due from Janssen. As a result, we recorded the upfront payment of $60 million from this transaction as a liability related to the sale of future royalties, and up to an additional $95 million in potential milestone payments will also be recorded as a liability related to the sale of future royalties and amortized as interest expense over the estimated remaining life of the agreement. Under the terms of the agreement, all payments from Royalty Pharma to us, including the initial upfront payment of $60 million as well as amortized interest expense and potential milestone payments, are not repayable to Royalty Pharma in the event that Janssen discontinues the clinical development of seltorexant or ceases to pursue its commercialization at a future date for any reason.

The liability related to sale of future royalties and the related interest expense is based on our current estimates of future royalties expected to be paid over the life of the arrangement. We will periodically assess the expected royalty payments using a combination of internal projections and forecasts from external sources. To the extent our future estimates of royalty payments are greater or less than previous estimates or the estimated timing of such payments is materially different than its previous estimates, we will recognize related non-cash interest expense or other income.

During the third quarter of 2024, we made a significant revision to our estimates for the timing and amount of future royalty payments to be earned over the life of the co-development and license agreement with Janssen. As a result, the estimate of undiscounted royalty payments were less than the original carrying value of the upfront $60 million payment received from Royalty Pharma. Therefore, under the retrospective interest model, as of December 31, 2024 we adjusted the liability related to the sale of future royalties (the "Royalty Obligation") to the initial upfront payment received of $60 million and recognized $26.6 million as a component of Other Income, representing the amount of amortized non-cash interest expense through June 30, 2024. In addition, the Company does not expect to recognize non-cash interest expense in the future related to the Royalty Obligation, as the effective annual interest rate is negative.

For further discussion of the sale of future royalties, please refer to Note 5, Sale of Future Royalties, to our financial statements appearing elsewhere in this Form 10-K.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by Financial Accounting Standards Board ("FASB") and are adopted by us as of the specified effective date. Our significant accounting policies are described in Note 2 to our financial statements appearing elsewhere in this Form 10-K. Except as described in Note 2, 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 and cash flows, or do not apply to our operations.

Smaller Reporting Company Status

We are a "smaller reporting company" as defined in the Securities Exchange Act of 1934, as amended ("Exchange Act"). We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as the market value of our voting and non-voting common stock held by non-affiliates is less than $250 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our voting and non-voting common stock held by non-affiliates is less than $700 million measured on the last business day of our second fiscal quarter.

ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk

We are a smaller reporting company as defined by Rule12b-2 of the Exchange Act and are not required to provide the information required under this item.

ITEM 8. Financial Statements and Supplementary Data

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Minerva Neurosciences, Inc. and subsidiaries (the "Company") as of December 31, 2024 and 2023, the related consolidated statements of operations, stockholders' deficit, and cash flows, for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

Critical Audit Matter

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

Liability Related to the Sale of Future Royalties - Refer to Notes 2 and 5 to the financial statements

Critical Audit Matter Description

As described in Notes 2 and 5 to the consolidated financial statements, on January 19, 2021, the Company entered into an agreement with Royalty Pharma under which Royalty Pharma acquired the Company's royalty interest in seltorexant for an upfront payment of $60 million and up to an additional $95 million in potential milestone payments. Management applied significant judgment in determining the appropriate accounting treatment for the transaction and accounted for the sale of future royalties to Royalty Pharma as a debt financing, as the Company continues to have significant involvement in the generation of the cash flows. The proceeds from the transaction were recorded as a liability related to the sale of future royalties, to be amortized under the interest method over the estimated life of the agreement.

We identified the valuation of the liability related to the sale of future royalties as a critical audit matter because of the significant judgment by management in determining the appropriate accounting for the transaction and the valuation of the liability.

How We Addressed the Matter in Our Audit

Our audit procedures included both consideration of the accounting treatment, and the recognition and valuation of the liability. To test the estimated value of the liability related to the sale of future royalties and the change in estimate, our audit procedures included the following, among others:

- Tested changes in significant estimates and assumptions used by management.
- Recalculated the liability related to the sale of future royalties and associated other income/expense.
- Corroborated third-party information used in recalculation, focusing on the probabilities and timing of payments, using public data.
- Evaluated the accounting treatment of the remeasurement of the liability.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
February 25, 2025

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

MINERVA NEUROSCIENCES, INC.

Consolidated Balance Sheets

	December 31, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 21,362,008	$ 40,912,575
Restricted cash	100,000	100,000
Prepaid expenses and other current assets	806,895	989,865
Total current assets	22,268,903	42,002,440
Equipment, net	5,442	10,884
Capitalized software, net	—	17,027
Goodwill	14,869,399	14,869,399
Total assets	**$ 37,143,744**	**$ 56,899,750**
Liabilities and Stockholders' Deficit		
Current liabilities		
Accounts payable	$ 1,607,844	$ 1,805,320
Accrued expenses and other current liabilities	1,229,000	1,535,097
Total current liabilities	2,836,844	3,340,417
Liability related to the sale of future royalties	60,000,000	82,016,823
Total liabilities	62,836,844	85,357,240
Commitments and contingencies (Note 9)		
Stockholders' deficit		
Preferred stock; $.0001 par value; 100,000,000 shares authorized; none issued or outstanding as of December 31, 2024 and 2023, respectively	—	—
Common stock; $0.0001 par value; 125,000,000 shares authorized; 6,993,406 shares issued and outstanding as of December 31, 2024 and December 31, 2023	699	699
Additional paid-in capital	369,682,764	368,357,239
Accumulated deficit	(395,376,563)	(396,815,428)
Total stockholders' deficit	(25,693,100)	(28,457,490)
Total liabilities and stockholders' deficit	**$ 37,143,744**	**$ 56,899,750**

See accompanying notes to the consolidated financial statements.

MINERVA NEUROSCIENCES, INC.

Consolidated Statements of Operations

	Year Ended December 31,	
	2024	2023
Expenses		
Research and development	$ 11,898,595	$ 12,705,253
General and administrative	9,949,791	10,414,323
Total expenses	21,848,386	23,119,576
Loss from operations	(21,848,386)	(23,119,576)
Foreign exchange losses	(1,926)	(40,235)
Investment income	1,272,354	1,437,405
Non-cash interest expense for the sale of future royalties	(4,562,223)	(8,282,947)
Other income	26,579,046	—
Net income (loss)	$ 1,438,865	$ (30,005,353)
Net income (loss) per share, basic	$ 0.19	$ (4.61)
Weighted average shares outstanding, basic	7,568,981	6,506,372
Net income (loss) per share, diluted	$ 0.19	$ (4.61)
Weighted average shares outstanding, diluted	7,573,763	6,506,372

See accompanying notes to the consolidated financial statements.

MINERVA NEUROSCIENCES, INC.

Consolidated Statements of Stockholders' Deficit

	Common Stock		Additional	Accumulated	
	Shares	Amount	Paid-In Capital	Deficit	Total
Balances at January 1, 2023	**5,340,193**	**$ 534**	**$ 346,785,322**	**$ (366,810,075)**	**$ (20,024,219)**
Issuance of common stock and warrants pursuant to a private placement	1,425,000	142	19,999,852	—	19,999,994
Costs related to issuance of common stock and warrants	—	—	(396,293)	—	(396,293)
Vesting of performance-based restricted stock units	228,213	23	(23)	—	—
Stock-based compensation	—	—	1,968,381	—	1,968,381
Net loss	—	—	—	(30,005,353)	(30,005,353)
Balances at December 31, 2023	**6,993,406**	**$ 699**	**$ 368,357,239**	**$ (396,815,428)**	**$ (28,457,490)**
Stock-based compensation			1,325,525		1,325,525
Net income	—	—	—	1,438,865	1,438,865
Balances at December 31, 2024	**6,993,406**	**$ 699**	**$ 369,682,764**	**$ (395,376,563)**	**$ (25,693,100)**

See accompanying notes to the consolidated financial statements.

MINERVA NEUROSCIENCES, INC.

Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2024	2023
Cash flows from operating activities:		
Net income (loss)	$ 1,438,865	$ (30,005,353)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	5,442	5,442
Amortization of capitalized software	17,027	25,540
Stock-based compensation expense	1,325,525	1,968,381
Non-cash interest expense associated with the sale of future royalties	4,562,223	8,282,947
Remeasurement of liability related to sale of future royalties	(26,579,046)	—
Changes in operating assets and liabilities		
Refundable regulatory fee	—	3,117,218
Prepaid expenses and other current assets	182,970	(141,748)
Accounts payable	(197,476)	835,653
Accrued expenses and other current liabilities	(306,097)	1,127,188
Net cash used in operating activities	(19,550,567)	(14,784,732)
Cash flows from investing activities:		
Net cash provided by investing activities	—	—
Cash flows from financing activities:		
Proceeds from sales of common stock and warrants in private placement	—	19,999,994
Costs paid in connection with private placements	—	(396,293)
Net cash provided by financing activities	—	19,603,701
Net (decrease) increase in cash, cash equivalents and restricted cash	(19,550,567)	4,818,969
Cash, cash equivalents, and restricted cash		
Beginning of period	41,012,575	36,193,606
End of period	$ 21,462,008	$ 41,012,575
Reconciliation of the Condensed Consolidated Statements of Cash Flows to the Condensed Consolidated Balance Sheets		
Cash and cash equivalents	$ 21,362,008	$ 40,912,575
Restricted cash	100,000	100,000
Total cash, cash equivalents, and restricted cash	$ 21,462,008	$ 41,012,575

See accompanying notes to the consolidated financial statements.

NOTE 1 — NATURE OF OPERATIONS AND LIQUIDITY

Nature of Operations

Minerva Neurosciences, Inc. ("Minerva" or the "Company") is a clinical-stage biopharmaceutical company focused on the development and commercialization of proprietary product candidates to treat patients suffering from central nervous system ("CNS") diseases. The Company's lead product candidate is roluperidone, a compound the Company is developing for the treatment of negative symptoms in patients with schizophrenia. The Company previously submitted a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") for roluperidone for the treatment of negative symptoms in schizophrenia in August 2022. On February 26, 2024, the FDA issued a Complete Response Letter ("CRL") regarding the NDA for roluperidone. Since receiving the CRL, the Company has continued to have interactions with the FDA with the goal of addressing the questions raised in the CRL.

The Company also has exclusive rights to develop and commercialize MIN-301, a compound for the treatment of Parkinson's disease. In addition, Minerva previously co-developed seltorexant with Janssen Pharmaceutica NV ("Janssen") for the treatment of insomnia disorder and adjunctive treatment of Major Depressive Disorder ("MDD"). During 2020, Minerva exercised its right to opt out of the joint development agreement with Janssen for the future development of seltorexant. As a result, the Company was entitled to collect royalties in the mid-single digits on potential future worldwide sales of seltorexant in certain indications, with no further financial obligations to Janssen. In January 2021, the Company sold its rights to these potential royalties to Royalty Pharma plc ("Royalty Pharma") for a $60 million up front payment and up to an additional $95 million in potential future milestone payments.

Liquidity

The accompanying financial statements have been prepared as though the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has limited capital resources and has incurred recurring operating losses and negative cash flows from operations since inception. As of December 31, 2024, the Company had an accumulated deficit of approximately $395.4 million and net cash used in operating activities was approximately $19.6 million during the year ended December 31, 2024. Management expects to continue to incur operating losses and negative cash flows from operations in the future. The Company has financed its operations to date from proceeds from the sale of common stock, warrants, loans, convertible promissory notes, collaboration agreements and royalty sales.

As of December 31, 2024, the Company had cash, cash equivalents, and restricted cash of $21.5 million, which it believes will be sufficient to meet the Company's operating commitments for the next 12 months from the date its financial statements are issued. The process of drug development can be costly and the timing and outcomes of clinical trials is uncertain. The assumptions upon which the Company has based its estimates are routinely evaluated and may be subject to change. The actual amount of the Company's expenditures will vary depending upon many factors, including, but not limited to, the design, timing and duration of future clinical trials, the progress of the Company's research and development programs, the infrastructure to support a commercial enterprise, and the level of financial resources available. The Company can adjust its operating plan spending levels based on the timing of future clinical trials, which are predicated upon adequate funding to complete the trials. The Company routinely evaluates the status of its clinical development programs as well as potential strategic options.

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

Further, if the Company does not satisfy The Nasdaq Capital Market continued listing requirements, its common stock may be subject to delisting, which could impact the Company's ability to complete additional equity financings on terms acceptable to the Company. On April 10, 2024, the Company received written notice from The Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that for the last 31 consecutive business days, the Company's minimum Market Value of Listed Securities was below the minimum of $35 million required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(b)(2) (the "MVLS Rule").

On January 10, 2025, the Company received a notice from Nasdaq indicating that following the Company's hearing before the Nasdaq Hearings Panel (the "Panel") on December 10, 2024, the Panel has granted the Company's request for continued listing on Nasdaq, subject to the following: (1) on or before March 31, 2025, the Company will have filed a public disclosure describing the transactions undertaken by the Company to achieve compliance and demonstrate long-term compliance with Nasdaq Listing Rule 5550(b)(1) (the "Equity Rule"), which requires issuers listed on The Nasdaq Capital Market to maintain minimum stockholders' equity of $2.5 million, and will have provided an indication of the Company's equity following those transactions; and (2) on or before March 31, 2025, the Company must have provided the Panel with income projections for the next 12 months, with all underlying assumptions clearly stated, and evidence compliance with all applicable criteria for continued listing on The Nasdaq Capital Market.

The Company is working to prepare and file, as applicable, the documents described above by March 31, 2025 to enable the Company to regain compliance with Nasdaq's listing standards. Notwithstanding, there can be no assurance that the Company will be able to regain compliance with Nasdaq's listing standards, including the continued listing requirements under the Equity Rule or the MVLS Rule, that the Company will be able to maintain compliance with the other continued listing requirements set forth in Nasdaq's listing standards or that the Company will be able to continue its listing on Nasdaq.

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

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

Consolidation

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

Significant risks and uncertainties

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

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

Use of estimates

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

Cash and cash equivalents

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

Restricted cash

Cash accounts with any type of restriction are classified as restricted. The Company maintained restricted cash balances as collateral for corporate credit cards in the amount of $0.1 million at December 31, 2024 and 2023.

Research and development costs

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

Stock-based compensation

The Company recognizes compensation cost relating to stock-based payment transactions using a fair-value measurement method, which requires all stock-based payments to employees, including grants of employee stock options, to be recognized in operating results as compensation expense based on fair value over the requisite service period of the awards. The Company determines the fair value of stock-based awards using the Black-Scholes option-pricing model which uses both historical and current market data to estimate fair value. The method incorporates various assumptions such as the risk-free interest rate, expected volatility, expected dividend yield, and expected life of the options. Forfeitures are recorded as they occur instead of estimating forfeitures that are expected to occur. The fair value of restricted stock units ("RSUs") is equal to the closing price of the Company's common stock on the date of grant. See Note 7 for information on the Company's performance-based restricted stock units ("PRSU") grants.

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

Foreign currency transactions

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

Income (loss) per share

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

Income taxes

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

allowance should be provided. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company uses a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken, or expected to be taken, in a tax return. The Company has elected to treat interest and penalties, to the extent they arise, as a component of income tax expense. There was no interest or penalties related to income taxes for the years ended December 31, 2024 or 2023. Income tax years beginning in 2021 for federal and state purposes are generally subject to examination by taxing authorities, although net operating losses from all prior years are subject to examinations and adjustments for at least three years following the year in which the tax attributes are utilized.

Concentration of credit risk

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

Equipment

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

Software

The Company accounts for capitalized software in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 350, *Intangibles—Goodwill and Other* ("ASC 350-40"), which provides guidance for computer software developed or obtained for internal use. The Company is required to continually evaluate the stage of the implementation process to determine whether costs are expensed or capitalized. Costs incurred during the preliminary project phase or planning and research phase are expensed as incurred. Costs incurred during the development phase, such as material and direct services costs, compensation costs of employees associated with the development and interest cost, are capitalized as incurred. Costs incurred during the post-implementation or operation phase, such as training and maintenance costs, are expensed as incurred. In addition, costs incurred to modify existing software that result in additional functionality are capitalized as incurred. Capitalized costs are amortized over the expected useful life of the asset.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40), Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. This new guidance requires a customer in a cloud computing arrangement (i.e., hosting arrangement) that is a service contract to follow the internal-use software guidance in ASC 350-40 to determine which implementation costs to capitalize as assets or expense as incurred. Also, capitalized implementation costs related to a hosting arrangement that is a service contract will be amortized over the term of the hosting arrangement, beginning when the module or component of the hosting arrangement is ready for its intended use.

Leases

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

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

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

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

Long-lived assets

The Company reviews the recoverability of all long-lived assets, including the related useful lives, whenever events or changes in circumstances indicate that the carrying amount of a long-lived asset might not be recoverable. If required, the Company compares the estimated undiscounted future net cash flows to the related asset's carrying value to determine whether there has been an impairment. If an asset is considered impaired, the asset is written down to fair value, which is based either on discounted cash flows or appraised values in the period the impairment becomes known. The Company believes that all long-lived assets are recoverable, and no impairment was deemed necessary at December 31, 2024 and 2023.

Goodwill

The Company tests its goodwill for impairment annually, or whenever events or changes in circumstances indicate an impairment may have occurred, by comparing its reporting unit's carrying value to its fair value. Impairment may result from, among other things, deterioration in the performance of the acquired business, adverse market conditions, adverse changes in applicable laws or regulations and a variety of other circumstances. If the Company determines that an impairment has occurred, it is required to record a write-down of the carrying value and charge the impairment as an operating expense in the period the determination is made. In evaluating the recoverability of the carrying value of goodwill, the Company must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the acquired assets. Changes in strategy or market conditions could significantly impact those judgments in the future and require an adjustment to the recorded balances. The Company has a single reporting unit, which is the level that the goodwill impairment test is performed. There was no impairment of goodwill for the years ended December 31, 2024 and 2023. As of December 31, 2024, $14.9 million of goodwill was associated with a reporting unit with zero or negative carrying value. As the reporting unit had a positive fair value, there was no impairment associated with this reporting unit.

Fair value of financial instruments

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

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

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

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

The following tables present information about the Company's cash equivalents and marketable securities as of December 31, 2024 and 2023, 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, 2024			
	Total	Level 1	Level 2	Level 3
Cash equivalents	$ 19,574,213	$ 19,574,213	$ —	$ —
Total fair value	$ 19,574,213	$ 19,574,213	$ —	$ —

	December 31, 2023			
	Total	Level 1	Level 2	Level 3
Cash equivalents	$ 27,351,596	$ 27,351,596	$ —	$ —
Total fair value	$ 27,351,596	$ 27,351,596	$ —	$ —

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

The Company's financial instruments consist of cash and cash equivalents, restricted cash, accounts payable, accrued expenses and liabilities related to the sale of future royalties. The carrying amounts of cash and cash equivalents, restricted cash, accounts payable, and accrued expenses approximate fair value because of their short-term nature.

Revenue recognition

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

When the Company enters into an arrangement that meets the definition of a collaboration under ASC 808, *Collaborative Arrangements*, the Company recognizes revenue as research and development is performed and its respective share of the expenses are incurred. The Company assesses whether the arrangement contains multiple elements or deliverables, which may include (1) licenses to the Company's technology, (2) research and development activities performed for the collaboration partner, and (3) participation on joint steering committees. Payments may include non-refundable, upfront payments, milestone payments upon achieving significant development events, and royalties on future sales. Each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting based on whether the deliverable has "stand-alone value" to the customer. The arrangement's consideration is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The estimated selling price of each deliverable is determined using the following hierarchy of values: (i) vendor-specific objective evidence of fair value, (ii) third-party evidence of selling price, and (iii) best estimate of selling price. The best estimate of selling price reflects the Company's best estimate of what the selling price would be if the deliverable was regularly sold by the Company on a stand-alone basis. The consideration allocated to each unit of accounting is then recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. Supply or service transactions may involve the charge of a nonrefundable initial fee with subsequent periodic payments for future products or services. The up-front fees, even if nonrefundable, are recognized as revenue as the products and/or services are delivered and performed over the term of the arrangement.

Liability related to the sale of future royalties

The Company treats the sale of future royalties to Royalty Pharma as a debt financing, as the Company has significant continuing involvement in facilitating the transfer of royalties to Royalty Pharma and Royalty Pharma has recourse against the Company relating to the payments due from Janssen. As a result, the Company recorded the upfront payment of $60 million from this transaction as a liability related to the sale of future royalties, and up to an additional $95 million in potential milestone payments will also be recorded as a liability related to the sale of future royalties and amortized as interest expense over the estimated remaining life of the agreement. Under the terms of the agreement, all payments from Royalty Pharma to the Company, including the initial upfront payment of $60 million as well as amortized interest expense and potential milestone payments, are not repayable to Royalty Pharma in the event that Janssen discontinues the clinical development of seltorexant or ceases to pursue its commercialization at a future date for any reason.

The liability related to sale of future royalties and the related interest expense is based on our current estimates of future royalties expected to be paid over the life of the arrangement. The Company will periodically assess the expected royalty payments using a combination of internal projections and forecasts from external sources. To the extent the Company's future estimates of royalty payments are greater or less than previous estimates or the estimated timing of such payments is materially different than its previous estimates, the Company will recognize related non-cash interest expense or other income.

For further discussion of the sale of future royalties, please refer to Note 5, Sale of Future Royalties.

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 ("CODM") in deciding how to allocate resources and in assessing performance. The Company's CODM is the Chief Executive Officer. The CODM evaluates performance of the segments based on net income (loss). The CODM also reviews operating results and previously forecasted financial information to make decisions about allocating resources and assessing performance for the entire Company.

The Company's operations are organized into one operating and one reportable segment focused on the development and commercialization of proprietary product candidates to treat patients suffering from CNS diseases. The one operating segment is managed on a consolidated basis. The operating segment's revenue would be generated from commercial sales or license agreements of the product candidates, however, none of the company's product candidates have been approved for commercialization and it has not received any revenue in connection with the sale or license of its product candidates. Furthermore, except for most of Asia, the Company has global commercialization rights for roluperidone and also owns worldwide rights for MIN-301 and the Sigma Ligands.

The CODM does not evaluate operating segments using asset or liability information and therefore it is not disclosed. The following table summarizes the reportable segment's financial information:

	Year Ended December 31,	
	2024	2023
Expenses		
Research and development staff related expenses [1]	$ 2,246,565	$ 2,742,809
Research and development drug product material expenses and associated costs [2]	3,298,851	687,133
Research and development stock compensation expenses (non-cash)	450,537	909,845
General and administrative staff related expenses [1]	3,374,711	3,841,422
General and administrative stock compensation expenses (non-cash)	874,988	1,058,536
Total	10,245,652	9,239,745
Other segment expense, net [3]	11,602,734	13,879,831
Total expenses	21,848,386	23,119,576
Loss from operations	(21,848,386)	(23,119,576)
Reconciling items:		
Foreign exchange losses	(1,926)	(40,235)
Investment income	1,272,354	1,437,405
Non-cash interest expense for the sale of future royalties	(4,562,223)	(8,282,947)
Other income	26,579,046	—
Net income (loss)	$ 1,438,865	$ (30,005,353)

(1) Salary, bonus, and fringe benefits are included in staff related expenses.
(2) Costs associated with the Company's drug substance validation campaign are included in drug product material expenses.
(3) Insurance, consultant, audit, legal, and the C18 study costs are included in other segment expense, net.

Comprehensive income (loss)

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

Recent accounting pronouncements

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

Recently adopted accounting pronouncements

In November 2023, the FASB issued ASU No. 2023-07, *Improvements to Reportable Segment Disclosures (Topic 280)*. This ASU updates reportable segment disclosure requirements by requiring disclosures of significant reportable segment expenses that are regularly provided to the CODM and included within each reported measure of a segment's profit or loss. This ASU also requires disclosure of the title and position of the individual identified as the CODM and an explanation of how the CODM uses the reported measures of a segment's profit or loss in assessing segment performance and deciding how to allocate resources. The ASU is effective for annual periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. We adopted this ASU retrospectively on December 31, 2024. Refer to *Segment information* for the inclusion of the new required disclosures.

NOTE 3 — ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities consist of the following:

	Year Ended December 31,	
	2024	2023
Research and development costs and other accrued expenses	$ 351,782	$ 777,680
Accrued bonus	363,181	590,769
Professional fees	514,037	166,648
Accrued expenses and other current liabilities	$ 1,229,000	$ 1,535,097

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

Basic income (loss) per share is calculated by dividing the net income (loss) by the weighted average number of shares of common stock outstanding. Diluted income (loss) per share is computed by dividing the net income (loss) by the weighted average number of shares of common stock outstanding, plus potential outstanding common stock for the period. Potential outstanding common stock includes stock options, but only to the extent that their inclusion is dilutive. Performance-based restricted stock units are excluded from the calculation of dilutive potential common shares until the performance conditions have been achieved on the basis of the assumption that the end of the reporting period was the end of the contingency period, if such shares issuable are dilutive.

In June 2023, in connection with the Private Placement (as defined and described in Note 6, Stockholders' Deficit), the Company issued and sold pre-funded warrants exercisable for an aggregate of 575,575 shares of common stock. The purchase price of the pre-funded warrants was $9.99 per share, which was paid to the Company upon issuance of the pre-funded warrants. The exercise price of the pre-funded warrants is $0.01 per share. The pre-funded warrants are exercisable by the holders at any time and do not expire. As the remaining shares underlying the pre-funded warrants are issuable for nominal consideration of $0.01 per share, 575,575 shares of common stock underlying the unexercised pre-funded warrants were considered outstanding for purposes of the calculation of income (loss) per share as of December 31, 2024.

The following table sets forth the computation of basic and diluted income (loss) per share for common stockholders:

	Year Ended December 31,	
	2024	2023
Net income (loss)	$ 1,438,865	$ (30,005,353)
Weighted average shares of common stock outstanding - basic	7,568,981	6,506,372
Dilutive effect	4,782	—
Weighted average shares of common stock outstanding - diluted	7,573,763	6,506,372
Net income (loss) per ordinary share:		
Basic	0.19	$ (4.61)
Diluted	0.19	$ (4.61)

The following securities outstanding at December 31, 2024 and 2023 have been excluded from the calculation of weighted average shares outstanding as their effect on the calculation of income (loss) per share is antidilutive:

	Year Ended December 31,	
	2024	2023
Common stock options	1,440,002	1,157,229
Performance-based restricted stock units	228,209	228,209
Common stock warrants	5,099	5,099

NOTE 5 — SALE OF FUTURE ROYALTIES

The Company had previously co-developed seltorexant with Janssen for the treatment of insomnia disorder and adjunctive treatment of MDD. During 2020, the Company exercised its right to opt out of the co-development and license agreement (the "Janssen Agreement") with Janssen for the future development of seltorexant and, as a result, the Company was entitled to collect royalties in the mid-single digits on potential future sales of seltorexant worldwide in certain indications, with no further financial obligations to Janssen.

On January 19, 2021, the Company entered into an agreement with Royalty Pharma under which Royalty Pharma acquired the Company's royalty interest in seltorexant for an upfront payment of $60 million and up to an additional $95 million in potential milestone payments. These milestone payments are contingent upon the achievement of certain clinical, regulatory and commercial milestones for seltorexant by Janssen or any other party in the event that Janssen sells seltorexant. Under the terms of the agreement, Royalty Pharma has recourse against the Company relating to payments due from Janssen and therefore, the Company is deemed to have significant continuing involvement. The Company has applied the debt recognition guidance under ASC 470, Debt, and recorded the upfront payment of $60 million on the balance sheet as a liability related to the sale of future royalties (the "Royalty Obligation") and will record any amortized interest expense and future milestone payments received from Royalty Pharma as well. No amounts received, including the initial upfront payment, amortized interest expense or potential milestone payments, are repayable to Royalty Pharma if Janssen discontinues the clinical development of seltorexant or ceases to pursue its commercialization at a future date for any reason. In accordance with ASC 470, the Company will account for any royalties received in the future as non-cash royalty revenue.

As royalties are remitted from Janssen to Royalty Pharma, the balance of the Royalty Obligation will be effectively repaid over the expected life of the Janssen Agreement. The $60 million payment received from Royalty Pharma and any potential future milestone payments from Royalty Pharma are recorded as part of the Royalty Obligation. The difference between the total expected royalties receivable from Janssen and the upfront and milestone payments potentially receivable from Royalty Pharma is being amortized as non-cash interest expense over the estimated remaining life of the Janssen Agreement. To determine the amount of non-cash interest to be amortized, the Company is required to make assumptions for the total amount of future royalty payments to be received from Janssen. At execution, the Company's estimate of this total non-cash interest expense resulted in an effective annual interest rate of approximately 10.5%.

The Company regularly evaluates the assumptions supporting future royalty estimates and, during the third quarter of 2024, noted that Janssen announced on clinicaltrials.gov a further Phase 3 study with seltorexant (42847922MDD3003) that has an estimated study completion date of November 30, 2027, which is significantly different from the assumption the Company used in its original estimates. As a result, the Company has made a significant revision to its estimates for the timing and amount of future royalty payments to be earned over the life of the Janssen Agreement and noted that the estimate of undiscounted royalty payments is now less than the original carrying value of the upfront payment received. Therefore, under the retrospective interest model, as of December 31, 2024 the Company adjusted the Royalty Obligation to the initial upfront payment received of $60 million and recognized $26.6 million as a component of Other Income, representing the amount of amortized non-cash interest expense through June 30, 2024. In addition, the Company does not expect to recognize non-cash interest expense in the future related to the Royalty Obligation, as the effective annual interest rate is negative.

NOTE 6 — STOCKHOLDERS' DEFICIT

Private Placement of Common Stock and Warrants

On June 27, 2023, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with certain institutional accredited investors (the "Investors"), pursuant to which the Company agreed to issue and sell to the Investors in a private placement (the "Private Placement") (i) an aggregate of 1,425,000 shares (the "Shares") of the Company's common stock at a purchase price of $10.00 per Share, and (ii) in lieu of additional shares of common stock, pre-funded warrants to purchase an

aggregate of 575,575 shares of common stock at a purchase price of $9.99 per pre-funded warrant. The price per pre-funded warrant represents the price of $10.00 per Share sold in the Private Placement, minus the $0.01 per share exercise price of each such pre-funded warrant. The pre-funded warrants are exercisable at any time after their original issuance and will not expire until exercised in full.

The pre-funded warrants issued in the Private Placement provide that a holder of the pre-funded warrants will not have the right to exercise any portion of its pre-funded warrants to the extent such holder, together with its affiliates, after giving effect to such exercise, would beneficially own in excess of the beneficial ownership limitation, as elected by such Investor, immediately after giving effect to such exercise (the "Beneficial Ownership Limitation"); provided, however, that each pre-funded warrant holder may increase or decrease the Beneficial Ownership Limitation by giving 61 days' notice to the Company, but not to any percentage in excess of 19.99%.

On June 30, 2023, the Private Placement closed and the Company received aggregate gross proceeds from the Private Placement of $20.0 million. The Company incurred approximately $0.4 million in offering expenses during 2023, which were included as a component of additional paid-in capital, resulting in net proceeds of $19.6 million from the Private Placement.

Pursuant to the Securities Purchase Agreement, the Company filed a registration statement on Form S-3 (File No. 333-273686), which was declared effective by the SEC on August 9, 2023, covering the resale of the Registrable Securities (as such term is defined in the Securities Purchase Agreement). The Company has agreed to use its commercially reasonable efforts to keep such registration statement effective until the earlier of (i) the third anniversary of the effective date of the initial registration statement covering the Registrable Securities; (ii) the date all Shares and all shares of common stock underlying the pre-funded warrants may be sold under Rule 144 of the Securities Act of 1933, as amended, without being subject to any volume, manner of sale or publicly available information requirements; or (iii) immediately prior to the closing of a Change of Control (as such term is defined in the Securities Purchase Agreement).

Pursuant to the Securities Purchase Agreement, in connection with the Private Placement, Boehringer Ingelheim International GmbH ("BI"), an Investor in the Private Placement, has the right to designate an observer to attend, subject to certain exceptions, meetings of the Company's board of directors and its committees, until the earlier of (i) the occurrence of a Change of Control and (ii) the date that it and its affiliates collectively hold less than 10% of the Company's common stock (which shall be calculated by including in the amount of common stock held by such Investor and its affiliates any shares of common stock issuable upon exercise of any portion of the pre-funded warrant issued to such Investor and not yet exercised). BI designated a board observer on August 29, 2023.

At-the-Market Equity Offering Program

In September 2022, the Company entered into an Open Market Sale Agreement (the "Sales Agreement") with Jefferies LLC ("Jefferies") pursuant to which the Company may offer and sell, from time to time, through Jefferies shares of the Company's common stock, by any method permitted by law deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. During the twelve months ended December 31, 2024, no shares of the Company's common stock were issued or sold under the Sales Agreement. As of December 31, 2024, an aggregate of $22.6 million was eligible for sale pursuant to the Sales Agreement under the Company's effective registration statement on Form S-3 (File No. 333-267424).

Term Loan Warrants

In connection with the Company's former Loan and Security Agreement with Oxford Finance LLC and Silicon Valley Bank (the "Lenders"), which provided for term loans to the Company in an aggregate principal amount of up to $15 million in two tranches on January 15, 2016, the Company issued the Lenders warrants to purchase 5,099 shares of common stock at a per share exercise price of $44.13. The warrants were 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 term loans were repaid in August 2018. All related warrants were outstanding and exercisable as of December 31, 2024.

NOTE 7 — STOCK AWARD PLAN AND STOCK-BASED COMPENSATION

In December 2013, the Company adopted the 2013 Equity Incentive Plan (as subsequently amended and restated, the "Plan"), which provides for the issuance of options, stock appreciation rights, stock awards and stock units. As of December 31, 2024, the total shares authorized for issuance under the Plan were 2,078,917.

Stock Option Awards

Stock option activity for employees and non-employees for the year ended December 31, 2024 is as follows:

	Shares Issuable Pursuant to Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Terms (years)	Total Intrinsic Value (in thousands)
Outstanding January 1, 2024	1,157,229	$ 11.36	8.5	$ 745
Granted	451,500	$ 2.12		
Exercised	—	$ —		
Cancelled/Forfeited	(115,000)	$ 12.05		
Expired	(6,495)	$ 48.00		
Outstanding December 31, 2024	1,487,234	$ 8.34	8.3	$ 46
Exercisable December 31, 2024	576,351	$ 15.37	7.0	$ —
Available for future grant	32,361			

The weighted average grant-date fair value of stock options outstanding on December 31, 2024 was $6.17 per share. Total unrecognized compensation costs related to non-vested stock options at December 31, 2024 were approximately $2.8 million and are expected to be recognized within future operating results over a weighted-average period of 2.6 years. Generally, stock options are granted using exercise prices equal to the market price at the date of grant, vest over four years for employees and one year for directors, and are exercisable over a maximum period of 10 years from their grant dates.

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

The Company uses the Black-Scholes model to estimate the fair value of stock options granted. For stock options granted during the years ended December 31, 2024 and 2023, the Company utilized the following assumptions:

	Year Ended December 31,	
	2024	2023
Expected term (years)	5.50 - 6.25	5.50 - 6.25
Risk free interest rate	4.08% - 4.10%	4.68% - 4.74%
Volatility	121% - 126%	115% - 119%
Dividend yield	0%	0%
Weighted average grant date fair value per share of common stock	$1.88	$5.67

Performance-Based Restricted Stock Units

On August 6, 2021, options to purchase 953,980 shares of the Company's common stock were exchanged for 476,640 PRSUs. Options surrendered in the one-time stock option exchange program (the "Exchange Program") were cancelled and shares subject to the cancelled options again became available for issuance under the Plan. The Exchange Program was treated as a Type II modification (Probable-to improbable) under ASC 718.

The Company used the pre-modification stock options for determining the compensation cost related to the PRSUs as the vesting conditions remain uncertain for the outstanding PRSUs. All expense related to the non-vested pre-modification stock options was fully recognized as of December 31, 2023.

On April 28, 2023, the Compensation Committee of the Company's board of directors certified the achievement of a performance condition occurring upon FDA acceptance of the NDA for roluperidone. As a result, 50% of the shares of common stock underlying the Company's PRSUs vested and the Company recognized approximately $0.2 million in non-cash compensation expense, representing 50% of the incremental cost of the PRSUs granted under the Exchange Program. The incremental cost was measured as

the excess of the fair value of each new PRSU, measured as of the date the new PRSUs were granted, over the fair value of the stock options surrendered in exchange for the new PRSU, measured immediately prior to the cancellation. The remaining PRSUs vest upon roluperidone receiving FDA marketing approval, provided that such approval occurs within five years after the August 6, 2021 grant date. As of December 31, 2024, 228,213 PRSUs have vested, 20,218 have been cancelled, and 228,209 remain outstanding.

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

	Year Ended December 31,	
	2024	2023
Research and development	$ 450,537	$ 909,845
General and administrative	874,988	1,058,536
Total	$ 1,325,525	$ 1,968,381

NOTE 8 — INCOME TAXES

The provision for federal, foreign and state income taxes for the years ended December 31, 2024 and 2023 are as follows:

	Year Ended December 31,	
	2024	2023
Current income tax provision (benefit)		
Federal	$ —	$ —
Foreign	—	—
State	—	—
Deferred income tax provision (benefit)		
Federal	—	—
Foreign	—	—
State	—	—
Total income tax provision (benefit)	$ —	$ —

Net deferred tax assets (liabilities) as of December 31, 2024 and 2023 consist of the following:

	Year Ended December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 42,922,972	$ 34,490,808
Research and development tax credits	145,115	145,115
Capitalized research and development costs	25,269,520	27,901,874
Stock-based compensation	8,860,595	8,911,005
Deferred start-up and license costs	2,464,112	3,011,692
Sale of royalties	16,392,000	22,406,996
Depreciation	39	—
Total deferred tax assets	96,054,353	96,867,490
Deferred tax asset valuation allowance	(96,054,353)	(96,867,059)
Net deferred tax assets	—	431
Deferred tax liabilities:		
Depreciation	—	(431)
Total deferred tax liabilities	—	(431)
Total	$ —	$ —

A reconciliation between the Company's effective tax rate and the federal statutory rate for the years ended December 31, 2024 and 2023 are as follows:

	Year Ended December 31,	
	2024	2023
Federal statutory rate	21.00%	21.00%
Permanent differences	14.99%	(0.57%)
State income taxes, net of federal benefit	0.00%	0.00%
Valuation allowance	(35.99%)	(20.44%)
Effective tax rate	0.00%	(0.00%)

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of the deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based upon the level of historical losses and the uncertainty of future taxable income over the periods which the Company will realize the benefits of its net deferred tax assets, management believes it is more likely than not that the Company will not realize the benefits on the balance of its net deferred tax asset and, accordingly, the Company has established a full valuation allowance on its net deferred tax assets. The valuation allowance decreased by approximately $0.8 million and increased by approximately $6.8 million during the years ended December 31, 2024 and 2023, respectively.

As of December 31, 2024, the Company had approximately $156.8 million of federal net operating losses that will begin to expire in 2036, if not utilized. Of the total federal net operating loss, approximately $135.4 million has an unlimited carryforward and therefore will not expire. As of December 31, 2024, the Company had approximately $7.7 million of New Jersey and approximately $148.1 million of Massachusetts operating losses that will begin to expire in 2029 and 2037, respectively, if not utilized. As of December 31, 2024, the Company had approximately $0.1 million of federal research and development credits that will begin to expire in 2027, if not utilized.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending income tax examinations. The Company's tax years are still open under statute from 2021 to present.

As of December 31, 2024 and 2023, the Company had no liability recorded for unrecognized tax benefit. The Company classifies penalties and interest expense related to income tax liabilities as an income tax expense. There were no interest and penalties recognized in the statements of operations for the years ended December 31, 2024 and 2023, or accrued on the balance sheets as of December 31, 2024 and 2023.

NOTE 9 — COMMITMENTS AND CONTINGENCIES

Legal Proceedings

From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of the Company's business activities. The Company is not aware of any claim or litigation, the outcome of which, if determined adversely to the Company, would have a material effect on the Company's financial position or results of operations.

Leases

On October 11, 2022, the Company entered into an office lease agreement with Regus to lease approximately 491 rentable square feet of office space located at 1500 District Avenue, Burlington, MA 01803. In January 2025, the Company renewed the month-to-month lease agreement commencing on February 1, 2025, with a monthly payment of $9,106. The Company has elected to not recognize the lease agreement on the balance sheet as the term of the agreement is 12 months or less.

NOTE 10 — RELATED PARTY TRANSACTIONS

None.

NOTE 11 — SUBSEQUENT EVENTS

None.

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 ("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 our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2024. Based on the evaluation of our disclosure controls and procedures as of December 31, 2024, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

Management Report on Internal Control over Financial Reporting

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

As of December 31, 2024, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013 Framework). Based on this assessment, our management concluded that, as of December 31, 2024, our internal control over financial reporting was effective based on those criteria. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

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

Changes in Internal Control over Financial Reporting

There were no changes in internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act, during the fourth quarter that would have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. Other Information

None.

ITEM 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

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,” “Information Regarding the Board and Corporate Governance,” “Executive Officers” and “Delinquent Section 16(a) Reports” appearing in the definitive proxy statement we will file in connection with our 2025 Annual Meeting of Stockholders and is incorporated by reference herein.

We have adopted a Code of Ethics and Business Conduct that applies to all officers, directors and employees, and have posted the text of the policy on our website (http://ir.minervaneurosciences.com/corporate-governance). In addition, we intend to promptly disclose on our website in the future (i) the date and nature of any amendment (other than technical, administrative or other non-substantive amendments) to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and relates to any element of the code of ethics definition enumerated in Item 406(b) of Regulation S-K, and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals that relates to one or more of the elements of the code of ethics definition enumerated in Item 406(b) of Regulation S-K, the name of such person who is granted the waiver and the date of the waiver.

We have adopted insider trading policies and procedures governing the purchase, sale, and/or other dispositions of our securities by directors, officers and employees. In addition, it is our intent to comply with the applicable laws and regulations relating to insider trading.

ITEM 11. Executive Compensation

The information required by this Item 11 will be contained in the sections entitled “Executive Compensation” and “Director Compensation” appearing in the definitive proxy statement we will file in connection with our 2025 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 “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” appearing in the definitive proxy statement we will file in connection with our 2025 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 “Transactions with Related Persons Related Person Transactions Policy and Procedures” appearing in the definitive proxy statement we will file in connection with our 2025 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 “Principal Accountant Fees and Services” appearing in the definitive proxy statement we will file in connection with our 2025 Annual Meeting of Stockholders and is incorporated by reference herein.

Part IV

ITEM 15. Exhibits and Financial Statement Schedules

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

(1) Financial Statements

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2024 and 2023

Consolidated Statements of Operations for the Years Ended December 31, 2024 and 2023

Consolidated Statements of Stockholders' Deficit for the Years Ended December 31, 2024 and 2023

Consolidated Statements of Cash Flows for the Years Ended December 31, 2024 and 2023

Notes to Consolidated Financial Statements

(2) Schedules

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

(3) Exhibits

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

Exhibit No.	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation of the Registrant	S-1/A	333-195169	3.1	June 10, 2014	
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant	8-K	001-36517	3.1	June 17, 2022	
3.3	Amended and Restated Bylaws of the Registrant	10-Q	001-36517	3.2	November 4, 2019	
4.1	Form of Common Stock Certificate	S-1/A	333-195169	4.1	June 10, 2014	
4.2	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934	10-K	001-36517	4.2	March 8, 2023	
10.1	Share Purchase Agreement between the Registrant, Mind-NRG SA and Various Shareholders dated as of February 11, 2014	S-1	333-195169	10.13	April 9, 2014	
10.2†	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	
10.3*	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	
10.4*	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	
10.5*	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	
10.6*	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	
10.7*	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	
10.8*	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	
10.9	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	
10.10	Form of Registration Rights Agreement between certain investors referenced therein and the Registrant, dated as of March 13, 2015	8-K	001-36517	10.3	March 18, 2015	
10.11	Second Amendment to License Agreement between Mitsubishi Tanabe Pharma Corporation and the Registrant, dated as of April 21, 2015	10-Q	001-36517	10.5	May 7, 2015	
10.12†	Amended and Restated Non-Employee Director Compensation Plan	10-Q	001-36517	10.1	November 7, 2023	
10.13	Common Stock Purchase Agreement, dated March 17, 2016, by and between David Kupfer and the Registrant	8-K	001-36517	10.1	March 18, 2016	

Exhibit No.	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith
10.14†	Employment Agreement, dated as of August 1, 2016, by and between Mind-NRG SARL and Dr. Remy Luthringer	10-Q	001-36517	10.1	August 4, 2016	
10.15†	Employment Agreement, dated as of August 1, 2016, by and between Mind-NRG SARL and Geoffrey Race	10-Q	001-36517	10.2	August 4, 2016	
10.16†	Employment Agreement, dated as of August 1, 2016, by and between the Registrant and Frederick Ahlholm	10-Q	001-36517	10.3	August 4, 2016	
10.17†	Form of Restricted Stock Unit Agreement under the Amended and Restated 2013 Equity Incentive Plan of the Registrant	8-K	001-36517	10.1	December 16, 2016	
10.18†	Form of Option Grant Agreement under the Amended and Restated 2013 Equity Incentive Plan	10-K	001-36517	10.36	March 13, 2017	
10.19	Amendment No. 1 to Co-Development and License Agreement dated June 13, 2017, by and between the Registrant and Janssen Pharmaceutica NV	8-K	001-36517	10.1	June 14, 2017	
10.20*	Commercial Supply Agreement by and between the Registrant and Catalent Germany Schorndorf GmbH, dated September 18, 2019	10-Q	001-36517	10.1	November 4, 2019	
10.21	Open Market Sale Agreement, dated as of September 14, 2022, by and between the Registrant and Jefferies LLC	S-3	333-267424	1.2	September 14, 2022	
10.22	Settlement Agreement, dated as of June 24, 2020, by and between the Registrant and Janssen Pharmaceutica, N.V.	10-Q	001-36517	10.2	August 3, 2020	
10.23†	Amended and Restated 2013 Equity Incentive Plan	10-Q	001-36517	10.2	November 7, 2023	
10.24*	Royalty Purchase Agreement, dated as of January 15, 2021, by and between the Registrant and RPI 2019 Intermediate Finance Trust (redacted)	10-K	001-36517	10.48	March 8, 2021	
10.25*	Remy Luthringer Supplemental Retention Benefits Letter Agreement (redacted)	10-Q	001-36517	10.1	May 12, 2021	
10.26	First Amendment to the Employment Agreement of Geoff Race by and between Mind-NRG SARL and Geoff Race, effective October 11, 2021	8-K	001-36517	10.1	October 12, 2021	
10.27	Amended and Restated Employment Agreement by and between Minerva Neurosciences, Inc. and Frederick Ahlholm, effective October 11, 2021	8-K	001-36517	10.2	October 12, 2021	
10.28	First Amendment to the Employment Agreement of Remy Luthringer by and between Mind-NRG SARL and Remy Luthringer, effective December 13, 2022	8-K	001-36517	10.1	December 13, 2022	
10.29	Second Amendment to the Employment Agreement of Remy Luthringer by and between Mind-NRG SARL and Remy Luthringer, effective March 6, 2023	10-K	001-36517	10.30	March 8, 2023	
10.30	Securities Purchase Agreement, dated June 27, 2023, by and among Minerva Neurosciences, Inc. and the purchasers party thereto	8-K	001-36517	10.1	June 28, 2023	
19.1	Statement of Company Policy on Insider Trading and Disclosure					X

Exhibit No.	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith
21.1	List of Subsidiaries	10-K	001-36517	21.1	March 1, 2022	
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
97	Incentive Compensation Recoupment Policy	10-K	001-36517	97	February 22, 2024	
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Document.					X
104	Cover Page formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.					X

† Indicates management contract or compensatory plan or arrangement.

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

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

The agreements and other documents filed as exhibits to this Annual Report on Form 10-K are not intended to provide factual information or other disclosure other than with respect to the terms of the agreements or other documents themselves, and you should not rely on them for that purpose. In particular, any representations and warranties made by us in these agreements or other documents were made solely within the specific context of the relevant agreement or document and may not describe the actual state of affairs as of the date they were made or at any other time.

ITEM 16. Form 10-K Summary

Not applicable.

SIGNATURES

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

MINERVA NEUROSCIENCES, INC.

By:

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

Date: February 25, 2025

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ Remy Luthringer, Ph.D. Remy Luthringer, Ph.D.	Executive Chairman and Chief Executive Officer *(Principal Executive Officer)*	February 25, 2025
/s/ Frederick Ahlholm Frederick Ahlholm	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	February 25, 2025
/s/ Geoffrey Race Geoffrey Race	President	February 25, 2025
/s/ Hans Peter Hasler Hans Peter Hasler	Member of the Board of Directors	February 25, 2025
/s/ David Kupfer, MD David Kupfer, MD	Member of the Board of Directors	February 25, 2025
/s/ Fouzia Laghrissi-Thode, MD Fouzia Laghrissi-Thode, MD	Member of the Board of Directors	February 25, 2025
/s/ Jan van Heek Jan van Heek	Member of the Board of Directors	February 25, 2025

Exhibit 19.1

MINERVA NEUROSCIENCES, INC.
INSIDER TRADING POLICY
(ADOPTED FEBRUARY 20, 2025)

INTRODUCTION

During the course of your relationship with Minerva Neurosciences, Inc. ("***Minerva***"), you may receive material information that is not yet publicly available ("***material nonpublic information***") about Minerva or other publicly traded companies that Minerva has business relationships with. Material nonpublic information may give you, or someone you pass that information on to, a leg up over others when deciding whether to buy, sell or otherwise transact in Minerva's securities or the securities of another publicly traded company. This policy sets forth guidelines with respect to transactions in Minerva securities and in the securities of other applicable publicly traded companies, in each case by our employees, directors and consultants and the other persons or entities subject to this policy as described below.

TRANSACTIONS SUBJECT TO THIS POLICY

This policy applies to all transactions in securities issued by Minerva, as well as derivative securities that are not issued by Minerva, such as exchange-traded put or call options or swaps relating to Minerva's securities. Accordingly, for purposes of this policy, the terms "***trade***," "***trading***" and "***transactions***" include not only purchases and sales of Minerva's common stock in the public market but also any other purchases, sales, transfers, gifts or other acquisitions and dispositions of common or preferred equity, options, warrants and other securities (including debt securities) and other arrangements or transactions that affect economic exposure to changes in the prices of these securities.

PERSONS SUBJECT TO THIS POLICY

This policy applies to you and all other employees, directors and consultants of Minerva and its subsidiaries. This policy also applies to members of your family who reside with you, any other persons with whom you share a household, any family members who do not live in your household but whose transactions in Minerva's securities are directed by you or are subject to your influence or control and any other individuals or entities whose transactions in securities you influence, direct or control (including, e.g., a venture or other investment fund, if you influence, direct or control transactions by the fund). However, this policy does not apply to any entity that invests in securities in the ordinary course of its business (e.g., a venture or other investment fund) if (and only if) such entity has established its own insider trading controls and procedures in compliance with applicable securities laws with respect to trading in Minerva's securities. The foregoing persons who are deemed subject to this policy are referred to in this policy as "***Related Persons***." You are responsible for making sure that your Related Persons comply with this policy.

STATEMENT OF POLICY

It is the policy of Minerva that an employee, director or consultant of Minerva (or any other person or entity subject to this policy) who is aware of material nonpublic information relating to Minerva **may not**, directly or indirectly:

1. engage in any transactions in Minerva's securities, except as otherwise specified under the heading "Exceptions to this Policy" below;
2. recommend the purchase or sale of any Minerva's securities;
3. disclose material nonpublic information to persons within Minerva whose jobs do not require them to have that information, or outside of Minerva to other persons, such as family, friends, business associates and investors, unless the disclosure is made in accordance with Minerva's policies regarding the protection or authorized external disclosure of information regarding Minerva; or
4. assist anyone engaged in the above activities.

The prohibition against insider trading is absolute. It applies ***even if*** the decision to trade is not based on such material nonpublic information. It also applies to transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure) and also to very small transactions. All that matters is whether you are aware of **any** material nonpublic information relating to Minerva at the time of the transaction.

The U.S. federal securities laws do not recognize any mitigating circumstances to insider trading. In addition, even the appearance of an improper transaction must be avoided to preserve Minerva's reputation for adhering to the highest standards of conduct. In some circumstances, you may need to forgo a planned transaction even if you planned it before becoming aware of the material nonpublic information. So, even if you believe you may suffer an economic loss or sacrifice an anticipated profit by waiting to trade, you must wait.

It is also important to note that the laws prohibiting insider trading are not limited to trading by the insider alone; advising others to trade on the basis of material nonpublic information is illegal and squarely prohibited by this policy. Liability in such cases can extend both to the "tippee"—the person to whom the insider disclosed material nonpublic information—and to the "tipper," the insider himself or herself. In such cases, you can be held liable for your own transactions, as well as the transactions by a tippee and even the transactions of a tippee's tippee. For these and other reasons, it is the policy of Minerva that no employee, director or consultant of Minerva (or any other person or entity subject to this policy) may either (a) recommend to another person or entity that they buy, hold or sell Minerva's securities **at any time** or (b) disclose material nonpublic information to persons within Minerva whose jobs do not require them to have that information, or outside of Minerva to other persons (unless the disclosure is made in accordance with Minerva's policies regarding the protection or authorized external disclosure of information regarding Minerva).

In addition, it is the policy of Minerva that no person subject to this policy who, in the course of his or her relationship with Minerva, learns of any confidential information that is material to another publicly traded company with which Minerva does business, including a supplier, partner or collaborator of Minerva, may trade in that other company's securities until the information becomes public or is no longer material to that other company.

There are no exceptions to this policy, except as specifically noted above or below.

MATERIAL NONPUBLIC INFORMATION

Material information

It is not always easy to figure out whether you are aware of material nonpublic information. But there is one important factor to determine whether nonpublic information you know about a public company is material: whether the information could be expected to affect the market price of that company's securities or to be considered important by investors who are considering trading that company's securities. If the information makes you want to trade, it would probably have the same effect on others. Keep in mind that both positive and negative information can be material.

There is no bright-line standard for assessing materiality; rather, materiality is based on an assessment of all of the facts and circumstances, and is often evaluated by relevant enforcement authorities with the benefit of hindsight. Depending on the specific details, the following items may be considered material nonpublic information until publicly disclosed within the meaning of this policy. There may be other types of information that would qualify as material information as well; use this list merely as a non-exhaustive guide:

- financial results or forecasts;
- status of product or product candidate development or regulatory approvals;
- clinical data relating to products or product candidates;
- timelines for pre-clinical studies or clinical trials;
- acquisitions or dispositions of assets, divisions or companies;
- public or private sales of debt or equity securities;
- stock splits, dividends or changes in dividend policy;
- the establishment of a repurchase program for Minerva's securities;
- gain or loss of a significant licensor, licensee or supplier;
- changes or new corporate partner relationships or collaborations;
- notice of issuance or denial of patents;
- regulatory developments;
- management or control changes;
- employee layoffs;
- a disruption in Minerva's operations or breach or unauthorized access of its property or assets, including its facilities and information technology infrastructure;
- tender offers or proxy fights;
- accounting restatements;
- litigation or settlements; and
- impending bankruptcy.

When information is considered public

The prohibition on trading when you have material nonpublic information lifts once that information becomes publicly disseminated. But for information to be considered publicly disseminated, it must be widely disseminated through a press release, a filing with the Securities and Exchange Commission (the "***SEC***"), or other widely disseminated announcement. Once information is publicly disseminated, it is still necessary to afford the investing public with sufficient time to absorb the information. Generally speaking, information will be considered publicly disseminated for purposes of this policy only after two full trading days have elapsed since the

information was publicly disclosed. For example, if we announce material nonpublic information before trading begins on Wednesday, then you may execute a transaction in our securities on Friday; if we announce material nonpublic information after trading ends on Wednesday, then you may execute a transaction in our securities on Monday. Depending on the particular circumstances, Minerva may determine that a longer or shorter waiting period should apply to the release of specific material nonpublic information.

QUARTERLY TRADING BLACKOUTS

Because our workplace culture tends to be open, odds are that the vast majority of our employees, directors and consultants will possess material nonpublic information at certain points during the year. To minimize even the appearance of insider trading among our employees, directors and consultants we have established "quarterly trading blackout periods" during which Minerva employees, directors, consultants and their Related Persons—regardless of whether they are aware of material nonpublic information or not—may not conduct any trades in Minerva securities. That means that, except as described in this policy, all Minerva employees, directors, consultants and their Related Persons will be able to trade in Minerva securities only during limited open trading window periods that generally will begin after two full trading days have elapsed since the public dissemination of Minerva's annual or quarterly financial results and end at the beginning of the next quarterly trading blackout period. Of course, even during an open trading window period, you may not (unless an exception applies) conduct any trades in Minerva securities if you are otherwise in possession of material nonpublic information.

For purposes of this policy, each "***quarterly trading blackout period***" will generally begin at the end of the day on the last day of each fiscal quarter and end after two full trading days have elapsed since the public dissemination of Minerva's financial results for that quarter. Please note that the quarterly trading blackout period may commence early or may be extended if, in the judgment of the Chief Executive Officer and General Counsel (or if the General Counsel is absent or is otherwise unavailable, the President or the Chief Financial Officer), there exists undisclosed information that would make trades by Minerva employees, directors and consultants inappropriate. It is important to note that the fact that the quarterly trading blackout period has commenced early or has been extended should be considered material nonpublic information that should not be communicated to any other person.

A Minerva employee, director or consultant who believes that special circumstances require him or her to trade during a quarterly trading blackout period should consult the General Counsel (or if the General Counsel is absent or is otherwise unavailable, the Chief Financial Officer) (the "***Clearing Officer***"). Permission to trade during a quarterly trading blackout period will be granted only where the circumstances are extenuating, the Clearing Officer concludes that the person is not in fact aware of any material nonpublic information relating to Minerva or its securities, and there appears to be no significant risk that the trade may subsequently be questioned.

EVENT-SPECIFIC TRADING BLACKOUTS

From time to time, an event may occur that is material to Minerva and is known by only a few directors, officers and/or employees. So long as the event remains material and nonpublic, the persons designated by the Chief Executive Officer and General Counsel (or if the General Counsel is absent or is otherwise unavailable, the President or the Chief Financial Officer) may not trade in Minerva's securities. In that situation, Minerva will notify the designated individuals that neither they nor their Related Persons may trade in the Minerva's securities. The existence of an event-specific trading blackout should also be considered material nonpublic information

and should not be communicated to any other person. Even if you have not been designated as a person who should not trade due to an event-specific trading blackout, you should not trade while aware of material nonpublic information. Exceptions will not be granted during an event-specific trading blackout.

The quarterly and event-driven trading blackouts do not apply to those transactions to which this policy does not apply, as described under the heading "Exceptions to this Policy" below.

EXCEPTIONS TO THIS POLICY

This policy does not apply in the case of the following transactions, except as specifically noted:

1. ***Option and Warrant Exercises***. This policy does not apply to the exercise of options granted under Minerva's equity compensation plans, or the exercise of warrants, for cash or, where permitted under the option or warrant, by a net exercise transaction with the Company or by delivery to Minerva of already-owned Minerva stock. This policy does, however, apply to any sale of stock as part of a broker-assisted cashless exercise or any other market sale, whether or not for the purpose of generating the cash needed to pay the exercise price or pay taxes.

2. ***Tax Withholding Transactions***. This policy does not apply to the surrender of shares directly to Minerva to satisfy tax withholding obligations as a result of the issuance of shares upon vesting or exercise of restricted stock units, options or other equity awards granted under Minerva's equity compensation plans. Of course, any market sale of the stock received upon exercise or vesting of any such equity awards remains subject to all provisions of this policy whether or not for the purpose of generating the cash needed to pay the exercise price or pay taxes.

3. ***10b5-1 Automatic Trading Programs***. Under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended ("***Exchange Act***"), and as permitted by Minerva, employees, directors and consultants may establish a trading plan under which a broker is instructed to buy and sell Minerva securities based on pre-determined criteria (a "***10b5-1 Trading Plan***"). So long as a 10b5-1 Trading Plan is properly established, purchases and sales of Minerva securities pursuant to that Trading Plan are not subject to this policy. To be properly established, an eligible person's Trading Plan must be established in compliance with the requirements of Rule 10b5-1 of the Exchange Act and any applicable 10b5-1 trading plan guidelines of Minerva at a time when Minerva was not in a trading blackout period and they were not otherwise aware of any material nonpublic information relating to Minerva or the securities subject to the Trading Plan. Moreover, all 10b5-1 Trading Plans must be reviewed and approved by Minerva before being established to confirm that the 10b5-1 Trading Plan complies with all pertinent company policies and applicable securities laws.

4. ***401(k) Plan***. To the extent applicable, this policy does not apply to purchases of Minerva's securities in Minerva's 401(k) plan resulting from your periodic contribution of money to the plan pursuant to your payroll deduction election. This policy does apply, however, to certain elections you may make under the 401(k) plan, including: (a) an election to increase or decrease the percentage of your periodic contributions that will be allocated to the Minerva stock fund; (b) an election to make an intra-plan transfer of an existing account balance into or out of the Minerva stock fund; (c) an election to borrow money against your 401(k) plan account if the loan will result in a liquidation of some or all of your Minerva stock fund balance; and (d) an election to pre-pay

a plan loan if the pre-payment will result in allocation of loan proceeds to the Minerva stock fund.

SPECIAL AND PROHIBITED TRANSACTIONS

1.***Inherently Speculative Transactions*.** No Minerva employee, director or consultant may engage in short sales, transactions in put options, call options or other derivative securities on an exchange or in any other organized market, or in any other inherently speculative transactions with respect to Minerva's stock.

2.***Hedging Transactions.*** Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds. Such hedging transactions may permit a Minerva employee, director or consultant to continue to own Minerva's securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, the Minerva employee, director or consultant may no longer have the same objectives as Minerva's other stockholders. Therefore, Minerva employees, directors and consultants are prohibited from engaging in any such transactions.

3.***Margin Accounts and Pledged Securities***. Securities held in a margin account as collateral for a margin loan may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when the pledgor is aware of material nonpublic information or otherwise is not permitted to trade in Minerva's securities, Minerva employee, director and consultants are prohibited from holding Minerva's securities in a margin account or otherwise pledging Minerva's securities as collateral for a loan.

4.***Standing and Limit Orders***. Standing and limit orders (except standing and limit orders under approved Trading Plans, as discussed above) create heightened risks for insider trading violations similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructions to a broker, and as a result the broker could execute a transaction when a Minerva employee, director or consultant is in possession of material nonpublic information. Minerva therefore discourages placing standing or limit orders on Minerva's securities. If a person subject to this policy determines that they must use a standing order or limit order (other than under an approved Trading Plan as discussed above), the order should be limited to short duration and the person using such standing order or limit order is required to cancel such instructions immediately in the event restrictions are imposed on their ability to trade pursuant to the "Quarterly Trading Blackouts" and "Event-Specific Trading Blackouts" provisions above.

PRE-CLEARANCE AND ADVANCE NOTICE OF TRANSACTIONS

In addition to the requirements above, executive officers, directors and other applicable employees who have been notified that they are subject to pre-clearance requirements face a further restriction: Even during an open trading window, they may not engage in any transaction in, or enter into, modify or terminate any contract, instruction or written plan or arrangement in, Minerva's securities without first obtaining pre-clearance from the Clearing Officer or his or her designee (or the Chief Executive Officer if the insider requesting pre-clearance is the Clearing Officer) or his or her designee at least two business days in advance. Pre-cleared transactions

not completed within two business days will require new pre-clearance. Minerva may choose to shorten this period.

Insiders shall provide to the Clearing Officer or his or her designee any documentation reasonably requested by him or her in furtherance of the foregoing procedures. The Clearing Officer or his or her designee does not assume the responsibility for, and approval from the Clearing Officer or his or her designee does not protect the insider from, the consequences of prohibited insider trading. The existence of the foregoing approval procedures does not in any way obligate the Clearing Officer or his or her designee to approve any trade requested by an insider.

Persons subject to pre-clearance must also give advance notice of their plans to exercise an outstanding stock option or warrant to the Clearing Officer or his or her designee. Once any transaction takes place, the officer, director or applicable employee must immediately notify the Clearing Officer or his or her designee so that Minerva may assist in any reporting requirements under Section 16(a) of the Exchange Act.

Short-Swing Trading, Control Stock and Section 16 Reports

Officers and directors subject to the reporting obligations under Section 16 of the Exchange Act should take care to avoid short-swing transactions (within the meaning of Section 16(b) of the Exchange Act) and the restrictions on sales by control persons (Rule 144 under the Securities Act of 1933, as amended), and should file all appropriate Section 16(a) reports (Forms 3, 4 and 5) and any notices of sale required by Rule 144.

Prohibition of Trading During Pension Plan Blackouts

No director or executive officer of Minerva may, directly or indirectly, purchase, sell or otherwise transfer any equity security of Minerva (other than an exempt security) during any “blackout period’’ (as defined in Regulation BTR under the Exchange Act) if a director or executive officer acquires or previously acquired such equity security in connection with his or her service or employment as a director or executive officer. This prohibition does not apply to any transactions that are specifically exempted, including but not limited to, purchases or sales of Minerva’s securities made pursuant to, and in compliance with, a Trading Plan; compensatory grants or awards of equity securities pursuant to a plan that, by its terms, permits executive officers and directors to receive automatic grants or awards and specifies the terms of the grants and awards; or acquisitions or dispositions of equity securities involving a *bona fide* gift or by will or the laws of descent or pursuant to a domestic relations order. Minerva will notify each director and executive officer of any blackout periods in accordance with the provisions of Regulation BTR. Because Regulation BTR is very complex, no director or executive officer of Minerva should engage in any transactions in Minerva’s securities, even if believed to be exempt from Regulation BTR, without first consulting with the Clearing Officer.

Policy’s Duration

This policy continues to apply to your transactions in Minerva’s securities and the securities of other applicable public companies as more specifically set forth in this policy, even after your relationship with Minerva has ended. If you are aware of material nonpublic information when your relationship with Minerva ends, you may not trade Minerva’s securities or the securities of other applicable publicly traded companies until the material nonpublic information has been publicly disseminated or is no longer material. Further, if you leave Minerva during a trading blackout

period, then you may not trade Minerva's securities or the securities of other applicable companies until the trading blackout period has ended.

INDIVIDUAL RESPONSIBILITY

Persons subject to this policy have ethical and legal obligations to maintain the confidentiality of information about Minerva and to not engage in transactions in Minerva's securities or the securities of other applicable public companies while aware of material nonpublic information, as more specifically set forth in this policy. Each individual is responsible for making sure that he or she complies with this policy, and that any family member, household member or other person or entity whose transactions are subject to this policy, as discussed under the heading "Persons Subject to this Policy" above, also comply with this policy. In all cases, the responsibility for determining whether an individual is aware of material nonpublic information rests with that individual, and any action on the part of Minerva or any employee or director of Minerva pursuant to this policy (or otherwise) does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws. You could be subject to severe legal penalties and disciplinary action by Minerva for any conduct prohibited by this policy or applicable securities laws. See "Penalties" below.

PENALTIES

Anyone who engages in insider trading or otherwise violates this policy may be subject to both civil liability and criminal penalties. Violators also risk disciplinary action by Minerva, including termination of employment. Anyone who has questions about this policy should contact their own attorney or Minerva's Clearing Officer. Please also see Frequently Asked Questions, which are attached as **EXHIBIT A**.

AMENDMENTS

Minerva is committed to continuously reviewing and updating its policies and procedures. Minerva therefore reserves the right to amend, alter or terminate this policy at any time and for any reason.

EXHIBIT A
INSIDER TRADING POLICY
FREQUENTLY ASKED QUESTIONS

1. ***What is insider trading?***

A: Generally speaking, insider trading is the buying or selling of stocks, bonds, futures or other securities by someone who possesses or is otherwise aware of material nonpublic information about the securities or the issuer of the securities. Insider trading also includes trading in derivatives (such as put or call options) where the price is linked to the underlying price of a company's stock. It does not matter whether the decision to buy or sell was influenced by the material nonpublic information, how many shares you buy or sell, or whether it has an effect on the stock price. Bottom line: If, during the course of your relationship with Minerva, you become aware of material nonpublic information about Minerva and you trade in Minerva's securities, you have broken the law and violated our insider trading policy. In addition, our insider trading policy provides that if in the course of your relationship with Minerva, you learn of any confidential information that is material to another publicly traded company with which Minerva does business, including a or supplier, partner or collaborator of Minerva, you may not trade in that other company's securities until the information becomes public or is no longer material to that other company.

2. ***Why is insider trading illegal?***

A: If company insiders are able to use their confidential knowledge to their financial advantage, other investors would not have confidence in the fairness and integrity of the market. This ensures that there is an even playing field by requiring those who are aware of material nonpublic information to refrain from trading.

3. ***What is material nonpublic information?***

A: Information is material if it would influence a reasonable investor to buy or sell a stock, bond future or other security. This could mean many things: financial results, clinical or regulatory results, potential acquisitions or major contracts to name just a few. Information is nonpublic if it has not yet been publicly disseminated within the meaning of our insider trading policy.

4. ***Who can be guilty of insider trading?***

A: Anyone who buys or sells a security while aware of material nonpublic information, or provides material nonpublic information that someone else uses to buy or sell a security, may be guilty of insider trading. This applies to all individuals, including officers, directors and others who don't even work at Minerva. Regardless of who you are, if you know something material about the value of a security that not everyone knows and you trade (or convince someone else to trade) in that security, you may be found guilty of insider trading.

5. ***Does Minerva have an insider trading policy?***

A: Yes, the insider trading policy is attached to this FAQ.

6. ***What if I work in a foreign office?***

A: The same rules apply to U.S. and foreign employees and consultants. The Securities and Exchange Commission (the U.S. government agency in charge of investor protection) and the Financial Industry Regulatory Authority (a private regulator that oversees U.S. securities exchanges) routinely investigate trading in a company's securities conducted by individuals and firms based abroad. In addition, as a Minerva director, employee or consultant, our policies apply to you no matter where you work.

7. ***What if I don't buy or sell anything, but I tell someone else material nonpublic information and they buy or sell?***

A: That is called "tipping." You are the "tipper" and the other person is called the "tippee." If the tippee buys or sells based on that material nonpublic information, both you and the "tippee" could be found guilty of insider trading. In fact, if you tell family members who tell others and those people then trade on the information, those family members and the "tippee" might be found guilty of insider trading too. To prevent this, you may not discuss material nonpublic information about the company with anyone outside Minerva, including spouses, family members, friends or business associates (unless the disclosure is made in accordance with Minerva's policies regarding the protection or authorized external disclosure of information regarding Minerva). This includes anonymous discussions on the internet about Minerva or companies with which Minerva does business.

8. ***What if I don't tell them the information itself; I just tell them whether they should buy or sell?***

A: That is still tipping, and you can still be responsible for insider trading. You may never recommend to another person that they buy, hold or sell Minerva's common stock or any derivative security related to Minerva's common stock, since that could be a form of tipping.

9. ***What are the sanctions if I trade on material nonpublic information or tip off someone else?***

A: In addition to disciplinary action by Minerva—which may include termination of employment—you may be liable for civil sanctions for trading on material nonpublic information. The sanctions may include return of any profit made or loss avoided as well as penalties of up to three times any profit made or any loss avoided. Persons found liable for tipping material nonpublic information, even if they did not trade themselves, may be liable for the amount of any profit gained or loss avoided by everyone in the chain of tippees as well as a penalty of up to three times that amount. In addition, anyone convicted of criminal insider trading could face prison and additional fines.

10. ***What is "loss avoided"?***

A: If you sell common stock or a related derivative security before negative news is publicly announced, and as a result of the announcement the stock price declines, you have avoided the loss caused by the negative news.

11. ***Am I restricted from trading securities of any companies other than Minerva, for example a partner or competitor of Minerva?***

A: Yes, you may be restricted from doing so due to your awareness of material nonpublic information. U.S. insider trading laws generally restrict everyone aware of material nonpublic

information about a company from trading in that company's securities, regardless of whether the person is directly connected with that company, except in limited circumstances. You should be particularly conscious of this restriction if, through your position at Minerva, you sometimes obtain sensitive, material information about other companies and their business dealings with Minerva. Please also refer to Question 1 above and our insider trading policy with respect to restrictions on trading in the securities of other public companies.

12. ***So if I do not trade Minerva securities when I have material nonpublic information, and I don't "tip" other people, I am in the clear, right?***

A: Not necessarily. Even if you do not violate U.S. law, you may still violate our policies. For example, employees and consultants may violate our policies by breaching their confidentiality obligations or by recommending Minerva stock as an investment, even if these actions do not violate securities laws. Our policies are stricter than the law requires so that we and our employees and consultants can avoid even the appearance of wrongdoing. Therefore, please review the entire policy carefully.

13. ***So when can I buy or sell my Minerva securities?***

A: If you are aware of material nonpublic information, you may not buy or sell our common stock until two full trading days have elapsed since the information was publicly disclosed. At that point, the information is considered publicly disseminated for purposes of our insider trading policy. For example, if we announce material nonpublic information before trading begins on Wednesday, then you may execute a transaction in our securities on Friday; if we announce material nonpublic information after trading ends on Wednesday, then you may execute a transaction in our securities on Monday. **Even if you are not aware of any material nonpublic information, you may not trade our common stock during any trading "blackout" period**. Our insider trading policy describes the quarterly trading blackout period, and additional event-driven trading blackout periods may be announced by email.

14. ***If I have an open order to buy or sell Minerva securities on the date a blackout period commences, can I leave it to my broker to cancel the open order and avoid executing the trade?***

A: No, unless it is in connection with a 10b5-1 trading plan (see Question 27 below). If you have any open orders when a blackout period commences other than in connection with a 10b5-1 trading plan, it is your responsibility to cancel these orders with your broker. If you have an open order and it executes after a blackout period commences not in connection with a 10b5-1 trading plan, you will have violated our insider trading policy and may also have violated insider trading laws.

15. ***Am I allowed to trade derivative securities of Minerva's common stock?***

A: No. Under our policies, you may not trade in derivative securities related to our common stock, which include publicly traded call and put options. In addition, under our policies, you may not engage in short selling of our common stock at any time.

"Derivative securities" are securities other than common stock that are speculative in nature because they permit a person to leverage their investment using a relatively small amount of money. Examples of derivative securities include "put options" and "call options." These are

different from employee options and other equity awards granted under our equity compensation plans, which are not derivative securities for purposes of our policy.

"Short selling" is profiting when you expect the price of the stock to decline, and includes transactions in which you borrow stock from a broker, sell it, and eventually buy it back on the market to return the borrowed shares to the broker. Profit is realized if the stock price decreases during the period of borrowing.

16. ***Why does Minerva prohibit trading in derivative securities and short selling?***

A: Many companies with volatile stock prices have adopted similar policies because of the temptation it represents to try to benefit from a relatively low-cost method of trading on short-term swings in stock prices, without actually holding the underlying common stock, and encourages speculative trading. We are dedicated to building stockholder value, short selling our common stock conflicts with our values and would not be well-received by our stockholders.

17. ***Can I purchase Minerva securities on margin or hold them in a margin account?***

A: Under our policies, you may not purchase our common stock on margin or hold it in a margin account at any time.

"Purchasing on margin" is the use of borrowed money from a brokerage firm to purchase our securities. Holding our securities in a margin account includes holding the securities in an account in which the shares can be sold to pay a loan to the brokerage firm.

18. ***Why does Minerva prohibit me from purchasing Minerva securities on margin or holding them in a margin account?***

A: Margin loans are subject to a margin call whether or not you possess material nonpublic information at the time of the call. If a margin call were to be made at a time when you were aware of material nonpublic information and you could not or did not supply other collateral, you may be liable under insider trading laws because of the sale of the securities (through the margin call). The sale would be attributed to you even though the lender made the ultimate determination to sell. The U.S. Securities and Exchange Commission takes the view that you made the determination to not supply the additional collateral and you are therefore responsible for the sale.

19. ***Can I pledge my Minerva shares as collateral for a personal loan?***

A: No. Pledging your shares as collateral for a personal loan could cause the pledgee to transfer your shares during a trading blackout period or when you are otherwise aware of material nonpublic information. As a result, you may not pledge your shares as collateral for a loan.

20. ***Can I hedge my ownership position in Minerva?***

A: Hedging or monetization transactions, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds are prohibited by our insider trading policy. Since such hedging transactions allow you to continue to own Minerva's securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership, you may no longer have the same objectives as Minerva's

other shareholders. Therefore, our insider trading policy prohibits you from engaging in any such transactions.

21. ***Can I exercise options granted to me under Minerva's equity compensation plans during a trading blackout period or when I possess material nonpublic information?***

A: Yes. You may exercise the options for cash (or via net exercise transaction with the company) and receive shares, but you may not sell the shares (even to pay the exercise price or any taxes due) during a trading blackout period or any time that you are aware of material nonpublic information. To be clear, you may not effect a broker-assisted cashless exercise (these cashless exercise transactions include a market sale) during a trading blackout period or any time that you are aware of material nonpublic information

22. ***Am I subject to trading blackout periods if I am no longer an employee or consultant of Minerva?***

A: It depends. If your employment with Minerva ends during a trading blackout period, you will be subject to the remainder of that trading blackout period. If your employment with Minerva ends on a day that the trading window is open, you will not be subject to the next trading blackout period. However, even if you are not subject to our trading blackout period after you leave Minerva, you should not trade in Minerva securities if you are aware of material nonpublic information. That restriction stays with you as long as the information you possess is material and not publicly disseminated within the meaning of our insider trading policy.

23. ***Can I gift stock while I possess material nonpublic information or during a trading blackout period?***

A: Because of the potential for the appearance of impropriety, you may not make gifts, whether to charities, to a trust or otherwise, of Minerva's common stock when you possess material nonpublic information or during a trading blackout period.

24. ***What if I purchased publicly traded options or other derivative securities before I became a Minerva employee or consultant?***

A: The same rules apply as for employee stock options. You may exercise the publicly traded options at any time, but you may not sell the securities during a trading blackout period or at any time that you are aware of material nonpublic information.

25. ***May I own shares of a mutual fund that invests in Minerva?***

A: Yes.

26. ***Are mutual fund shares holding Minerva common stock subject to the trading blackout periods?***

A: No. You may trade in mutual funds holding Minerva common stock at any time.

27. ***May I use a "routine trading program" or "10b5-1 plan"?***

A: Subject to the requirements discussed in our insider trading policy and any 10b5-1 trading plan guidelines, eligible persons may use a routine trading program. A routine trading

program, also known as a 10b5-1 plan, allows you to set up a highly structured program with your stock broker where you specify ahead of time the date, price, and amount of securities to be traded. If you wish to create a 10b5-1 plan, please contact the Clearing Officer to confirm you are an eligible person and to obtain approval.

28. ***What happens if I violate our insider trading policy?***

A: Violating our policies may result in disciplinary action, which may include termination of your employment or other relationship with Minerva. In addition, you may be subject to criminal and civil sanctions.

29. ***Who should I contact if I have questions about our insider trading policy or specific trades?***

A: You should contact the Clearing Officer.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-267424 and 333-273686 on Form S-3 and Nos. 333-242460, 333-225672, 333-223593, 333-222368, 333-216637, 333-210147, 333-203738, and 333-198753 on Form S-8 of our report dated February 25, 2025, relating to the financial statements of Minerva Neurosciences, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2024.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
February 25, 2025

Exhibit 31.1

CERTIFICATIONS

I, Remy Luthringer, certify that:

1. I have reviewed this annual report on Form 10-K of Minerva Neurosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2025

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

Exhibit 31.2

CERTIFICATIONS

I, Frederick Ahlholm, certify that:

1. I have reviewed this annual report on Form 10-K of Minerva Neurosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2025

/s/ Frederick Ahlholm
Frederick Ahlholm
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATIONS PURSUANT TO 18 U.S.C. SECTION 1350 AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Remy Luthringer**,** Chief Executive Officer of Minerva Neurosciences, Inc. (the "Company"), and Frederick Ahlholm, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2024, to which this Certification is attached as Exhibit 32.1 (the "Annual Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 25, 2025

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

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Minerva Neurosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.