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

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

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

The number of shares of Registrant's Common Stock, $0.0001 par value per share, outstanding as of October 31, 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)

	September 30, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 12,286,646	$ 21,362,008
Restricted cash	100,000	100,000
Prepaid expenses and other current assets	633,533	806,895
Total current assets	13,020,179	22,268,903
Equipment, net	1,360	5,442
Goodwill	14,869,399	14,869,399
Deferred offering costs	201,114	—
Total assets	**$ 28,092,052**	**$ 37,143,744**
Liabilities and Stockholders' Deficit		
Current liabilities		
Accounts payable	$ 944,492	$ 1,607,844
Accrued expenses and other current liabilities	1,727,830	1,229,000
Total current liabilities	2,672,322	2,836,844
Liability related to the sale of future royalties	60,000,000	60,000,000
Total liabilities	62,672,322	62,836,844
Commitments and contingencies (Note 8)		
Stockholders' deficit		
Preferred stock; $0.0001 par value; 100,000,000 shares authorized; none issued or outstanding as of September 30, 2025 and December 31, 2024	—	—
Common stock; $0.0001 par value; 125,000,000 shares authorized; 6,993,406 shares issued and outstanding as of September 30, 2025 and December 31, 2024	699	699
Additional paid-in capital	370,551,108	369,682,764
Accumulated deficit	(405,132,077)	(395,376,563)
Total stockholders' deficit	(34,580,270)	(25,693,100)
Total liabilities and stockholders' deficit	**$ 28,092,052**	**$ 37,143,744**

See accompanying notes to condensed consolidated financial statements.

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Expenses				
Research and development	$ 925,377	$ 1,887,913	$ 3,585,856	$ 9,915,699
General and administrative	1,918,971	2,478,787	6,535,525	7,410,532
Total expenses	2,844,348	4,366,700	10,121,381	17,326,231
Loss from operations	(2,844,348)	(4,366,700)	(10,121,381)	(17,326,231)
Foreign exchange losses	(6,246)	(13,108)	(35,732)	(12,309)
Investment income	106,640	313,967	401,599	1,032,630
Non-cash interest expense for the sale of future royalties	—	—	—	(4,562,223)
Other income	—	26,579,046	—	26,579,046
Net (loss) income	$ (2,743,954)	$ 22,513,205	$ (9,755,514)	$ 5,710,913
Net (loss) income per share, basic	$ (0.36)	$ 2.97	$ (1.29)	$ 0.75
Weighted average shares outstanding, basic	7,568,981	7,568,981	7,568,981	7,568,981
Net (loss) income per share, diluted	$ (0.36)	$ 2.97	$ (1.29)	$ 0.75
Weighted average shares outstanding, diluted	7,568,981	7,568,981	7,568,981	7,578,267

See accompanying notes to condensed consolidated financial statements.

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Stockholders' Deficit
(Unaudited)

	Common Stock		Additional	Accumulated	
	Shares	Amount	Paid-In Capital	Deficit	Total
Balances at January 1, 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)**
Stock-based compensation	—	—	307,708	—	307,708
Net income	—	—	—	22,513,205	22,513,205
Balances at September 30, 2024	**6,993,406**	**$ 699**	**$ 369,433,114**	**$ (391,104,515)**	**$ (21,670,702)**
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)**
Stock-based compensation	—	—	$ 272,897	—	272,897
Net loss	—	—	—	$ (2,743,954)	(2,743,954)
Balances at September 30, 2025	**6,993,406**	**$ 699**	**$ 370,551,108**	**$ (405,132,077)**	**$ (34,580,270)**

See accompanying notes to condensed consolidated financial statements.

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,	
	2025	**2024**
Cash flows from operating activities:		
Net (loss) income	$ (9,755,514)	$ 5,710,913
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation and amortization	4,082	4,082
Amortization of capitalized software	—	17,027
Stock-based compensation expense	868,344	1,075,875
Non-cash interest expense associated with the sale of future royalties	—	4,562,223
Remeasurement of liability related to sale of future royalties	—	(26,579,046)
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	173,362	(317,480)
Accounts payable	(783,784)	(1,252,128)
Accrued expenses and other current liabilities	463,314	2,394,751
Net cash used in operating activities	(9,030,196)	(14,383,783)
Cash flows from investing activities:		
Net cash provided by investing activities	—	—
Cash flows from financing activities:		
Costs paid in connection with private placements	(45,166)	—
Net cash (used in) provided by financing activities	(45,166)	—
Net decrease in cash, cash equivalents and restricted cash	(9,075,362)	(14,383,783)
Cash, cash equivalents and restricted cash		
Beginning of period	21,462,008	41,012,575
End of period	$ 12,386,646	$ 26,628,792
Reconciliation of the Condensed Consolidated Statements of Cash Flows to the Condensed Consolidated Balance Sheets		
Cash and cash equivalents	$ 12,286,646	$ 26,528,792
Restricted cash	100,000	100,000
Total cash, cash equivalents and restricted cash	$ 12,386,646	$ 26,628,792
Supplemental disclosure of non-cash financing activities		
Deferred offering costs included in accounts payable or in accrued expenses and other current liabilities	$ 155,948	$ —

See accompanying notes to condensed consolidated financial statements.

NOTE 1 — NATURE OF OPERATIONS AND LIQUIDITY

Nature of Operations

Minerva Neurosciences, Inc. ("Minerva" or the "Company") is a clinical-stage biopharmaceutical company focused on the development and commercialization of proprietary product candidates to treat patients suffering from central nervous system ("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 clinical trials of roluperidone (C03 and C07), this confirmatory trial will include patients diagnosed with schizophrenia who present with stable impairing negative symptoms and stable positive symptoms for the six months prior to entering the trial. The FDA has confirmed that roluperidone can be studied in monotherapy, as in the two previous clinical trials. The confirmatory Phase 3 trial will evaluate a 64 mg dose of roluperidone in a 1:1 randomized double-blind, placebo-controlled trial design. The two previous trials tested both 32 mg and 64 mg doses of roluperidone.

The FDA also confirmed that the sole primary endpoint to assess efficacy would be the change from Baseline in PANSS Marder negative symptoms factor score ("NSFS") at 12 weeks of treatment with roluperidone compared to placebo. Minerva agreed with the FDA that best efforts will be made to secure 25-30% of patients from the U.S., subject to competitive recruitment. The FDA and Minerva have agreed that, to support a monotherapy indication, they will assess relapses of positive symptoms on an observational basis for at least 52 weeks in patients treated in monotherapy with roluperidone, placebo or antipsychotics. The FDA stated 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 with the efficacy primary endpoint at week 12.

The Company also 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. To the Company's knowledge, Janssen is currently recruiting patients under a Phase 3 trial with seltorexant.

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 September 30, 2025, the Company had an accumulated deficit of approximately $405.1 million and net cash used in operating activities was approximately $9.0 million during the nine months ended September 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 convertible preferred stock, common stock, warrants, loans, convertible promissory notes, collaboration agreements and royalty sales.

As of September 30, 2025, the Company had cash, cash equivalents, and restricted cash of $12.4 million. The Company believes that this amount, together with the net proceeds from the private placement that was closed on October 23, 2025, as described below, will be sufficient to meet the Company's operating commitments for at least twelve months from the date that its interim condensed financial statements are issued. On October 23, 2025, the Company completed a private placement of preferred stock and warrants for up to $200 million in gross proceeds, before deducting placement agent fees and other expenses, through a private placement that included an initial upfront funding of $80 million in gross proceeds in exchange for 80,000 shares of the Company's Series A

convertible preferred stock, and up to an additional $80 million in gross proceeds if all 80,000 Tranche A warrants are exercised, subject to the terms and conditions specified therein. Additional proceeds of $40 million may be received in connection with cash exercise of all 40,000 Tranche B warrants upon the achievement of a milestone event.

The net proceeds of this private placement will be used to finance the confirmatory Phase 3 trial of roluperidone, preparation and resubmission of its NDA, the readiness of the commercial launch of roluperidone in the U.S., if approved, and for working capital and general corporate purposes.

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.

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 September 30, 2025, the results of operations for the three and nine months ended September 30, 2025 and 2024 and cash flows for the nine months ended September 30, 2025 and 2024. The results of operations for the three and nine months ended September 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 September 30, 2025 and December 31, 2024.

Deferred offering costs

Deferred offering costs include certain legal, accounting and other costs directly attributable to the Company's private placement of preferred stock and warrants, which closed on October 23, 2025. These amounts will be offset against the proceeds of the placement.

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.

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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Expenses				
Research and development staff related expenses [1]	$ 275,886	$ 432,373	$ 1,189,274	$ 1,868,212
Research and development drug product material expenses and associated costs [2]	(6,400)	445,536	49,258	2,983,297
Research and development stock compensation expenses (non-cash)	74,376	84,776	274,206	361,269
General and administrative staff related expenses [1]	905,684	857,216	2,762,841	2,575,492
General and administrative stock compensation expenses (non-cash)	198,521	222,932	594,139	714,605
Total	1,448,067	2,042,833	4,869,718	8,502,875
Other segment expense, net [3]	1,396,281	2,323,867	5,251,663	8,823,356
Total expenses	2,844,348	4,366,700	10,121,381	17,326,231
Loss from operations	(2,844,348)	(4,366,700)	(10,121,381)	(17,326,231)
Reconciling items:				
Foreign exchange losses	(6,246)	(13,108)	(35,732)	(12,309)
Investment income	106,640	313,967	401,599	1,032,630
Non-cash interest expense for the sale of future royalties	—	—	—	(4,562,223)
Other income	—	26,579,046	—	26,579,046
Net (loss) income	$ (2,743,954)	$ 22,513,205	$ (9,755,514)	$ 5,710,913

(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:

	September 30, 2025	December 31, 2024
Research and development costs and other accrued expenses	$ 322,129	$ 351,782
Accrued bonus	1,044,268	363,181
Professional fees	197,087	514,037
Vacation pay	164,346	—
Accrued expenses and other current liabilities	$ 1,727,830	$ 1,229,000

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

Basic (loss) income per share is calculated by dividing the net (loss) income by the weighted average number of shares of common stock outstanding. Diluted (loss) income per share is computed by dividing the net (loss) income by the weighted average number of shares of common stock outstanding, plus potential outstanding common stock for the period. Potential outstanding common stock includes stock options, 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) income per share as of September 30, 2025.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Net (loss) income	$ (2,743,954)	$ 22,513,205	$ (9,755,514)	$ 5,710,913
Weighted average shares of common stock outstanding - basic	7,568,981	7,568,981	7,568,981	7,568,981
Dilutive effect	—	—	—	9,286
Weighted average shares of common stock outstanding - diluted	7,568,981	7,568,981	7,568,981	7,578,267
Net (loss) income per ordinary share:				
Basic	$ (0.36)	$ 2.97	$ (1.29)	$ 0.75
Diluted	$ (0.36)	$ 2.97	$ (1.29)	$ 0.75

The following securities outstanding at September 30, 2025 and 2024 have been excluded from the calculation of weighted average shares outstanding as their effect on the calculation of (loss) income per share is antidilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Common stock options	1,439,806	1,060,109	1,439,806	1,010,377
Performance-based restricted stock units	217,495	228,209	217,495	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 (MDD3003) that has an estimated study completion date in November 2027, which is significantly different from the assumption the Company used in its original estimates. In summary, there are four trials in the current Phase 3 program. Study MDD3001, which evaluated the efficacy and safety of seltorexant as an adjunctive treatment to baseline antidepressants in adult and elderly patients with MDD with insomnia symptoms, met all primary and secondary endpoints. MDD3002 was stopped based on the interim analysis results as recommended by the Independent Data Monitoring Committee. Janssen reported on September 22, 2025 that the MDD3005 study, in which seltorexant was evaluated against quetiapine, did not show statistical significance on the primary endpoint. MDD3003 is a study of adjunctive treatment with seltorexant in adult and elderly participants with MDD and insomnia symptoms and is currently recruiting.

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 nine months ended September 30, 2025, no shares of the Company's common stock were issued or sold under the Sales Agreement. The Company's Registration Statement on Form S-3 (File No. 333-267424) expired on September 23, 2025, and therefore no sales can be made under the Sales Agreement until such time as the Company files a new Registration Statement on Form S-3. Based on the public float of the Company's common stock as of the date of the filing of the Company's Annual Report on Form 10-K for the year ended December 31, 2024, the Company is currently subject to General Instruction I.B.6 of Form S-3 and therefore may not sell more than one-third of the market value of its common stock held by non-affiliates until the Company's public float exceeds $75.0 million.

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 September 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 nine months ended September 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		
Cancelled/Forfeited	(43,366)	$ 3.68		
Outstanding September 30, 2025	1,439,806	$ 8.39	7.5	$ —
Exercisable September 30, 2025	756,743	$ 12.66	6.6	$ —
Available for future grant	90,503			

The weighted average grant-date fair value of stock options outstanding on September 30, 2025 was $6.20 per share. Total unrecognized compensation costs related to non-vested stock options at September 30, 2025 were approximately $1.8 million and are expected to be recognized within future operating results over a weighted-average period of 2.0 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 nine months ended September 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 September 30, 2025, 228,213 PRSUs have vested, 30,932 have been cancelled, and 217,495 remain outstanding.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Research and development	$ 74,376	$ 84,776	$ 274,205	$ 361,270
General and administrative	198,521	222,932	594,139	714,605
Total	$ 272,897	$ 307,708	$ 868,344	$ 1,075,875

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 office space located at 1500 District Avenue, Burlington, MA 01803. In September 2025, the Company amended its month-to-month lease agreement to reduce the rentable office space, effective October 1, 2025, with a revised monthly payment of $1,146. 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 EVENT

On October 21, 2025, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with certain accredited investors, pursuant to which the Company agreed to issue and sell, in a private placement (the "Private Placement"), (i) 80,000 shares of Series A Convertible Preferred Stock, par value $0.0001 per share ("Series A Preferred Stock"), at a purchase price of $1,000 per share, (ii) tranche A warrants (the "Preferred Tranche A Warrants") to acquire shares of Series A Preferred Stock and (iii) tranche B warrants (the "Preferred Tranche B Warrants," together with the Preferred Tranche A Warrants, the "Preferred Warrants") to acquire shares of Series A Preferred Stock for an aggregate offering price of up to $200 million. The closing of the Private Placement took place on October 23, 2025 (the "Closing Date").

Pursuant to the Certificate of Designation of Preferences, Rights and Limitations of the Series A Convertible Voting Preferred Stock (the "Certificate of Designation"), each share of Series A Preferred Stock is, subject to the stockholder approval and certain beneficial ownership conversion limitations, automatically convertible into shares of common stock, par value $0.0001 per share, of the Company.

Each Preferred Tranche A Warrant has an exercise price of $1,000 and may only be exercised for cash. The Preferred Tranche A Warrants are immediately exercisable for an aggregate of 80,000 shares of Series A Preferred Stock for an aggregate cash exercise price of $80 million until the tenth day following the date of the Company's public announcement that it has achieved, on a statistically significant basis, the primary endpoint of its Phase 3 confirmatory trial of roluperidone in schizophrenia at the 12-week timepoint (the "Milestone Event").

Each Preferred Tranche B Warrant has an exercise price of $1,000 and may be exercised by a cashless exercise. The Preferred Tranche B Warrants are exercisable for an aggregate of 40,000 shares of Series A Preferred Stock for an aggregate cash exercise price of $40 million commencing on the earlier of (i) the Company's public announcement of the Milestone Event and (ii) the three year anniversary of the Closing Date. The Preferred Tranche B Warrants will expire on the four (4)-year anniversary of the Closing Date.

The Preferred Warrants are subject to forfeiture in the event the applicable investor engages in any short sales involving the Company's securities during the 48-months period following the Closing Date. In addition, the Tranche B Warrant Shares are subject to reduction if the applicable investor sells or transfers any shares of Series A Preferred Stock or shares of its common stock received upon conversion of the Series A Preferred Stock, except to affiliates for no consideration.

Subject to the terms and limitations contained in the Certificate of Designation, the Series A Preferred Stock issued in the Private Placement will not become convertible until the Company's stockholders approve the issuance of all common stock issuable upon conversion of the Series A Preferred Stock and the Preferred Warrants Shares (the "Stockholder Approval"). On the first (1st) trading day following the announcement of the Stockholder Approval, each share of Series A Preferred Stock shall automatically convert into the number of shares of common stock, at the conversion price of $2.11 per share, rounded down to the nearest whole share, subject to the terms and limitations contained in the Certificate of Designation, including that shares of Series A Preferred Stock shall not be convertible if the conversion would result in a holder beneficially owning more than 9.99% of the Company's outstanding shares of common stock as of the applicable conversion date.

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 ("SEC") 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. We are currently developing roluperidone for the treatment of negative symptoms in patients diagnosed with schizophrenia. In addition, we previously co-developed seltorexant with Janssen Pharmaceutica NV ("Janssen"), a subsidiary of Johnson & Johnson, for the treatment of insomnia disorder and adjunctive treatment of Major Depressive Disorder ("MDD"). As a result of our collaboration with Janssen, 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. To our knowledge, Janssen is currently recruiting patients under a Phase 3 trial with seltorexant.

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 clinical trials of roluperidone (C03 and C07), the confirmatory trial will include patients diagnosed with schizophrenia who present with stable impairing negative symptoms and stable positive 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 sole primary endpoint to assess efficacy 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 with the efficacy primary endpoint at week 12.

We have not received any regulatory approvals to commercialize any of our product candidates, and we have not generated any revenue from the sales or license of our product candidates. We routinely evaluate the status of our drug development programs as well as potential strategic options. We have incurred significant operating losses since inception and expect to continue to incur net losses and negative cash flows from operating activities for the foreseeable future. As of September 30, 2025 and December 31, 2024, we had an accumulated deficit of $405.1 million and $395.4 million, respectively. For the nine months ended September 30, 2025 and 2024, we recorded net loss of $9.8 million and a net income of $5.7 million, respectively. We expect our clinical and administrative costs will increase as we begin to incur clinical trial costs and hire additional support staff to support the Phase 3 trial of roluperidone.

Recent Developments

On October 21, 2025, we entered into a securities purchase agreement (the "Securities Purchase Agreement") with certain accredited investors, pursuant to which we agreed to issue and sell, in a private placement (the "Private Placement"), (i) 80,000 shares of Series A Convertible Preferred Stock, par value $0.0001 per share ("Series A Preferred Stock"), at a purchase price of $1,000 per share, (ii) tranche A warrants (the "Preferred Tranche A Warrants") to acquire shares of Series A Preferred Stock (the "Tranche A Warrant Shares") and (iii) tranche B warrants (the "Preferred Tranche B Warrants," together with the Preferred Tranche A Warrants, the "Preferred Warrants") to acquire shares of Series A Preferred Stock for an aggregate offering price of up to $200 million. The closing of the Private Placement took place on October 23, 2025.

The gross proceeds of the Private Placement are estimated to be up to approximately $200 million, before deducting fees paid to the placement agent of the Private Placement and other estimated offering expenses payable by us, including initial upfront gross proceeds of $80 million in exchange for shares of the Series A Preferred Stock, up to an additional $80 million in gross proceeds if all Preferred Tranche A Warrants are exercised, subject to the terms and conditions specified therein, and up to an additional $40 million in gross proceeds if all Preferred Tranche B Warrants are exercised by cash payment upon the achievement of certain milestone event.

This private placement followed our announcement in August 2025 of our alignment with the FDA on the design of a confirmatory Phase 3 trial of roluperidone. We expect the net proceeds of this private placement will be sufficient to fund the confirmatory Phase 3 trial of roluperidone and our resubmission of our NDA, to prepare for a potential commercial launch of roluperidone in the U.S., if approved, and for working capital and general corporate purposes.

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

Foreign exchange losses are comprised primarily of 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 (loss) or gain.

Investment Income

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

Non-Cash Interest Expense for the Sale of Future Royalties

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

Other Income

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

Results of Operations

Comparison of Three Months Ended September 30, 2025 versus September 30, 2024

Research and Development Expenses

Research and development expenses were $0.9 million and $1.9 million for the three months ended September 30, 2025 and 2024, respectively, a decrease of approximately $1.0 million. The decrease in research and development expenses was primarily due to lower costs associated with our drug substance validation campaign, consultant fees, and lower compensation expenses. Non-cash stock compensation costs included in research and development expenses were $0.1 million for both the three months ended September 30, 2025 and 2024.

General and Administrative Expenses

General and administrative expenses were $1.9 million and $2.5 million for the three months ended September 30, 2025 and 2024, respectively, a decrease of approximately $0.6 million. The decrease in general and administrative expenses was primarily due to lower professional service fees and insurance costs. Non-cash stock compensation costs included in general and administrative expenses were $0.2 million for both the three months ended September 30, 2025 and 2024.

Foreign Exchange Losses

Foreign exchange losses were $6 thousand and $13 thousand for the three months ended September 30, 2025 and 2024, respectively, a decrease of $7 thousand, primarily due to currency movements.

Investment Income

Investment income was $107 thousand and $314 thousand for the three months ended September 30, 2025 and 2024, respectively, a decrease of approximately $207 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 for both the three months ended September 30, 2025 and 2024.

Other Income

Other income was zero and $26.6 million for the three months ended September 30, 2025 and 2024, respectively, a decrease of $26.6 million, due to recognizing other income in the third quarter of 2024 as a result of the adjustment to the carrying amount of the liability related to the sale of future royalties.

Comparison of Nine Months Ended September 30,2025 versus September 30, 2024

Research and Development Expenses

Research and development expenses were $3.6 million and $9.9 million for the nine months ended September 30, 2025 and 2024, respectively, a decrease of approximately $6.3 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 $0.3 million and $0.4 million for the nine months ended September 30, 2025 and 2024, respectively.

General and Administrative Expenses

General and administrative expenses were $6.5 million and $7.4 million for the nine months ended September 30, 2025 and 2024, respectively, a decrease of approximately $0.9 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 $0.6 million and $0.7 million for the nine months ended September 30, 2025 and 2024, respectively.

Foreign Exchange Losses

Foreign exchange losses were $36 thousand and $12 thousand for the nine months ended September 30, 2025 and 2024, respectively, an increase of $24 thousand, primarily due to currency movements.

Investment Income

Investment income was $0.4 million and $1.0 million for the nine months ended September 30, 2025 and 2024, respectively, a decrease of approximately $0.6 million, primarily due to cash and cash equivalents balances and interest rates.

Non-cash interest expense for the sale of future royalties

Non-cash interest expense for the sale of future royalties was zero and $4.6 million for the nine months ended September 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.

Other Income

Other income was zero and $26.6 million for the nine months ended September 30, 2025 and 2024, respectively, a decrease of $26.6 million, due to recognizing other income in the third quarter of 2024 as a result of the adjustment to the carrying amount of the liability related to the sale of future royalties.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2025, we had an accumulated deficit of approximately $405.1 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 September 30, 2025, we had cash, cash equivalents, and restricted cash of $12.4 million. We believe that this amount, together with the net proceeds from the Private Placement that was closed on October 23, 2025, will be sufficient to meet our operating commitments 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.

Private Placement

On October 21, 2025, we entered into the Securities Purchase Agreement with certain accredited investors, pursuant to which we agreed to issue and sell, in the Private Placement, (i) 80,000 shares of Series A Convertible Preferred Stock, at a purchase price of $1,000 per share, (ii) Preferred Tranche A Warrants to acquire shares of Series A Preferred Stock and (iii) Preferred Tranche B Warrants to acquire shares of Series A Preferred Stock for an aggregate offering price of up to $200 million. The closing of the Private Placement took place on October 23, 2025 (the "Closing Date").

Pursuant to the Certificate of Designation of Preferences, Rights and Limitations of the Series A Convertible Voting Preferred Stock (the "Certificate of Designation"), each share of Series A Preferred Stock is, subject to the stockholder approval and certain beneficial ownership conversion limitations, automatically convertible into shares of common stock, par value $0.0001 per share, of the Company.

Each Preferred Tranche A Warrant has an exercise price of $1,000 and may only be exercised for cash. The Preferred Tranche A Warrants are immediately exercisable for an aggregate of 80,000 shares of Series A Preferred Stock for an aggregate cash exercise price of $80 million until the tenth day following the date of our public announcement that we have achieved, on a statistically significant basis, the primary endpoint of our Phase 3 confirmatory trial of roluperidone in schizophrenia at the 12-week timepoint (the "Milestone Event").

Each Preferred Tranche B Warrant has an exercise price of $1,000 and may be exercised by a cashless exercise. The Preferred Tranche B Warrants are exercisable for an aggregate of 40,000 shares of Series A Preferred Stock for an aggregate cash exercise price of $40 million commencing on the earlier of (i) our public announcement of the Milestone Event and (ii) the three year anniversary of the Closing Date. The Preferred Tranche B Warrants will expire on the four (4)-year anniversary of the Closing Date.

The Preferred Warrants are subject to forfeiture in the event the applicable investor engages in any short sales involving our securities during the 48-months period following the Closing Date. In addition, the Tranche B Warrant Shares are subject to reduction if the applicable investor sells or transfers any shares of Series A Preferred Stock or shares of our common stock received upon conversion of the Series A Preferred Stock, except to affiliates for no consideration.

Subject to the terms and limitations contained in the Certificate of Designation, the Series A Preferred Stock issued in the Private Placement will not become convertible until our stockholders approve the issuance of all common stock issuable upon conversion of the Series A Preferred Stock and the Preferred Warrants Shares (the "Stockholder Approval"). On the first (1st) trading day following the announcement of the Stockholder Approval, each share of Series A Preferred Stock shall automatically convert into the number of shares of common stock, at the conversion price of $2.11 per share, rounded down to the nearest whole share, subject to the terms and limitations contained in the Certificate of Designation, including that shares of Series A Preferred Stock shall not be convertible if the conversion would result in a holder beneficially owning more than 9.99% of outstanding shares of our common stock as of the applicable conversion date.

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 nine months ended September 30, 2025, no shares of our common stock were issued or sold under the Sales Agreement. Our Registration Statement on Form S-3 (File No. 333-267424) expired on September 23, 2025, and therefore no sales can be made under the Sales Agreement until such time as we file a new Registration Statement on Form S-3. Based on the public float of our common stock as of the date of the filing of the Annual Report on Form 10-K for the year ended December 31, 2024, we are currently subject to General Instruction I.B.6 of Form S-3 and therefore may not sell more than one-third of the market value of our common stock held by non-affiliates until our public float exceeds $75.0 million.

Seltorexant Royalties

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

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

Uses of Funds

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

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third party funding, commercialization, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. There can be no assurance that such additional funding, if available, can be obtained on terms acceptable to us, and our ability to raise additional capital may be adversely impacted by global economic conditions, geopolitical conflicts, such as the war in Ukraine and hostilities in the Middle East, and other factors. If we are unable to obtain additional financing, future operations would need to be scaled back or discontinued. We believe that our existing cash, cash equivalents, and restricted cash, together with the net proceeds from the Private Placement that was closed on October 23, 2025, will be sufficient to meet our cash commitments for at least the next 12 months after the date that the financial statements are issued. The timing of future capital requirements depends upon many factors including the size and timing of future clinical trials, the timing and scope of any strategic partnering activity and the progress of other research and development activities.

Cash Flows

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

	Nine Months Ended September 30,	
	2025	2024
	(dollars in millions)	
Net cash (used in) provided by:		
Operating activities	$ (9.0)	$ (14.4)
Investing activities	—	—
Financing activities	(0.1)	—
Net decrease in cash	$ (9.1)	$ (14.4)

Net Cash Used in Operating Activities

Net cash used in operating activities of approximately $9.0 million during the nine months ended September 30, 2025 was primarily due to our net loss of $9.8 million and a $0.8 million decrease in accounts payable, partially offset by stock-based compensation expense of $0.9 million, a $0.5 million increase in accrued expenses, and a $0.2 million decrease in prepaid expenses.

Net cash used in operating activities of approximately $14.4 million during the nine months ended September 30, 2024 was primarily due to our net income of $5.7 million, non-cash interest expense for the sale of future royalties of $4.6 million, a $2.4 million increase in accrued expenses and stock-based compensation expense of $1.1 million, offset by the adjustment to the carrying amount of the liability related to the sale of future royalties of $26.6 million, a $1.3 million decrease in accounts payable and a $0.3 million increase in prepaid expenses.

Net Cash Provided by Investing Activities

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

Net Cash (Used in) Provided by Financing Activities

Net cash used in financing activities of approximately $0.1 million during the nine months ended September 30, 2025 was primarily due to fees paid in connection with the private placement.

Net cash provided by financing activities was zero during the nine months ended September 30, 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 nine months ended September 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 Rule12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 4. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

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

Our management, with the participation of our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2025. Based on the evaluation of our disclosure controls and procedures as of September 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 September 30, 2025, we had an accumulated deficit of approximately $405.1 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. 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 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Clinical and Regulatory Updates —Roluperidone (MIN-101)—Complete Response Letter (CRL)" in our Annual Report on Form 10-K for the year ended December 31, 2024 for more information. While the FDA has confirmed the requirement for an additional confirmatory clinical trial to address the deficiencies cited in the CRL and resubmit the NDA, and we expect to use the net proceeds from our private placement that was closed on October 23, 2025 to fund such confirmatory Phase 3 trial and our resubmission of 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 September 30, 2025, we had cash, cash equivalents, and restricted cash of $12.4 million. We believe that this amount, together with the net proceeds from the private placement that was closed on October 23, 2025, will be sufficient to meet our operating commitments 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 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 to continue advancing the development, regulatory approval process and potential commercialization of roluperidone and other potential product candidates that we may develop in the future. Because the length of time and activities associated with successful development of product candidates are highly uncertain, we are unable to estimate with certainty the actual funds we will require for development and any approved marketing and commercialization activities. Additional capital may not be available in sufficient amounts, 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.

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 at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance.

Further, Congress and the current administration are 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 predicable timelines and closer involvement of the National Health Service.

Legislators, policymakers and healthcare insurance funds in the EU may continue to propose and implement cost-containing measures to keep healthcare costs down; particularly due to the financial strain that the COVID-19 pandemic has placed on national healthcare systems of the EU Member States. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of EU and other foreign

countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

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.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's registration statement on Form S-1/A (File No. 333-195169) filed with the SEC on June 10, 2014).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's quarterly report on Form 10-Q (File No. 001-36517) filed with the SEC on November 4, 2019).
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Minerva Neurosciences, Inc., effective June 17, 2022 (incorporated by reference to Exhibit 3.1 to the Registration's current report on Form 8-K (File No. 001-36517) filed with the SEC on June 17, 2022).
3.4	Certificate of Designation of Preferences, Rights and Limitations of the Series A Convertible Voting Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registration's current report on Form 8-K (File No. 001-36517) filed with the SEC on October 21, 2025).
4.1	Form of Preferred Tranche A Warrant (incorporated by reference to Exhibit 4.1 to the Registration's current report on Form 8-K (File No. 001-36517) filed with the SEC on October 21, 2025).
4.2	Form of Preferred Tranche B Warrant (incorporated by reference to Exhibit 4.2 to the Registration's current report on Form 8-K (File No. 001-36517) filed with the SEC on October 21, 2025).
10.1#	Form of Securities Purchase Agreement, dated October 21, 2025, by and among Minerva Neurosciences, Inc. and the purchasers named therein (incorporated by reference to Exhibit 10.1 to the Registration's current report on Form 8-K (File No. 001-36517) filed with the SEC on October 21, 2025).
10.2#	Form of Support Agreement (incorporated by reference to Exhibit 10.2 to the Registration's current report on Form 8-K (File No. 001-36517) filed with the SEC on October 21, 2025).
31.1*	Certification of Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer (Principal Financial Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
32.1+	Certification of Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer) pursuant to Section 906 of Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document – 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.
# Schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.
+ 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: November 5, 2025

EXHIBIT 31.1

CERTIFICATION

I, Remy Luthringer, certify that:

1. I have reviewed this Form 10-Q of Minerva Neurosciences, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: November 5, 2025

/s/ Remy Luthringer Ph.D.

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

EXHIBIT 31.2

CERTIFICATION

I, Frederick Ahlholm, certify that:

1. I have reviewed this Form 10-Q of Minerva Neurosciences, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: November 5, 2025

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

EXHIBIT 32.1

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

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

(1) The Company's Quarterly Report on Form 10-Q for the period ended September 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.

/s/ Remy Luthringer, Ph.D.

Date: November 5, 2025

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

/s/ Frederick Ahlholm

Date: November 5, 2025

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.