

**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 **June 30, 2025**

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
(State or Other Jurisdiction of
Incorporation or Organization)

26-0784194
(I.R.S. Employer
Identification No.)

1500 District Avenue
Burlington, MA
(Address of Principal Executive Offices)

01803
(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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 Exchange Act). YES NO

The number of shares of Registrant's Common Stock, \$0.0001 par value per share, outstanding as of August 8, 2025, 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, 2024 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)

	June 30, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	\$ 15,247,910	\$ 21,362,008
Restricted cash	100,000	100,000
Prepaid expenses and other current assets	199,615	806,895
Total current assets	<u>15,547,525</u>	<u>22,268,903</u>
Equipment, net	2,721	5,442
Goodwill	14,869,399	14,869,399
Total assets	<u>\$ 30,419,645</u>	<u>\$ 37,143,744</u>
Liabilities and Stockholders' Deficit		
Current liabilities		
Accounts payable	\$ 896,799	\$ 1,607,844
Accrued expenses and other current liabilities	1,632,059	1,229,000
Total current liabilities	2,528,858	2,836,844
Liability related to the sale of future royalties	60,000,000	60,000,000
Total liabilities	<u>62,528,858</u>	<u>62,836,844</u>
Commitments and contingencies (Note 8)		
Stockholders' deficit		
Preferred stock; \$0.0001 par value; 100,000,000 shares authorized; none issued or outstanding as of June 30, 2025 and December 31, 2024	—	—
Common stock; \$0.0001 par value; 125,000,000 shares authorized; 6,993,406 shares issued and outstanding as of June 30, 2025 and December 31, 2024	699	699
Additional paid-in capital	370,278,211	369,682,764
Accumulated deficit	(402,388,123)	(395,376,563)
Total stockholders' deficit	<u>(32,109,213)</u>	<u>(25,693,100)</u>
Total liabilities and stockholders' deficit	<u>\$ 30,419,645</u>	<u>\$ 37,143,744</u>

See accompanying notes to condensed consolidated financial statements.

MINERVA NEUROSCIENCES, INC.

**Condensed Consolidated Statements of Operations
(Unaudited)**

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
Expenses				
Research and development	\$ 1,298,041	\$ 3,860,499	\$ 2,660,479	\$ 8,027,786
General and administrative	2,076,108	2,417,069	4,616,554	4,931,745
Total expenses	<u>3,374,149</u>	<u>6,277,568</u>	<u>7,277,033</u>	<u>12,959,531</u>
Loss from operations	(3,374,149)	(6,277,568)	(7,277,033)	(12,959,531)
Foreign exchange (losses) gains	(21,110)	(4,694)	(29,486)	799
Investment income	136,671	360,755	294,959	718,663
Non-cash interest expense for the sale of future royalties	—	(2,311,980)	—	(4,562,223)
Net loss	<u>\$ (3,258,588)</u>	<u>\$ (8,233,487)</u>	<u>\$ (7,011,560)</u>	<u>\$ (16,802,292)</u>
Net loss per share, basic and diluted	<u>\$ (0.43)</u>	<u>\$ (1.09)</u>	<u>\$ (0.93)</u>	<u>\$ (2.22)</u>
Weighted average shares outstanding, basic and diluted	<u>7,568,981</u>	<u>7,568,981</u>	<u>7,568,981</u>	<u>7,568,981</u>

See accompanying notes to condensed consolidated financial statements.

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Stockholders' Deficit
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount			
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)
Stock-based compensation	—	—	329,318	—	329,318
Net loss	—	—	—	(8,233,487)	(8,233,487)
Balances at June 30, 2024	6,993,406	\$ 699	\$ 369,125,406	\$ (413,617,720)	\$ (44,491,615)
Balances at January 1, 2025	6,993,406	\$ 699	\$ 369,682,764	\$ (395,376,563)	\$ (25,693,100)
Stock-based compensation	—	—	297,229	—	297,229
Net loss	—	—	—	(3,752,972)	(3,752,972)
Balances at March 31, 2025	6,993,406	\$ 699	\$ 369,979,993	\$ (399,129,535)	\$ (29,148,843)
Stock-based compensation	—	—	298,218	—	298,218
Net loss	—	—	—	(3,258,588)	(3,258,588)
Balances at June 30, 2025	6,993,406	\$ 699	\$ 370,278,211	\$ (402,388,123)	\$ (32,109,213)

See accompanying notes to condensed consolidated financial statements.

MINERVA NEUROSCIENCES, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30,	
	2025	2024
Cash flows from operating activities:		
Net loss	\$ (7,011,560)	\$ (16,802,292)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,721	2,721
Amortization of capitalized software	—	12,770
Stock-based compensation expense	595,447	768,167
Non-cash interest expense associated with the sale of future royalties	—	4,562,223
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	607,280	561,847
Accounts payable	(711,045)	(976,975)
Accrued expenses and other current liabilities	403,059	1,839,964
Net cash used in operating activities	<u>(6,114,098)</u>	<u>(10,031,575)</u>
Cash flows from investing activities:		
Net cash provided by investing activities	<u>—</u>	<u>—</u>
Cash flows from financing activities:		
Net cash provided by financing activities	<u>—</u>	<u>—</u>
Net decrease in cash, cash equivalents and restricted cash	<u>(6,114,098)</u>	<u>(10,031,575)</u>
Cash, cash equivalents and restricted cash		
Beginning of period	21,462,008	41,012,575
End of period	<u>\$ 15,347,910</u>	<u>\$ 30,981,000</u>
Reconciliation of the Condensed Consolidated Statements of Cash Flows to the Condensed Consolidated Balance Sheets		
Cash and cash equivalents	\$ 15,247,910	\$ 30,881,000
Restricted cash	100,000	100,000
Total cash, cash equivalents and restricted cash	<u>\$ 15,347,910</u>	<u>\$ 30,981,000</u>

See accompanying notes to condensed consolidated financial statements.

MINERVA NEUROSCIENCES, INC.
Notes to Condensed Consolidated Financial Statements
As of June 30, 2025 and for the Three and Six Months Ended June 30, 2025 and 2024
(Unaudited)

NOTE 1 — NATURE OF OPERATIONS AND LIQUIDITY

Nature of Operations

Minerva Neurosciences, Inc. (“Minerva” or the “Company”) is a clinical-stage biopharmaceutical company focused on the development and commercialization of proprietary product candidates to treat patients suffering from central nervous system (“CNS”) diseases. The Company’s lead product candidate is roluperidone, a compound the Company is developing for the treatment of negative symptoms in patients with schizophrenia. The Company previously submitted a New Drug Application (“NDA”) with the U.S. Food and Drug Administration (“FDA”) for roluperidone for the treatment of negative symptoms in schizophrenia in August 2022. On February 26, 2024, the FDA issued a Complete Response Letter (“CRL”) regarding the NDA for roluperidone. The Company has had multiple interactions with the FDA following receipt of the CRL for its NDA in February 2024 and the FDA has confirmed the requirement for an additional confirmatory clinical trial to address the deficiencies cited in the CRL and resubmit the NDA.

As in the two previous studies (C03 and C07), the required confirmatory clinical trial would include patients diagnosed with schizophrenia who present with impairing negative symptoms and stable positive symptoms. Patients would be selected based on stable positive symptoms and impairing negative symptoms for the six months prior to entering the trial. Minerva agreed with the FDA that best efforts will be made to secure 25-30% of patients from the United States (subject to competitive recruitment). The FDA has confirmed that roluperidone can be studied in monotherapy where patients would receive a double-blinded single daily 64 mg dose of roluperidone or placebo. The FDA has also confirmed that, the primary endpoint would be the change from Baseline in PANSS Marder negative symptoms factor score (“NSFS”) at 12 weeks of treatment with roluperidone compared to placebo. The FDA advised that, to support a monotherapy indication, it would be necessary to assess relapses on an observational basis for at least 52 weeks, in patients treated in monotherapy with roluperidone, placebo or antipsychotics. The FDA has stated that it would consider a resubmission of the NDA that included a double-blind, placebo- or active-controlled trial of roluperidone with a duration of at least 52 weeks.

The trial’s potential sole key secondary endpoint would be the comparison of the change from Baseline in the Personal and Social Performance scale total score (“PSP”) to Week 12, which is a scale to assess patients’ social functioning. The trial will also potentially measure the change from Baseline in Clinical Global Impression of Severity (“CGI-S”), change from Baseline in NSFS, PSP, and CGI-S at earlier timepoints and safety & tolerability.

The FDA has agreed that an adjunctive trial with antipsychotics would not be required for resubmission of the NDA if Minerva could provide robust, controlled data demonstrating the efficacy and safety of long-term monotherapy with roluperidone in subjects with negative symptoms of schizophrenia.

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 June 30, 2025, the Company had an accumulated deficit of approximately \$402.4 million and net cash used in operating activities was approximately \$6.1 million during the six months ended June 30, 2025. 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 June 30, 2025, the Company had cash, cash equivalents, and restricted cash of \$15.3 million. Given the cash, cash equivalents, and restricted cash balance as of June 30, 2025, along with the current projections of cash to be used for operations, the Company believes that its existing cash, cash equivalents, and restricted cash will not be sufficient to fund its operating expenses and capital requirements. However, management has the ability to mitigate this condition through cost reduction initiatives. Based on the implementation of these initiatives, the Company believes it will have sufficient liquidity to meet its obligations for at least twelve months from the date these 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 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 March 17, 2025, the Company was formally notified that the Nasdaq Hearings Panel (the "Panel") of the Nasdaq Stock Market LLC ("Nasdaq") determined that the Company regained compliance with Nasdaq Listing Rule 5550(b)(3) (the "Net Income Rule"), which requires listed companies to maintain a minimum of \$500,000 of net income from continuing operations. Pursuant to Nasdaq Listing Rule 5815(d)(4)(A), the Company will be subject to a discretionary panel monitor for a period of one year from March 17, 2025. If, within that one-year monitoring period, the Company fails to maintain compliance with any Nasdaq continued listing requirement, the Listing Qualifications Staff (the "Staff") of Nasdaq will issue a Delist Determination Letter, and the Company will have an opportunity to request a new hearing with the initial Panel or a newly convened Hearings Panel if the initial Panel is unavailable. Notwithstanding Nasdaq Listing Rule 5810(c)(2), the Company will not be permitted to provide the Staff with a plan of compliance with respect to any deficiency that arises during the one-year monitoring period, and the Staff will not be permitted to grant additional time for the Company to regain compliance with respect to any deficiency.

As previously disclosed, on April 10, 2024, the Company received written notice from Nasdaq notifying the Company that for the last 31 consecutive business days, the Company's minimum Market Value of Listed Securities was below the minimum of \$35 million required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(b)(2). In addition, on January 10, 2025, the Company received a notice from Nasdaq indicating that following the Company's hearing before the Panel on December 10, 2024, the Panel granted the Company's request for continued listing on Nasdaq through March 31, 2025, subject to the Company's compliance with Nasdaq Listing Rule 5550(b)(1) (the "Equity Rule"), among other conditions. While the Company had initially planned to regain compliance with the Equity Rule, upon review of the Company's Annual Report on Form 10-K for the year ended December 31, 2024, the Staff confirmed that the Company demonstrated compliance with the Net Income Rule. Accordingly, the Panel determined to continue the listing of the Company's securities on Nasdaq and closed the matter.

There can be no assurance that the Company will be able to maintain compliance with Nasdaq's listing standards or that the Company will be able to continue its listing on Nasdaq.

Review of Strategic Alternatives

As a result of the requirement for the confirmatory study and the Company's current cash position, the Company is taking additional steps to reduce costs. The Company has also initiated a review process to explore strategic alternatives to maximize value for its stockholders. There can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or as to the timing of any such agreements or transactions. Minerva does not intend to discuss or disclose further developments regarding the exploration of strategic alternatives unless and until its board of directors has approved a definitive action or otherwise determined that further disclosure is appropriate or required by law.

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 June 30, 2025, the results of operations for the three and six months ended June 30, 2025 and 2024 and cash flows for the six months ended June 30, 2025 and 2024. The results of operations for the three and six months ended June 30, 2025 are not necessarily indicative of the results to be expected for the full year. The consolidated balance sheet as of December 31, 2024 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, 2024 included in the Company’s Annual Report on Form 10-K filed with the SEC on February 25, 2025.

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 June 30, 2025 and December 31, 2024.

Segment information

Operating segments are defined as components of an enterprise (business activity from which it earns revenue and incurs expenses) about which discrete financial information is available and regularly reviewed by the chief operating decision maker (“CODM”) in deciding how to allocate resources and in assessing performance. The Company’s CODM is the Chief Executive Officer. The CODM

evaluates performance of the segments based on net income (loss). The CODM also reviews operating results and previously forecasted financial information to make decisions about allocating resources and assessing performance for the entire Company.

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

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
Expenses				
Research and development staff related expenses ⁽¹⁾	\$ 447,397	\$ 410,356	\$ 913,388	\$ 1,435,838
Research and development drug product material expenses and associated costs ⁽²⁾	24,757	1,751,062	55,658	2,537,761
Research and development stock compensation expenses (non-cash)	100,130	84,109	199,829	276,494
General and administrative staff related expenses ⁽¹⁾	914,526	836,260	1,857,157	1,718,275
General and administrative stock compensation expenses (non-cash)	198,088	245,209	395,618	491,673
Total	<u>1,684,898</u>	<u>3,326,996</u>	<u>3,421,650</u>	<u>6,460,041</u>
Other segment expense, net ⁽³⁾	<u>1,689,251</u>	<u>2,950,572</u>	<u>3,855,383</u>	<u>6,499,490</u>
Total expenses	<u>3,374,149</u>	<u>6,277,568</u>	<u>7,277,033</u>	<u>12,959,531</u>
Loss from operations	<u>(3,374,149)</u>	<u>(6,277,568)</u>	<u>(7,277,033)</u>	<u>(12,959,531)</u>
Reconciling items:				
Foreign exchange (losses) gains	(21,110)	(4,694)	(29,486)	799
Investment income	136,671	360,755	294,959	718,663
Non-cash interest expense for the sale of future royalties	—	(2,311,980)	—	(4,562,223)
Net loss	<u>\$ (3,258,588)</u>	<u>\$ (8,233,487)</u>	<u>\$ (7,011,560)</u>	<u>\$ (16,802,292)</u>

(1) Salary, bonus, and fringe benefits are included in staff related expenses.

(2) Costs associated with the Company's drug substance validation campaign are included in drug product material expenses.

(3) Insurance, consultant, audit, legal, and the C18 study costs are included in other segment expense, net.

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.

NOTE 3 — ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities consist of the following:

	<u>June 30, 2025</u>	<u>December 31, 2024</u>
Research and development costs and other accrued expenses	\$ 317,386	\$ 351,782
Accrued bonus	756,394	363,181
Professional fees	435,882	514,037
Vacation pay	122,397	—
Accrued expenses and other current liabilities	<u>\$ 1,632,059</u>	<u>\$ 1,229,000</u>

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, but only to the extent that their inclusion is dilutive. Performance-based restricted stock units are excluded from the calculation of dilutive potential common shares until the performance conditions have been achieved on the basis of the assumption that the end of the reporting period was the end of the contingency period, if such issuable shares are dilutive.

In June 2023, in connection with a private placement, 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 June 30, 2025.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Net loss	\$ (3,258,588)	\$ (8,233,487)	\$ (7,011,560)	\$ (16,802,292)
Weighted average shares of common stock outstanding	7,568,981	7,568,981	7,568,981	7,568,981
Net loss per share of common stock – basic and diluted	\$ (0.43)	\$ (1.09)	\$ (0.93)	\$ (2.22)

The following securities outstanding at June 30, 2025 and 2024 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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Common stock options	1,483,172	1,063,234	1,483,172	1,063,234
Performance-based restricted stock units	228,209	228,209	228,209	228,209
Common stock warrants	—	5,099	—	5,099

NOTE 5 — SALE OF FUTURE ROYALTIES

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

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

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

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

NOTE 6 — STOCKHOLDERS' DEFICIT

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 six months ended June 30, 2025, no shares of the Company's common stock were issued or sold under the Sales Agreement. As of June 30, 2025, 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).

NOTE 7 — STOCK AWARD PLAN AND STOCK-BASED COMPENSATION

In December 2013, the Company adopted the 2013 Equity Incentive Plan (as subsequently amended and restated, the "Plan"), which provides for the issuance of options, stock appreciation rights, stock awards and stock units. As of June 30, 2025, the total shares authorized for issuance under the Plan were 2,078,917.

Stock Option Awards

Stock option activity for employees and non-employees for the six months ended June 30, 2025 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, 2025	1,487,234	\$ 8.34	8.3	\$ 46
Granted	—	\$ —		
Exercised	—	\$ —		
Expired	(4,062)	\$ 42.47		
Outstanding June 30, 2025	<u>1,483,172</u>	\$ 8.25	7.8	\$ —
Exercisable June 30, 2025	<u>696,708</u>	\$ 13.33	6.8	\$ —
Available for future grant	<u>36,423</u>			

The weighted average grant-date fair value of stock options outstanding on June 30, 2025 was \$6.11 per share. Total unrecognized compensation costs related to non-vested stock options at June 30, 2025 were approximately \$2.2 million and are expected to be recognized within future operating results over a weighted-average period of 2.2 years. Generally, stock options are granted using exercise prices equal to the market price at the date of grant, vest over four years for employees and one year for directors and are exercisable over a maximum period of 10 years from their grant dates.

The expected term of the employee-related options was estimated using the “simplified” method as defined by the SEC’s Staff Accounting Bulletin No. 107, *Share-Based Payment*. The volatility assumption was determined by examining the historical volatility of the Company and volatilities for industry peer companies. The risk-free interest rate assumption is based on the U.S. Treasury instruments, the term of which was consistent with the expected term of the options. The dividend assumption is based on the Company’s history and expectation of dividend payouts. The Company has never paid dividends on its common stock and does not anticipate paying dividends on its common stock in the foreseeable future. Accordingly, the Company has assumed no dividend yield for the purpose 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 six months ended June 30, 2025 and 2024.

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 June 30, 2025, 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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Research and development	\$ 100,130	\$ 84,109	\$ 199,829	\$ 276,494
General and administrative	198,088	245,209	395,618	491,673
Total	\$ 298,218	\$ 329,318	\$ 595,447	\$ 768,167

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 2025, the Company renewed the month-to-month lease agreement commencing on February 1, 2025, with a monthly payment of \$9,106. The Company has elected to not recognize the lease agreement on the balance sheet as the term of the agreement is 12 months or less.

NOTE 9 — SUBSEQUENT EVENTS

On July 4, 2025, tax legislation known as the One Big Beautiful Bill Act (“OBBBA”) was enacted in the United States. The Company is currently evaluating the impact of U.S. tax law changes introduced by OBBBA on the consolidated financial statements. Due to the timing of enactment, the Company will recognize any such impact in the Quarterly Report on Form 10-Q for the period ending September 30, 2025.

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, 2024 as filed with the Securities and Exchange Commission on February 25, 2025. 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 ("CRL") regarding our NDA for roluperidone. We have had multiple interactions with the FDA following receipt of the CRL for our NDA in February 2024 and the FDA has confirmed the requirement for an additional confirmatory clinical trial to address the deficiencies cited in the CRL and resubmit the NDA.

As in the two previous studies (C03 and C07), the required confirmatory clinical trial would include patients diagnosed with schizophrenia who present with impairing negative symptoms and stable positive symptoms. Patients would be selected based on stable positive symptoms and impairing negative symptoms for the six months prior to entering the trial. We agreed with the FDA that best efforts will be made to secure 25-30% of patients from the United States (subject to competitive recruitment). The FDA has confirmed that roluperidone can be studied in monotherapy where patients would receive a double-blinded single daily 64 mg dose of roluperidone or placebo. The FDA has also confirmed that, the primary endpoint would be the change from Baseline in PANSS Marder negative symptoms factor score ("NSFS") at 12 weeks of treatment with roluperidone compared to placebo. The FDA advised that, to support a monotherapy indication, it would be necessary to assess relapses on an observational basis for at least 52 weeks, in patients treated in monotherapy with roluperidone, placebo or antipsychotics. The FDA has stated that it would consider a resubmission of the NDA that included a double-blind, placebo- or active-controlled trial of roluperidone with a duration of at least 52 weeks.

The trial's potential sole key secondary endpoint would be the comparison of the change from Baseline in the Personal and Social Performance scale total score ("PSP") to Week 12, which is a scale to assess patients' social functioning. The trial will also potentially measure the change from Baseline in Clinical Global Impression of Severity ("CGI-S"), change from Baseline in NSFS, PSP, and CGI-S at earlier timepoints and safety & tolerability.

The FDA has agreed that an adjunctive trial with antipsychotics would not be required for resubmission of the NDA if we could provide robust, controlled data demonstrating the efficacy and safety of long-term monotherapy with roluperidone in subjects with negative symptoms of schizophrenia.

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 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 June 30, 2025 and December 31, 2024, we had an accumulated deficit of \$402.4 million and \$395.4 million, respectively. For the six months ended June 30, 2025 and 2024, we recorded net losses of \$7.0 million and \$16.8 million, respectively.

Review of Strategic Alternatives

As a result of the requirement for the confirmatory study and our current cash position, we are taking additional steps to reduce costs. We have also initiated a review process to explore strategic alternatives to maximize value for our stockholders. There can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or as to the timing of any such agreements or transactions. We do not intend to discuss or disclose further developments regarding the exploration of strategic alternatives unless and until our board of directors has approved a definitive action or otherwise determined that further disclosure is appropriate or required by law.

Complete Response Letter (CRL)

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

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

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

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

Macroeconomic Considerations

Results of our operations have varied and may vary in the future based on the impact of changes in the domestic or global economy. Negative conditions in the general economy both in the United States and abroad, including conditions resulting from changes in inflation and fluctuations in interest rates, financial and credit market fluctuations, international trade relations and tariffs, pandemics, political turmoil, natural catastrophes and warfare in the United States or elsewhere, could negatively affect our business. It is not possible at this time to estimate the long-term impact that these and related events could have on our business, as the impact will depend on future developments, which are highly uncertain and cannot be predicted.

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 (Losses) Gains

Foreign exchange (losses) gains 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 June 30, 2025 versus June 30, 2024

Research and Development Expenses

Research and development expenses were \$1.3 million and \$3.9 million for the three months ended June 30, 2025 and 2024, respectively, a decrease of approximately \$2.6 million. The decrease in research and development expenses was primarily due to lower costs associated with our drug substance validation campaign and lower consultant fees. Non-cash stock compensation costs included in research and development expenses were \$0.1 million for both the three months ended June 30, 2025 and 2024.

General and Administrative Expenses

General and administrative expenses were \$2.1 million and \$2.4 million for the three months ended June 30, 2025 and 2024, respectively, a decrease of approximately \$0.3 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 June 30, 2025 and 2024.

Foreign Exchange Losses

Foreign exchange losses were \$21 thousand and \$5 thousand for the three months ended June 30, 2025 and 2024, respectively, an increase of \$16 thousand, primarily due to currency movements.

Investment Income

Investment income was \$137 thousand and \$361 thousand for the three months ended June 30, 2025 and 2024, respectively, a decrease of approximately \$224 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 zero and \$2.3 million for the three months ended June 30, 2025 and 2024, respectively, a decrease of \$2.3 million. The decrease in non-cash interest expense for the sale of future royalties was due to revising our estimates for the timing and amount of future royalty payments to be received under the royalty arrangement. During the third quarter of 2024, we adjusted the carrying amount of our liability related to the sale of future royalties to the initial payment of \$60 million. This adjustment resulted in the recognition of \$26.6 million in other income during the third quarter of 2024, representing the amount of non-cash interest expense amortized through June 30, 2024.

Comparison of Six Months Ended June 30, 2025 versus June 30, 2024

Research and Development Expenses

Research and development expenses were \$2.7 million and \$8.0 million for the six months ended June 30, 2025 and 2024, respectively, a decrease of approximately \$5.3 million. The decrease in research and development expenses was primarily due to lower costs associated with our drug substance validation campaign, costs for the C18 study, consultant fees, and lower compensation expenses. Non-cash stock compensation costs included in research and development expenses were \$0.2 million and \$0.3 million for the six months ended June 30, 2025 and 2024, respectively.

General and Administrative Expenses

General and administrative expenses were \$4.6 million and \$4.9 million for the six months ended June 30, 2025 and 2024, respectively, a decrease of approximately \$0.3 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 \$0.4 million and \$0.5 million for the six months ended June 30, 2025 and 2024.

Foreign Exchange (Losses) Gains

Foreign exchange losses were \$29 thousand and foreign exchange gains were \$1 thousand for the six months ended June 30, 2025 and 2024, respectively, a decrease of \$30 thousand, primarily due to currency movements.

Investment Income

Investment income was \$295 thousand and \$719 thousand for the six months ended June 30, 2025 and 2024, respectively, a decrease of approximately \$424 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 zero and \$4.6 million for the six months ended June 30, 2025 and 2024, respectively, a decrease of \$4.6 million. The decrease in non-cash interest expense for the sale of future royalties was due to revising our estimates for the timing and amount of future royalty payments to be received under the royalty arrangement. During the third quarter of 2024, we adjusted the carrying amount of our liability related to the sale of future royalties to the initial payment of \$60 million. This adjustment resulted in the recognition of \$26.6 million in other income during the third quarter of 2024, representing the amount of non-cash interest expense amortized through June 30, 2024.

Liquidity and Capital Resources

Sources of Liquidity

As of June 30, 2025, we had an accumulated deficit of approximately \$402.4 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 June 30, 2025, we had cash, cash equivalents, and restricted cash of \$15.3 million. Given the cash, cash equivalents, and restricted cash balance as of June 30, 2025, along with the current projections of cash to be used for operations, we believe that our existing cash, cash equivalents, and restricted cash will not be sufficient to fund our operating expenses and capital requirements. However, management has the ability to mitigate this condition through cost reduction initiatives. Based on the implementation of these initiatives, we believe we will have sufficient liquidity to meet our obligations for at least twelve months from 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 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.

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 six months ended June 30, 2025, no shares of our common stock were issued or sold under the Sales Agreement. As of June 30, 2025, an aggregate of \$22.6 million was eligible for sale pursuant to the Sales Agreement under our effective registration statement on Form S-3 (File No. 333-267424).

Seltorexant Royalties

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

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

Uses of Funds

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

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third party funding, commercialization, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. There can be no assurance that such additional funding, if available, can be obtained on terms acceptable to us, and our ability to raise additional capital may be adversely impacted by global economic conditions, geopolitical conflicts, such as the war in Ukraine and hostilities in the Middle East, and other factors. If we are unable to obtain additional financing, future operations would need to be scaled back or discontinued. 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.

	Six Months Ended June 30,	
	2025	2024
	(dollars in millions)	
Net cash used in:		
Operating activities	\$ (6.1)	\$ (10.0)
Investing activities	—	—
Financing activities	—	—
Net decrease in cash	<u>\$ (6.1)</u>	<u>\$ (10.0)</u>

Net Cash Used in Operating Activities

Net cash used in operating activities of approximately \$6.1 million during the six months ended June 30, 2025 was primarily due to our net loss of \$7.0 million and a \$0.7 million decrease in accounts payable, partially offset by stock-based compensation expense of \$0.6 million, a \$0.6 million decrease in prepaid expenses, and a \$0.4 million increase in accrued expenses.

Net cash used in operating activities of approximately \$10.0 million during the six months ended June 30, 2024 was primarily due to our net loss of \$16.8 million and a \$1.0 million decrease in accounts payable, partially offset by non-cash interest expense for the sale of future royalties of \$4.6 million, a \$1.8 million increase in accrued expenses, stock-based compensation expense of \$0.8 million, and a \$0.6 million decrease in prepaid expenses.

Net Cash Provided by Investing Activities

Net cash provided by investing activities was zero during the six months ended June 30, 2025 and 2024.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was zero during the six months ended June 30, 2025 and 2024.

Critical Accounting Policies and Estimates

In our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, our most critical accounting policies and estimates upon which our financial status depends were identified as those relating to research and development costs; goodwill; 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 six months ended June 30, 2025.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board 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, 2024 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 Rule 12b-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 June 30, 2025. Based on the evaluation of our disclosure controls and procedures as of June 30, 2025, 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, 2024, as filed with the Securities and Exchange Commission ("SEC") on February 25, 2025. 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, 2024, 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 June 30, 2025, we had an accumulated deficit of approximately \$402.4 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—Complete Response Letter" for more information. While we have had multiple interactions with the FDA following receipt of the CRL for our NDA in February 2024 and the FDA has confirmed the requirement for an additional confirmatory clinical trial to address the deficiencies cited in the CRL and resubmit the NDA, 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 June 30, 2025, we had cash, cash equivalents, and restricted cash of \$15.3 million. Given the cash, cash equivalents, and restricted cash balance as of June 30, 2025, along with the current projections of cash to be used for operations, we believe that our existing cash, cash equivalents, and restricted cash will not be sufficient to fund our operating expenses and capital requirements. However, management has the ability to mitigate this condition through cost reduction initiatives. Based on the implementation of these initiatives, we believe we will have sufficient liquidity to meet our obligations for at least twelve months from the date 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, including the confirmatory clinical trial required by the FDA for roluperidone. See the section titled “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations—Overview” for more information. The assumptions upon which we have based our estimates are routinely evaluated and may be subject to change. The actual amount of our expenditures will vary depending upon a number of factors, including, but not limited to, the design, timing and duration of future clinical trials, the progress of our research and development programs, the infrastructure to support a commercial enterprise, the cost of a commercial product launch, and the level of financial resources available.

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

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

- the cost of establishing sales, marketing and distribution capabilities for our product candidates for which we may receive regulatory approval and that we determine to commercialize ourselves or in collaboration with our partners.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to delay, limit or terminate the development or commercialization of one or more of our product candidates or other operations, including exploring strategic alternatives and partnership opportunities and potentially discontinue operations altogether. In addition, when we need to secure additional financing, such additional fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Any of these events could significantly harm our business, financial condition and prospects, and our stockholders could lose all or part of their investment in our company.

We may not be successful in identifying and implementing any potential strategic alternatives in a timely manner or at all. Even if we successfully consummate any strategic transaction, or series of transactions, from our strategic assessment, we may fail to realize all or any of the anticipated benefits of any such transaction, or we may be exposed to other operational and financial risks.

As a result of the requirement by the FDA for the confirmatory study of roluperidone and our current cash position, we are taking additional steps to reduce costs. We have also initiated a review process to explore strategic alternatives to maximize value for our stockholders. Despite management devoting significant efforts to identify and evaluate potential strategic alternatives, there can be no assurance that this strategic review process will result in us pursuing any transaction or that we will be able to successfully consummate any particular strategic transaction on attractive terms, on a timely basis, or at all. The process of evaluating our strategic alternatives may be costly, time-consuming and complex, and we may incur significant legal, accounting and advisory fees and other expenses, some of which may be incurred regardless of whether we successfully enter into a transaction. Any such expenses will decrease the remaining cash available for use in our business. In addition, speculation regarding any developments related to the review of strategic alternatives and perceived uncertainties related to the future of us could cause our stock price to fluctuate significantly.

Even if we successfully consummate any strategic transaction, or series of transactions, from our strategic assessment, our ability to realize the anticipated benefits of any potential strategic transaction will depend on a number of factors, including our ability to integrate with any future business partner, our ability to obtain value for portions of our business, if divested, and our ability to generate future stockholder value. The process may be disruptive to our business and the expected benefits may not be achieved within the anticipated time frame, or at all. The failure to meet the challenges involved and to realize the anticipated benefits of any potential transaction could adversely affect our business and financial condition.

There can be no assurance that a strategic transaction will be completed. If a strategic transaction is not completed, our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, with the passage of time, the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, if applicable, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up.

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

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

- the success of competitive products or technologies;
- adverse results or delays in our preclinical or clinical trials or those of our competitors;
- regulatory actions, including adverse regulatory decision, with respect to our products or our competitors' products;
- failure to successfully develop or commercialize any of our product candidates;
- the perception of limited market sizes or pricing for any of our product candidates;

- the results of our efforts to in-license or acquire additional product candidates or products;
- failure to maintain our existing strategic collaborations or enter into new collaborations;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts, or any inability to obtain additional funding;
- sales of our common stock by us, our insiders or our other stockholders;
- changes in laws or regulations applicable to our products, including changes in the structure of healthcare payment systems, including coverage and reimbursement;
- significant lawsuits, including stockholder litigation and litigation filed by us or filed against us pertaining to patent infringement or other violations of intellectual property rights;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

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

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

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

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

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

On March 17, 2025, we were formally notified that the Nasdaq Hearings Panel (the “Panel”) of the Nasdaq Stock Market LLC (“Nasdaq”) determined that we regained compliance with Nasdaq Listing Rule 5550(b)(3) (the “Net Income Rule”), which requires listed companies to maintain a minimum of \$500,000 of net income from continuing operations. Pursuant to Nasdaq Listing Rule 5815(d)(4)(A), we will be subject to a discretionary panel monitor for a period of one year from March 17, 2025. If, within that one-year monitoring period, we fail to maintain compliance with any Nasdaq continued listing requirement, the Listing Qualifications Staff (the “Staff”) of Nasdaq will issue a Delist Determination Letter, and we will have an opportunity to request a new hearing with the initial Panel or a newly convened Hearings Panel if the initial Panel is unavailable. Notwithstanding Nasdaq Listing Rule 5810(c)(2), we will not be permitted to provide the Staff with a plan of compliance with respect to any deficiency that arises during the one-year monitoring period, and the Staff will not be permitted to grant additional time for us to regain compliance with respect to any deficiency.

As previously disclosed, on April 10, 2024, we received written notice from Nasdaq notifying us that for the last 31 consecutive business days, our minimum Market Value of Listed Securities was below the minimum of \$35 million required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(b)(2). In addition, on January 10, 2025, we received a notice from Nasdaq indicating that following our hearing before the Panel on December 10, 2024, the Panel granted our request for continued listing on Nasdaq through March 31, 2025, subject to our compliance with Nasdaq Listing Rule 5550(b)(1) (the “Equity Rule”), among other conditions. While we had initially planned to regain compliance with the Equity Rule, upon review of our Annual Report on Form 10-K for the year ended December 31, 2024, the Staff confirmed that we demonstrated compliance with the Net Income Rule. Accordingly, the Panel determined to continue the listing of our securities on Nasdaq and closed the matter.

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 elsewhere in this Quarterly Report on Form 10-Q.

There can be no assurance that we will be able to maintain compliance with Nasdaq’s listing standards or that we will be able to continue our listing on Nasdaq. 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.

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

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

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, “ACA”) broadened access to health insurance, reduced or constrained the growth of healthcare spending, enhanced remedies against healthcare fraud and abuse, add imposed new transparency requirements for healthcare and health insurance industries, imposed new taxes and fees on pharmaceutical manufacturers and imposed additional health policy reforms. Since the ACA’s enactment, there have been executive, judicial and Congressional challenges and amendments to certain aspects of the ACA. For example, the IRA, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and additional healthcare reform measures of the second Trump administration will impact the ACA and our business. For example, on July 4, 2025, the annual reconciliation bill, the “One Big Beautiful Bill Act” (“OBBBA”), was signed into law which is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program.

OBBBA also narrows access to ACA marketplace exchange enrollment and declines to extend the ACA enhanced advanced premium tax credits, set to expire in 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance.

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

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

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

In December 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and began to apply on January 12, 2025, through a phased implementation. The Regulation is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and provides the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation permits EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for drug candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected. In light of the fact that the United Kingdom has left the EU, Regulation No 2021/2282 on HTA does not apply in the United Kingdom. However, the UK Medicines and Healthcare products Regulation Agency is working with UK HTA bodies and other national organizations, such as the Scottish Medicines Consortium, the National Institute for Health and Care Excellence, and the All-Wales Medicines Strategy Group, to introduce new pathways supporting innovative approaches to the safe, timely and efficient development of medicinal products, including relaunching the Innovative Licensing and Access Pathway with more predictable timelines and closer involvement of the National Health Service.

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

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

The tax regimes we are subject to or operate under, including income and non-income taxes, are unsettled and may be subject to significant change. Changes in tax laws, regulations, or rulings, or changes in interpretations of existing laws and regulations, could materially affect our financial position and results of operations. For example, legislation referred to as the One Big Beautiful Bill Act (the “OBBBA”) enacted in 2025, the Inflation Reduction Act enacted in 2022 (the “IRA”), the Coronavirus Aid, Relief, and Economic Security Act enacted in 2020, and the Tax Cuts and Jobs Act enacted in 2017 (the “Tax Act”) made many significant changes to the U.S. tax laws. For example, for tax years beginning after December 31, 2024, the OBBBA restores the tax deductibility of domestic research and development expenses in the year incurred, which expenses had been required under the Tax Act to be

capitalized and subsequently amortized over five years. The OBBBA did not change the tax treatment of expenses incurred in research and development activities conducted outside the United States, which expenses continue to be required to be capitalized and amortized over 15 years. The IRA includes provisions that impact the U.S. federal income taxation of corporations, including imposing a minimum tax on the book income of certain large corporations and an excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. We are evaluating the potential impacts changes under the OBBBA may have on our business. Future guidance from the U.S. Internal Revenue Service and other tax authorities with respect to any such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation or sunset in future years.

In addition, our tax position could be adversely impacted by changes in tax laws applicable to corporate multinationals which have been proposed, and, in some cases, enacted by various countries, and by other international tax developments including the implementation of the base erosion and profit shifting project led by the Organization for Economic Cooperation and Development and certain tax initiatives proposed by the European Commission. These changes and developments include changes to the existing framework in respect of income taxes, as well as the imposition of new types of non-income taxes (such as taxes based on a percentage of revenue) which could apply to our business. These types of changes to the taxation of our activities could increase our worldwide effective tax rate, increase the amount of taxes imposed on our business and our compliance costs, and harm our financial position. Such changes may also apply retroactively to our historical operations and result in taxes greater than the amounts estimated and recorded in our financial statements.

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.

<u>Exhibit Number</u>	<u>Description</u>
3.1	<u>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).</u>
3.2	<u>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).</u>
3.3	<u>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 Registrant's current report on Form 8-K (File No. 001-36517) filed with the SEC on June 17, 2022).</u>
31.1*	<u>Certification of Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002.</u>
31.2*	<u>Certification of Chief Financial Officer (Principal Financial Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002.</u>
32.1 ⁺	<u>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.</u>
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Document
104*	Cover Page 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: August 14, 2025

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: August 14, 2025

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

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: August 14, 2025

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

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 June 30, 2025, 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.

Date: August 14, 2025

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

Date: August 14, 2025

/s/ Frederick Ahlholm
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.
