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

FORM 10-Q

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

For the quarterly period ended March 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 No. 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

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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

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 definitions 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 is a shell company (as defined in Rule 12b-2 of the Act). YES ☐ NO ☒

The number of shares of Registrant's Common Stock, $0.0001 par value per share, outstanding as of April 26, 2024 was 6,993,406.

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Unless the context suggests otherwise, references in this Quarterly Report on Form 10-Q, or Quarterly Report, to "Minerva," "the Company," "we," "us," and "our" refer to Minerva Neurosciences, Inc. and, where appropriate, its subsidiaries.

This Quarterly Report on Form 10-Q contains forward-looking statements. 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 Quarterly Report on Form 10-Q under Part II, Item IA, "Risk Factors" and in our Annual Report on Form 10-K for the year ended December 31, 2023 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.

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

PART I – Financial Information
Item 1 – Financial Statements

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Balance Sheets
(Unaudited)

	March 31, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 34,818,304	$ 40,912,575
Restricted cash	100,000	100,000
Prepaid expenses and other current assets	702,546	989,865
Total current assets	35,620,850	42,002,440
Equipment, net	9,524	10,884
Capitalized software, net	10,642	17,027
Goodwill	14,869,399	14,869,399
Total assets	**$ 50,510,415**	**$ 56,899,750**
Liabilities and Stockholders' Deficit		
Current liabilities		
Accounts payable	$ 1,435,568	$ 1,805,320
Accrued expenses and other current liabilities	1,395,227	1,535,097
Total current liabilities	2,830,795	3,340,417
Liability related to the sale of future royalties	84,267,066	82,016,823
Total liabilities	87,097,861	85,357,240
Commitments and contingencies (Note 8)		
Stockholders' deficit		
Preferred stock; $0.0001 par value; 100,000,000 shares authorized; none issued or outstanding as of March 31, 2024 and December 31, 2023	—	—
Common stock; $0.0001 par value; 125,000,000 shares authorized; 6,993,406 shares issued and outstanding as of March 31, 2024 and December 31, 2023	699	699
Additional paid-in capital	368,796,088	368,357,239
Accumulated deficit	(405,384,233)	(396,815,428)
Total stockholders' deficit	(36,587,446)	(28,457,490)
Total liabilities and stockholders' deficit	**$ 50,510,415**	**$ 56,899,750**

See accompanying notes to condensed consolidated financial statements.

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended March 31,	
	2024	2023
Expenses		
Research and development	$ 4,167,287	$ 2,653,553
General and administrative	2,514,676	2,694,965
Total expenses	6,681,963	5,348,518
Loss from operations	(6,681,963)	(5,348,518)
Foreign exchange gains (losses)	5,493	(8,686)
Investment income	357,908	364,218
Non-cash interest expense for the sale of future royalties	(2,250,243)	(1,977,426)
Net loss	$ (8,568,805)	$ (6,970,412)
Net loss per share, basic and diluted	$ (1.13)	$ (1.31)
Weighted average shares outstanding, basic and diluted	7,568,981	5,340,193

See accompanying notes to condensed consolidated financial statements.

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Stockholders' Deficit
(Unaudited)

	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)**
Stock-based compensation	—	—	376,459	—	376,459
Net loss	—	—	—	(6,970,412)	(6,970,412)
Balances at March 31, 2023	**5,340,193**	**$ 534**	**$ 347,161,781**	**$ (373,780,487)**	**$ (26,618,172)**
Balances at January 1, 2024	**6,993,406**	**$ 699**	**$ 368,357,239**	**$ (396,815,428)**	**$ (28,457,490)**
Stock-based compensation	—	—	438,849	—	438,849
Net loss	—	—	—	(8,568,805)	(8,568,805)
Balances at March 31, 2024	**6,993,406**	**$ 699**	**$ 368,796,088**	**$ (405,384,233)**	**$ (36,587,446)**

See accompanying notes to condensed consolidated financial statements.

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Three Months Ended March 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (8,568,805)	$ (6,970,412)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,360	1,360
Amortization of capitalized software	6,385	6,385
Stock-based compensation expense	438,849	376,459
Non-cash interest expense associated with the sale of future royalties	2,250,243	1,977,426
Changes in operating assets and liabilities		
Refundable regulatory fee	—	3,117,218
Prepaid expenses and other current assets	287,319	252,072
Accounts payable	(369,752)	(8,669)
Accrued expenses and other current liabilities	(139,870)	1,132,754
Net cash used in operating activities	(6,094,271)	(115,407)
Cash flows from investing activities:		
Net cash provided by investing activities	—	—
Cash flows from financing activities:		
Net cash provided by financing activities	—	—
Net decrease in cash, cash equivalents and restricted cash	(6,094,271)	(115,407)
Cash, cash equivalents and restricted cash		
Beginning of period	41,012,575	36,193,606
End of period	$ 34,918,304	$ 36,078,199
Reconciliation of the Condensed Consolidated Statements of Cash Flows to the Condensed Consolidated Balance Sheets		
Cash and cash equivalents	$ 34,818,304	$ 35,978,199
Restricted cash	100,000	100,000
Total cash, cash equivalents and restricted cash	$ 34,918,304	$ 36,078,199

See accompanying notes to condensed 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 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 regarding such NDA for roluperidone.

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 interim condensed consolidated 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 March 31, 2024, the Company had an accumulated deficit of approximately $405.4 million and net cash used in operating activities was approximately $6.1 million during the three months ended March 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 March 31, 2024, the Company had cash, cash equivalents, and restricted cash of $34.9 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 a deficiency letter from The Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that for the last 31 consecutive business days, the market value of listed securities ("MVLS requirement") for its common stock had been below the minimum MVLS requirement of $35 million pursuant to Nasdaq Listing Rule 5550(b)(2). In accordance with the listing rules of Nasdaq, the Company has been provided with a grace period of 180 calendar days, or until October 7, 2024, to regain compliance. If the Company does not regain compliance within the grace period, the Company expects that Nasdaq would provide notice that its securities are subject to delisting.

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

The interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim reporting and the requirements of the Securities and Exchange Commission ("SEC") in accordance with Regulation S-X, Rule 8-03. Under those rules, certain notes and financial information that are normally required for annual financial statements can be condensed or omitted. In the opinion of the Company's management, the accompanying financial statements contain all adjustments (consisting of items of a normal and recurring nature) necessary to present fairly the financial position as of March 31, 2024, the results of operations for the three months ended March 31, 2024 and 2023 and cash flows for the three months ended March 31, 2024 and 2023. The results of operations for the three months ended March 31, 2024 are not necessarily indicative of the results to be expected for the full year. The consolidated balance sheet as of December 31, 2023 was derived from the audited annual financial statements. The accompanying unaudited condensed consolidated financial statements and notes thereto should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2023 included in the Company's Annual Report on Form 10-K filed with the SEC on February 22, 2024.

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 each of March 31, 2024 and December 31, 2023.

Recent accounting pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board and are adopted by the Company as of the specified effective date. The Company believes that the impact of recently issued, but not yet adopted, accounting pronouncements will not have a material impact on the condensed consolidated financial statements or do not apply to the Company.

NOTE 3 — ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities consist of the following:

	March 31, 2024	December 31, 2023
Research and development costs and other accrued expenses	$ 496,403	$ 777,680
Accrued severance	379,234	—
Accrued bonus	363,650	590,769
Professional fees	119,814	166,648
Vacation pay	36,126	—
Accrued expenses and other current liabilities	$ 1,395,227	$ 1,535,097

NOTE 4 — NET LOSS PER SHARE OF COMMON STOCK

Diluted loss per share is the same as basic loss per share for all periods presented as the effects of potentially dilutive items were anti-dilutive given the Company's net loss. Basic loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding, plus potential outstanding common stock for the period. Potential outstanding common stock includes stock options and shares underlying RSUs, but only to the extent that their inclusion is dilutive.

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 loss per share as of March 31, 2024.

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

	Three Months Ended March 31,	
	2024	2023
Net loss	$ (8,568,805)	$ (6,970,412)
Weighted average shares of common stock outstanding	7,568,981	5,340,193
Net loss per share of common stock – basic and diluted	$ (1.13)	$ (1.31)

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

	Three Months Ended March 31,	
	2024	2023
Common stock options	1,115,357	700,929
Performance-based restricted stock units	228,209	456,422
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 joint development 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, the Company has significant continuing involvement as Royalty Pharma has recourse against the Company relating to the payments due from Janssen. As such, the Company applied the debt recognition guidance under ASC 470, *Debt*, and recorded the upfront payment of $60 million as a liability related to the sale of future royalties ("Royalty Obligation"), which will be amortized under the

interest method over the estimated 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. In addition, in accordance with ASC 470, Debt, 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 life of the co-development and license agreement (the "Agreement") with Janssen. In order to determine the amortization of the Royalty Obligation, the Company is required to estimate the total amount of future royalty payments to Royalty Pharma over the life of the Agreement. In addition to the $60 million upfront payment, 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. At execution, the Company's estimate of this total interest expense resulted in an effective annual interest rate of approximately 10.5%. As of March 31, 2024, the Company estimated the effective annual interest rate to be approximately 10.97%. This estimate contains significant assumptions, which are considered Level 3 fair value inputs, regarding the timing and amount of expected royalty and milestone payments that impact the interest expense that will be recognized over the royalty period. The Company will periodically assess the estimated royalty payments to Royalty Payments from Janssen and to the extent the amount or timing of such payments is materially different than the original estimates, an adjustment will be recorded prospectively to increase or decrease interest expense. There are a number of factors that could materially affect the amount and timing of royalty payments to Royalty Pharma from Janssen, and correspondingly, the amount of interest expense recorded by the Company, most of which are not within the Company's control. Such factors include, but are not limited to, delays or discontinuation of development of seltorexant, regulatory approval, changing standards of care, the introduction of competing products, manufacturing or other delays, generic competition, intellectual property matters, adverse events that result in regulatory authority imposed restrictions on the use of the drug products, significant changes in foreign exchange rates as the royalties remitted to Royalty Pharma are made in U.S. dollars ("USD") while the underlying sales of seltorexant will be made in currencies other than USD and other events or circumstances that are not currently foreseen. Changes to any of these factors could result in increases or decreases to both royalty revenues and interest expense. Janssen is currently conducting one Phase 3 study with seltorexant, completed a Phase 3 study during 2023, and discontinued a Phase 3 study during 2022.

The following table shows the activity of the Royalty Obligation since the transaction inception through March 31, 2024:

	March 31, 2024
Upfront payment from the sale of future royalties	$ 60,000,000
Non-cash interest expense associated with the sale of future royalties	24,267,066
Liability related to the sale of future royalties	$ 84,267,066

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 three months ended March 31, 2024, no shares of the Company's common stock were issued or sold under the Sales Agreement. As of March 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 March 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.

Stock Option Awards

Stock option activity for employees and non-employees for the three months ended March 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	—	$ —		
Exercised	—	$ —		
Cancelled/Forfeited	(41,872)	$ 7.02		
Outstanding March 31, 2024	1,115,357	$ 11.52	8.3	$ —
Exercisable March 31, 2024	450,498	$ 20.06	7.0	$ —
Available for future grant	404,238			

The weighted average grant-date fair value of stock options outstanding on March 31, 2024 was $8.41 per share. Total unrecognized compensation costs related to non-vested stock options at March 31, 2024 were approximately $2.9 million and are expected to be recognized within future operating results over a weighted-average period of 2.9 years.

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. There were no stock options granted during the three months ended March 31, 2024 and 2023.

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 March 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:

	Three Months Ended March 31,	
	2024	2023
Research and development	$ 192,385	$ 184,727
General and administrative	246,464	191,732
Total	$ 438,849	$ 376,459

NOTE 8 — 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 2024, the Company renewed the month-to-month lease agreement commencing on February 1, 2024, with a monthly payment of $8,697. 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.

Item 2. ***Management's Discussion and Analysis of Financial Condition and Results of Operations***

You should read the following discussion of our financial condition and results of operations in conjunction with our condensed consolidated financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q and with our annual audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2023 as filed with the Securities and Exchange Commission on February 22, 2024. This discussion and analysis contains forward-looking statements that involve significant risks and uncertainties. Our actual results, performance or experience could differ materially from what is indicated by any forward-looking statement due to various important factors, risks and uncertainties, including, but not limited to, those set forth under "Risk Factors" included elsewhere in this Quarterly Report on Form 10-Q.

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 regarding our NDA for roluperidone.

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 March 31, 2024 and December 31, 2023, we had an accumulated deficit of $405.4 million and $396.8 million, respectively. For the three months ended March 31, 2024 and 2023, we recorded net losses of $8.6 million and $7.0 million, respectively.

Clinical and Regulatory Updates

Complete Response Letter

On February 26, 2024, the FDA issued a Complete Response Letter ("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.

Preliminary Results

We enrolled 17 patients for this study who received at least one dose of roluperidone at 64 mg. Out of the 17 patients enrolled, 13 patients completed all 17 days of daily dosing. Two patients 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. We observed no new safety signals during the study, with few treatment-emergent adverse events (TEAEs), 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.

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.

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.

Results of Operations

Comparison of Three Months Ended March 31, 2024 versus March 31, 2023

Research and Development Expenses

Research and development expenses were $4.2 million and $2.7 million for the three months ended March 31, 2024 and 2023, respectively, an increase of approximately $1.5 million. The increase in research and development expenses was primarily due to costs associated with the FDA's review of our NDA and the conduct of the MIN-101C18 study. Non-cash stock compensation costs included in research and development expenses were $0.2 million for both the three months ended March 31, 2024 and 2023.

General and Administrative Expenses

General and administrative expenses were $2.5 million and $2.7 million for the three months ended March 31, 2024 and 2023, respectively, a decrease of approximately $0.2 million. The decrease in general and administrative expenses was primarily due to lower professional service fees. Non-cash stock compensation costs included in general and administrative expenses were $0.2 million for both the three months ended March 31, 2024 and 2023.

Foreign Exchange Gains (Losses)

Foreign exchange gains were $5 thousand and foreign exchange losses were $9 thousand for the three months ended March 31, 2024 and 2023, respectively, an increase of $14 thousand, primarily due to currency movements.

Investment Income

Investment income was $358 thousand and $364 thousand for the three months ended March 31, 2024 and 2023, respectively, a decrease of approximately $6 thousand, 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 $2.3 million and $2.0 million for the three months ended March 31, 2024 and 2023, respectively, an increase of $0.3 million. The increase was primarily due to the amortization of non-cash interest expense for the difference between the balance of the liability related to the sale of future royalties and the estimated amount of future royalties to be received over the royalty period.

Liquidity and Capital Resources

Sources of Liquidity

As of March 31, 2024, we had an accumulated deficit of approximately $405.4 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 March 31, 2024, we had

approximately $34.9 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 three months ended March 31, 2024, no shares of our common stock were issued or sold under the Sales Agreement. As of March 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, including the recent disruptions to and volatility in the credit and financial markets in the U.S. and worldwide resulting from the COVID-19 pandemic, 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.

	Three Months Ended March 31,	
	2024	2023
	(dollars in millions)	
Net cash used in:		
Operating activities	$ (6.1)	$ (0.1)
Investing activities	—	—
Financing activities	—	—
Net decrease in cash	$ (6.1)	$ (0.1)

Net Cash Used in Operating Activities

Net cash used in operating activities of approximately $6.1 million during the three months ended March 31, 2024 was primarily due to our net loss of $8.6 million, a $0.4 million decrease in accounts payable, and a $0.1 million decrease in accrued expenses, partially offset by non-cash interest expense for the sale of future royalties of $2.3 million, stock-based compensation expense of $0.4 million, and a $0.3 million decrease in prepaid expenses.

Net cash used in operating activities of approximately $0.1 million during the three months ended March 31, 2023 was primarily due to our net loss of $7.0 million, partially offset by a $3.1 million decrease in refundable regulatory fees, non-cash interest expense for the sale of future royalties of $2.0 million, an increase in accrued expenses of $1.1 million, stock-based compensation expense of $0.4 million, and a $0.3 million decrease in prepaid expenses.

Net Cash Provided by Investing Activities

Net cash provided by investing activities was zero during the three months ended March 31, 2024 and 2023.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was zero during the three months ended March 31, 2024 and 2023.

Critical Accounting Policies and Estimates

In our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, our most critical accounting policies and estimates upon which our financial status depends were identified as those relating to research and development costs; in-process research and development; goodwill; income taxes; and the liability related to the sale of future royalties. We reviewed our policies and determined that those policies were our most critical accounting policies for the three months ended March 31, 2024.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") and are adopted by us as of the specified effective date. See Note 2 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 and Note 2 in our condensed consolidated financial statements appearing elsewhere in this Form 10-Q for a description of recent accounting pronouncements applicable to our financial statements. We believe that the impact of recently issued, but not yet adopted, accounting pronouncements will not have a material impact on the condensed consolidated financial statements 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 3. ***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 4. ***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 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 March 31, 2024. Based on the evaluation of our disclosure controls and procedures as of March 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.

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 our latest fiscal quarter that would have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

Item 1. ***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 Quarterly Report on Form 10-Q, 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 1A. ***Risk Factors***

We operate in a rapidly changing environment that involves a number of risks which could materially affect our business, financial condition or future results, some of which are beyond our control. In addition to the other information set forth in this Quarterly Report on Form 10-Q, the risks and uncertainties that we believe are most important for you to consider are discussed in Part I-Item 1A under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the Securities and Exchange Commission ("SEC") on February 22, 2024. The risk factors set forth below are risk factors containing changes, which may be material, from the risk factors previously disclosed in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, as filed with the SEC.

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. As of March 31, 2024, we had an accumulated deficit of approximately $405.4 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 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—Clinical and Regulatory Updates—Complete Response Letter" for more information. 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 March 31, 2024, we had cash, cash equivalents, and restricted cash of $34.9 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 our interim 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 to continue advancing 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 or on reasonable terms, if at all, and our ability to raise additional capital may be adversely impacted by global economic conditions, including the recent disruptions to and volatility in the credit and financial markets in the U.S. and worldwide resulting from the COVID-19 pandemic, 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 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.

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 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—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 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—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.

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 and fewer business development opportunities.

As previously reported, on April 10, 2024, we received a deficiency letter from Nasdaq notifying us that for the last 31 consecutive business days, the market value of listed securities ("MVLS requirement") for our common stock had been below the minimum MVLS requirement of $35 million pursuant to Nasdaq Listing Rule 5550(b)(2). In accordance with the listing rules of Nasdaq, we have been provided with a grace period of 180 calendar days, or until October 7, 2024, to regain compliance. If we do not regain compliance within the grace period, we expect that Nasdaq would provide notice that our securities are subject to delisting.

While we will continue to monitor our market value of listed securities and consider available options to regain compliance with the MVLS requirements, which may include applying for an extension of the compliance period or appealing to a Nasdaq Hearings Panel, there can be no assurance that we will be able to regain compliance with the MVLS requirements or otherwise maintain compliance with the other Nasdaq listing requirements.

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,*" described in our Annual Report on Form 10-K for the year ended December 31, 2023.

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.

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 may 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. In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—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 of up to $7,500 per intentional violation 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 may 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 may adopt similarly stringent interpretations of their 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. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, 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 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.

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 become more common and has increased risks to our information technology systems and data, as more of 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. For example, an external contractor experienced a cyberattack in 2019, which resulted in a disruption to patient recruitment in our Phase 3 clinical trial of roluperidone. 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. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

The following exhibits are incorporated by reference or filed as part of this report.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's registration statement on Form S-1/A (File No. 333-195169) filed with the SEC on June 10, 2014).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's quarterly report on Form 10-Q (File No. 001-36517) filed with the SEC on November 4, 2019).
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Minerva Neurosciences, Inc., effective June 17, 2022 (incorporated by reference to Exhibit 3.1 to the Registration's current report on Form 8-K (File No. 001-36517) filed with the SEC on June 17, 2022).
31.1*	Certification of Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer (Principal Financial Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
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.
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Document
104*	Cover Page Interactive Data file (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101)

* Filed herewith.
+ These certifications are being furnished solely to accompany this quarterly 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.

SIGNATURE

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/ Frederick Ahlholm

Frederick Ahlholm
Chief Financial Officer
(Principal Financial Officer)
(On behalf of the Registrant)

Date: May 1, 2024

EXHIBIT 31.1

CERTIFICATION

I, Remy Luthringer, certify that:

1. I have reviewed this Form 10-Q 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: May 1, 2024

/s/ Remy Luthringer Ph.D.

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

EXHIBIT 31.2

CERTIFICATION

I, Frederick Ahlholm, certify that:

1. I have reviewed this Form 10-Q 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: May 1, 2024

/s/ Frederick Ahlholm

Frederick Ahlholm

Chief Financial Officer

(Principal Financial Officer)

EXHIBIT 32.1

STATEMENT PURSUANT TO 18 U.S.C. § 1350

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, Executive Chairman and Chief Executive Officer (Principal Executive Officer) of Minerva Neurosciences, Inc. (the "Company") and Frederick Ahlholm, Chief Financial Officer (Principal Financial Officer) of the Company, each hereby certifies that, to the best of his knowledge:

(1) The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2024, to which this Certification is attached as Exhibit 32.1 (the "Quarterly 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 Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Remy Luthringer, Ph.D.

Date: May 1, 2024

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

/s/ Frederick Ahlholm

Date: May 1, 2024

Frederick Ahlholm
Chief Financial Officer
(Principal Financial Officer)

This certification accompanies the Form 10-Q 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-Q), irrespective of any general incorporation language contained in such filing.