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, 2026

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 November 3, 2026, was 49,835,241.

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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, 2025 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, 2026	December 31, 2025
Assets		
Current assets		
Cash and cash equivalents	$ 20,216,241	$ 82,301,813
Marketable securities	56,728,533	—
Restricted cash	100,000	100,000
Prepaid expenses and other current assets	6,364,023	697,676
Total current assets	83,408,797	83,099,489
Goodwill	14,869,399	14,869,399
Total assets	**$ 98,278,196**	**$ 97,968,888**
Liabilities, Redeemable Preferred Stock and Stockholders' Deficit		
Current liabilities		
Accounts payable	$ 653,173	$ 639,707
Accrued expenses and other current liabilities	1,872,768	1,650,766
Total current liabilities	2,525,941	2,290,473
Warrant liability	121,534,829	171,464,575
Liability related to the sale of future royalties	60,000,000	60,000,000
Total liabilities	184,060,770	233,755,048
Commitments and contingencies (Note 9)		
Redeemable preferred stock		
Series A convertible preferred stock; $0.0001 par value; 200,000 shares authorized; liquidation preference of $0; 5,539 shares issued and outstanding as of September 30, 2026 and 3,296 shares issued and outstanding as of December 31, 2025	11,741,322	4,961,922
Stockholders' deficit		
Common stock; $0.0001 par value; 250,000,000 shares authorized; 49,835,241 shares issued and outstanding as of September 30, 2026 and 43,274,398 shares issued and outstanding as of December 31, 2025	4,984	4,327
Additional paid-in capital	598,462,398	548,047,331
Accumulated deficit	(695,991,278)	(688,799,740)
Total stockholders' deficit	(97,523,896)	(140,748,082)
Total liabilities, redeemable preferred stock and stockholders' deficit	**$ 98,278,196**	**$ 97,968,888**

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,	
	2026	2025	2026	2025
Expenses				
Research and development	$ 5,155,658	$ 925,377	$ 17,597,859	$ 3,585,856
General and administrative	4,278,019	1,918,971	19,149,529	6,535,525
Total expenses	9,433,677	2,844,348	36,747,388	10,121,381
Loss from operations	(9,433,677)	(2,844,348)	(36,747,388)	(10,121,381)
Foreign exchange losses	(8,630)	(6,246)	(24,785)	(35,732)
Investment income	587,041	106,640	1,786,234	401,599
Changes in fair value of the warrant liability	109,601,827	—	27,794,401	—
Net income (loss)	$ 100,746,561	$ (2,743,954)	$ (7,191,538)	$ (9,755,514)
Undistributed earnings attributable to participating preferred stock	(5,084,462)	—	—	—
Net income (loss) attributable to common stockholders	$ 95,662,099	$ (2,743,954)	$ (7,191,538)	$ (9,755,514)
Net income (loss) per share, basic	$ 1.94	$ (0.36)	$ (0.15)	$ (1.29)
Weighted average shares outstanding, basic	49,293,243	7,568,981	46,617,325	7,568,981
Net income (loss) per share, diluted	$ (0.19)	$ (0.36)	$ (0.45)	$ (1.29)
Weighted average shares outstanding, diluted	75,251,016	7,568,981	78,223,184	7,568,981

See accompanying notes to condensed consolidated financial statements.

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Redeemable Preferred Stock and Stockholders' Deficit
(Unaudited)

	Convertible Series A Preferred Stock		Common Stock				
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total
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)**
Balances at January 1, 2026	**3,296**	**$ 4,961,922**	**43,274,398**	**$ 4,327**	**$ 548,047,331**	**$ (688,799,740)**	**$ (140,748,082)**
Stock-based compensation	—	—	—	—	8,710,302	—	8,710,302
Exercise of tranche A warrants	—	—	567,600	57	3,428,247	—	3,428,304
Net loss	—	—	—	—	—	(125,404,384)	(125,404,384)
Balances at March 31, 2026	**3,296**	**$ 4,961,922**	**43,841,998**	**$ 4,384**	**$ 560,185,880**	**$ (814,204,124)**	**$ (254,013,860)**
Stock-based compensation	—	—	—	—	2,272,840	—	2,272,840
Issuance of Series A Preferred Stock upon exercise of tranche A warrants	9,400	27,753,512	—	—	—	—	—
Conversion of Series A Preferred Stock into common shares	(7,157)	(20,974,112)	3,385,261	339	20,973,773	—	20,974,112
Net income	—	—	—	—	—	17,466,285	17,466,285
Balances at June 30, 2026	**5,539**	**$ 11,741,322**	**47,227,259**	**$ 4,723**	**$ 583,432,493**	**$ (796,737,839)**	**$ (213,300,623)**
Stock-based compensation	—	—	—	—	3,208,562	—	3,208,562
Issuance of Series A Preferred Stock upon exercise of tranche A warrants	1,100	2,653,529	—	—	—	—	—
Conversion of Series A Preferred Stock into common shares	(1,100)	(2,653,529)	520,300	52	2,653,477	—	2,653,529
Issuance of common stock, net of issuance costs	—	—	2,087,682	209	9,167,866	—	9,168,075
Net income	—	—	—	—	—	100,746,561	100,746,561
Balances at September 30, 2026	**5,539**	**$ 11,741,322**	**49,835,241**	**$ 4,984**	**598,462,398**	**$ (695,991,278)**	**$ (97,523,896)**

See accompanying notes to condensed consolidated financial statements.

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,	
	2026	2025
Cash flows from operating activities:		
Net loss	$ (7,191,538)	$ (9,755,514)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization		4,082
Accretion of marketable securities	(934,575)	—
Stock-based compensation expense	14,191,704	868,344
Changes in fair value of the warrant liability	(27,794,401)	—
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	(5,604,866)	173,362
Accounts payable	190,228	(783,784)
Accrued expenses and other current liabilities	222,002	463,314
Net cash used in operating activities	(26,921,446)	(9,030,196)
Cash flows from investing activities:		
Purchase of marketable securities	(78,355,439)	—
Proceeds from the maturity and redemption of marketable securities	22,500,000	—
Net cash used in investing activities	(55,855,439)	—
Cash flows from financing activities:		
Proceeds from sales of common stock under at-the-market offering	9,999,997	—
Fees paid in connection with at-the-market offering	(813,489)	—
Proceeds from exercise of Tranche A warrants	11,700,000	—
Costs paid in connection with private placements	(195,195)	(45,166)
Net cash provided by (used in) financing activities	20,691,313	(45,166)
Net decrease in cash, cash equivalents and restricted cash	(62,085,572)	(9,075,362)
Cash, cash equivalents and restricted cash		
Beginning of period	82,401,813	21,462,008
End of period	$ 20,316,241	$ 12,386,646
Reconciliation of the Condensed Consolidated Statements of Cash Flows to the Condensed Consolidated Balance Sheets		
Cash and cash equivalents	$ 20,216,241	$ 12,286,646
Restricted cash	100,000	100,000
Total cash, cash equivalents and restricted cash	$ 20,316,241	$ 12,386,646
Supplemental disclosure of non-cash financing activities		
Deferred offering costs included in accounts payable or in accrued expenses and other current liabilities	$ —	$ 155,948
Unpaid at-the-market offering costs included in accounts payable	$ 18,433	$ —
Reduction of warrant liability upon exercise of warrants	$ 22,135,345	$ —
Issuance of common stock upon conversion of preferred stock	$ 27,055,945	$ —

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 certain proprietary product candidates to treat patients suffering from central nervous system ("CNS") diseases.

The Company's lead product candidate, roluperidone, is in development for the treatment of negative symptoms in patients diagnosed with schizophrenia. In August 2022, the Company 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. On February 26, 2024, the FDA issued a Complete Response Letter ("CRL") regarding the NDA for roluperidone. Subsequent to the CRL, the Company has had multiple interactions with the FDA to confirm the design of an additional Phase 3 confirmatory clinical trial to address the deficiencies cited in the CRL and resubmit the NDA.

In connection with the Company's interactions with the FDA subsequent to the CRL, the FDA 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. The FDA also 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 or antipsychotics. The Company informed the FDA that best efforts will be made to secure 25-30% of patients from the United States, subject to competitive recruitment.

The Company submitted the protocol for the new Phase 3 confirmatory trial, which the Company refers to as the C19 trial, to the FDA on December 3, 2025. Consistent with the previous Phase 2b (C03) and Phase 3 (C07) clinical trials of roluperidone, the C19 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 trial is designed to enroll 380 patients, randomized on a 1:1 basis to receive either placebo or a double-blinded single daily 64 mg dose of roluperidone.

The primary efficacy endpoint of the C19 trial is expected to be the change from baseline in the PANSS Marder negative symptoms factor score ("NSFS") at 12 weeks of treatment with roluperidone compared to placebo. Following the initial 12-week treatment period, patients are expected to enter a 52-week relapse assessment phase, during which patients will crossover to receive either a daily 64 mg dose of roluperidone or antipsychotics. On March 31, 2026, the Company announced that the first patient had been screened in the C19 trial. The Company expects topline efficacy results in the second half of 2027 and relapse assessment data in the second half of 2028.

In addition, the Company 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 the Company's collaboration with Janssen, it 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 cash payment and up to an additional $95 million in potential future milestone payments, subject to completion of Phase 3 trials by Janssen, and certain regulatory approvals and commercial milestones. To the Company's knowledge, Janssen is currently conducting two Phase 3 trials 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, 2026, the Company had an accumulated deficit of approximately $696.0 million and net cash used in operating activities was approximately $26.9 million during the nine months ended September 30, 2026.

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, 2026, the Company had cash, cash equivalents, marketable securities and restricted cash of $77.0 million. The Company believes that this amount 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.

During the three and nine months ended September 30, 2026, the Company issued and sold 2,087,682 shares of its common stock under the "at-the-market" offering program. The shares were sold at an average price of $4.79 per share for aggregate net proceeds to the Company of approximately $9.2 million, after deducting sales commissions and offering costs payable by the Company. See Note 6 for additional information regarding the Company's at-the-market offering program.

The net proceeds from the private placement and the at-the-market offering are being 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, 2026, the results of operations for the three and nine months ended September 30, 2026 and 2025 and cash flows for the nine months ended September 30, 2026 and 2025. The results of operations for the three and nine months ended September 30, 2026 are not necessarily indicative of the results to be expected for the full year. The consolidated balance sheet as of December 31, 2025 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, 2025 included in the Company's Annual Report on Form 10-K filed with the SEC on March 11, 2026.

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.

Marketable securities

Marketable securities consists of U.S. treasury securities, commercial paper, and corporate debt securities maturing in twelve months or less. Based on the Company's intentions regarding its marketable securities, all marketable securities are classified as held-to-maturity and are carried under the amortized cost approach. The Company's investments in U.S. treasury securities are classified as Level 1 within the fair value hierarchy and its investments in commercial paper and corporate debt securities are classified as Level 2. As of September 30, 2026, remaining final maturities of marketable securities ranged from October 2026 to September 2027, with a weighted average remaining maturity of approximately six months. The Company did not hold any marketable securities as of December 31, 2025. The following table provides the amortized cost basis, unrealized gains/(losses) and the fair value of investments in held-to-maturity securities as of September 30, 2026:

	September 30, 2026			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Marketable securities:				
U.S. Treasury securities	$ 9,479,607	$ —	$ (17,377)	$ 9,462,230
Commercial paper	$ 41,038,184	$ —	$ (92,104)	$ 40,946,080
Corporate debt securities	$ 6,210,742	$ —	$ (21,652)	$ 6,189,090
Marketable securities:	$ 56,728,533	$ —	$ (131,133)	$ 56,597,400

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, 2026 and December 31, 2025.

Deferred offering costs

Deferred offering costs consist of legal, accounting and other direct costs incurred in connection with the Company's registration statement on Form S-3 (File No. 333-294203), which was declared effective by the SEC on March 19, 2026, and the establishment of the Company's at-the-market offering program and related prospectus supplement filed on May 27, 2026. These costs were capitalized and offset against the proceeds from the offering under the registration statement.

Warrant liability

In conjunction with the issuance of Series A Preferred Stock and Preferred Tranche A and Tranche B Warrants, the Company established a warrant liability as of October 23, 2025, representing the fair value of the warrants issued, which was determined using a binomial valuation model. The Company accounts for these warrants as liabilities in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 480, Distinguishing Liabilities from Equity, due to the Fundamental Transaction provisions contained and defined in both the Tranche A and Tranche B Warrants, as such provisions do not distinguish between transactions that are within the Company's control and those that are not. Specifically, if, at any time while the warrants are

outstanding, the Company shall enter into or be party to a Fundamental Transaction, then the Company (or the successor entity) shall purchase all outstanding warrants from the holders by paying to the holders cash in an amount equal to the Black Scholes Value of the remaining unexercised portion of each warrant on the effective date of such Fundamental Transaction. As such, the warrant liability was initially measured at fair value and is remeasured at fair value at each reporting date, with changes in fair value recognized in earnings. The warrant liability is measured using Level 3 inputs within the fair value hierarchy. See Note 7 for additional information regarding the warrant liability and related valuation assumptions.

Fair value of financial instruments

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

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

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

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

The following tables present the carrying amount, fair value, and the applicable level within the fair value hierarchy for the Company's warrant liability as of September 30, 2026 and December 31, 2025, which is measured at fair value on a recurring basis:

	September 30, 2026			
	Total	Level 1	Level 2	Level 3
Liabilities:				
Warrant liability	$ 121,534,829	$ —	$ —	$ 121,534,829

	December 31, 2025			
	Total	Level 1	Level 2	Level 3
Liabilities:				
Warrant liability	$ 171,464,575	$ —	$ —	$ 171,464,575

The following tables present the carrying amounts and the applicable level within the fair value hierarchy for the Company's cash equivalents and marketable securities as of September 30, 2026 and December 31, 2025, which are not measured at fair value on a recurring basis. Cash equivalents consist of short-term, highly liquid investments with original maturities of 90 days or less, including money market accounts. Cash and cash equivalents are primarily held with major North American financial institutions. Deposits may exceed insured limits and are redeemable on demand, which reduces counterparty credit risk. Marketable securities consist of investments classified as held-to-maturity and are recorded at amortized cost:

	September 30, 2026			
	Total	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 4,469,751	$ 4,469,751	$ —	$ —
U.S. Treasury securities	$ 9,479,607	$ 9,479,607	$ —	$ —
Commercial paper	$ 41,038,184	$ —	$ 41,038,184	$ —
Corporate debt securities	$ 6,210,742	$ —	$ 6,210,742	$ —

	December 31, 2025			
	Total	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 79,327,870	$ 79,327,870	$ —	$ —

The Company's financial instruments consist of cash and cash equivalents, marketable securities, restricted cash, accounts payable, accrued expenses, warrant liability and liabilities related to the sale of future royalties. The carrying amounts of cash and cash equivalents, restricted cash, accounts payable, and accrued expenses approximate fair value because of their short-term nature. See Note 7 for additional information regarding the warrant liability and related valuation assumptions.

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 roluperidone. 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 roluperidone, however, roluperidone has not been approved for commercialization and the Company has not received any revenue in connection with the sale or license of roluperidone. 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,	
	2026	2025	2026	2025
Expenses				
Research and development staff related expenses [1]	$ 493,635	$ 275,886	$ 1,511,929	$ 1,189,274
External research and development costs [2]	3,330,446	570,623	12,874,056	2,114,531
Research and development stock compensation expenses (non-cash)	1,216,667	74,376	2,950,817	274,206
General and administrative staff related expenses [1]	851,893	905,684	3,430,660	2,762,841
General and administrative stock compensation expenses (non-cash)	1,991,895	198,521	11,240,887	594,139
Total	7,884,536	2,025,090	32,008,349	6,934,991
Other segment expense, net [3]	1,549,141	819,258	4,739,039	3,186,390
Total expenses	9,433,677	2,844,348	36,747,388	10,121,381
Loss from operations	(9,433,677)	(2,844,348)	(36,747,388)	(10,121,381)
Reconciling items:				
Foreign exchange losses	(8,630)	(6,246)	(24,785)	(35,732)
Investment income	587,041	106,640	1,786,234	401,599
Changes in fair value of the warrant liability	109,601,827	—	27,794,401	—
Net income (loss)	$ 100,746,561	$ (2,743,954)	$ (7,191,538)	$ (9,755,514)

(1) Staff related expenses consist of salary, bonus, accrued settlement payments, and fringe benefits.
(2) External research and development expenses primarily consist of the C19 trial costs and consultant fees in 2026 and consultant fees in 2025.
(3) Other segment expense, net primarily consists of insurance, consultant, audit, legal, board, facilities, travel, investor relations, and membership fees.

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.

Accounting pronouncements not yet adopted

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*. The standard requires public business entities to disclose detailed information about specific types of expenses that are relevant to certain line items on the income statement. This update is effective for us for annual periods beginning in our fiscal year ending December 31, 2027, and interim periods beginning in the first quarter of our fiscal year ending December 31, 2028. Early adoption is permitted. We are currently evaluating the impact that this update will have on our financial statement disclosures.

NOTE 3 — ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities consist of the following:

	September 30, 2026	December 31, 2025
Research and development costs and other accrued expenses	$ 420,647	$ 1,013,200
Professional fees	162,217	637,566
Accrued bonus	1,202,014	—
Vacation pay	87,890	—
Accrued expenses and other current liabilities	$ 1,872,768	$ 1,650,766

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

Basic income (loss) per share is calculated by dividing net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. The Company's Series A Preferred Stock is a participating security. Accordingly, for the three months ended September 30, 2026, in which the Company had net income attributable to common and participating stockholders, basic earnings per share was calculated using the two-class method. For the nine months ended September 30, 2026, the Company had net loss. Accordingly, all potential common shares were excluded from the calculation of basic earnings per share because they do not participate in losses. For the three and nine months ended September 30, 2025, the Company reported net losses and all potential common shares were anti-dilutive, and basic and diluted net loss per share were the same.

Diluted income (loss) per share is calculated by dividing net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period, adjusted for the effect of potentially dilutive securities. Potentially dilutive securities include common stock options, warrants, and Series A Preferred Stock, to the extent their inclusion is dilutive. Performance-based restricted stock units and performance related stock options are excluded from the calculation of diluted weighted average shares outstanding until the applicable performance conditions have been satisfied, based on the assumption that the end of the reporting period represents the end of the contingency period, if the effect is dilutive.

For the three and nine months ended September 30, 2026, diluted earnings per share was calculated using the if-converted method and treasury stock method for warrants. Incremental shares attributable to in-the-money warrants were included in diluted earnings per share. Out-of-the-money instruments and instruments for which the assumed proceeds exceeded the average market price of the Company's common stock during the period were excluded because their effect would have been anti-dilutive. Instruments whose inclusion would have been anti-dilutive to diluted net loss per share were also excluded.

Potentially dilutive securities were evaluated sequentially in accordance with ASC 260, *Earnings Per Share*. After including the dilutive effect of the Company's warrants, the assumed exercise of the Company's stock options under the treasury stock method would have reduced diluted earnings by increasing earnings per share (or reducing the loss per share). Accordingly, the stock options were considered anti-dilutive and were excluded from the calculation of diluted earnings (loss) per share.

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 income (loss) per share as of September 30, 2026 and 2025.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Net income (loss)	$ 100,746,561	$ (2,743,954)	$ (7,191,538)	$ (9,755,514)
Undistributed earnings attributable to participating preferred stock	(5,084,462)	—	—	—
Net income (loss) attributable to common stockholders - basic	$ 95,662,099	$ (2,743,954)	$ (7,191,538)	$ (9,755,514)
Adjustment for the change in fair value of the warrant liability	(109,601,827)	—	(27,794,401)	—
Net income (loss) attributable to common stockholders - diluted	$ (13,939,728)	$ (2,743,954)	$ (34,985,939)	$ (9,755,514)
Weighted average shares of common stock outstanding - basic	49,293,243	7,568,981	46,617,325	7,568,981
Effect of dilutive warrants [1]	25,957,773	—	31,605,859	—
Weighted average shares of common stock outstanding - diluted	75,251,016	7,568,981	78,223,184	7,568,981
Net income (loss) per share of common stock:				
Basic	$ 1.94	$ (0.36)	$ (0.15)	$ (1.29)
Diluted	$ (0.19)	$ (0.36)	$ (0.45)	$ (1.29)

(1) As of September 30, 2026, there were outstanding (i) Preferred Tranche A Warrants to purchase an aggregate of 68,300 shares of the Company's Series A Preferred Stock, which are convertible into 32,305,900 shares of its common stock and (ii) Preferred Tranche B Warrants to purchase an aggregate of 40,000 shares of the Company's Series A Preferred Stock, which are convertible into 18,920,000 shares of its common stock. Both the Tranche A Warrants and Tranche B Warrants are subject to the limitations on conversion set forth in the Certificate of Designation. See above in Note 4 for a description of the effect of dilutive warrants on the calculation of diluted earnings per share and Note 6 for additional information regarding the Company's Series A Preferred Stock and warrants.

The following securities outstanding at September 30, 2026 and 2025 have been excluded from the calculation of weighted average shares outstanding because their effect on the calculation of income (loss) per share is antidilutive. The determination of whether a security is antidilutive is made separately for each reporting period. Accordingly, the Series A Preferred Stock are included only in the nine-month period ended September 30, 2026, because they do not participate in losses and were antidilutive for that period:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Common stock options	13,435,264	1,439,806	13,435,264	1,439,806
Performance-based restricted stock units [2]	—	217,495	—	217,495
Series A Preferred Stock [3]	—	—	2,619,947	—

(2) All outstanding performance-based restricted stock units expired during August 2026.

(3) The dilutive effect of Series A Preferred Stock for the three months ended September 30, 2026 is included by allocating the undistributed earnings attributable to participating preferred stock in the basic earnings per share numerator. An aggregate of 5,539 shares of Series A Preferred Stock remain outstanding, which are convertible into an aggregate of 2,619,947 shares of common stock, subject to the limitations on conversion set forth in the Certificate of Designation. See Note 6 for additional information regarding the Company's Series A Preferred Stock. Shares of the Series A Preferred Stock are classified as temporary equity and excluded from the calculation of weighted average shares outstanding.

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%.

In September 2020, Janssen commenced two Phase 3 placebo-controlled studies, referred to as MDD3001 (NCT NCT04533529) and MDD3002 (NCT04532749), to evaluate the efficacy and safety of seltorexant as an adjunctive treatment to baseline antidepressants in adult and elderly patients with MDD with insomnia symptoms. In July 2022, Janssen announced that the MDD3002 study was stopped based on interim analysis results as recommended by the study's independent data monitoring committee. In May 2024, Janssen announced that the MDD3001 study met all primary and secondary endpoints.

In July 2024, Janssen commenced its MDD3003 study, a Phase 3 placebo-controlled study of adjunctive treatment with seltorexant in adult and elderly participants with MDD and insomnia symptoms. According to clinicaltrials.gov, the MDD3003 study is currently recruiting and has an estimated completion for the primary outcome measure in December 2026 and overall completion in December 2027.

In September 2025, Janssen reported that its MDD3005 study, a Phase 3 study in which seltorexant was evaluated against quetiapine as adjunctive treatment in adult and elderly participants with MDD and insomnia symptoms, did not show statistical significance on the primary endpoint.

In April 2026, Janssen commenced its MDD3011 study, a Phase 3 placebo-controlled study of monotherapy treatment with seltorexant in adult and elderly participants with MDD. MDD3011 study is currently recruiting and has an estimated completion for the primary outcome measure in August 2028 and overall completion in May 2029.

The Company regularly evaluates the assumptions supporting future royalty estimates. During the third quarter of 2024, the Company revised its estimates for the timing and amount of future royalty payments to be earned over the life of the Janssen Agreement, which is 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. 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 — REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

At-the-Market Equity Offering Program

On May 27, 2026, the Company entered into a Sales Agreement (the "Agreement") with Leerink Partners LLC (the "Agent") with respect to an "at-the-market" offering program, pursuant to which the Company may issue and sell, from time to time, shares of its common stock, par value $0.0001 per share. The issuance and sale, if any, of shares of the Company's common stock under the Agreement will be effected pursuant to the Company's registration statement on Form S-3 (File No. 333-294203), which became effective on March 19, 2026, and the related prospectus supplement dated May 27, 2026 (the "Prospectus Supplement"), in each case

filed with the U.S. Securities and Exchange Commission (the "SEC"). In accordance with the terms of the Agreement, under the Prospectus Supplement, the Company may offer and sell shares of its common stock having an aggregate offering price of up to $75.0 million from time to time through the Agent (such program, the "ATM Offering"). During the three and nine months ended September 30, 2026, the Company issued and sold 2,087,682 shares of its common stock under the Agreement. The shares were sold at an average price of $4.79 per share for aggregate net proceeds to the Company of approximately $9.2 million, after deducting sales commissions and offering costs payable by the Company.

Private Placement of Series A Preferred Stock and Warrants

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 Private Placement closed on October 23, 2025 (the "Closing Date"), pursuant to which the Company received aggregate gross proceeds of $80.0 million, before deducting placement agent fees, financial advisor fees, and other offering expenses. The Company incurred approximately $5.7 million in offering costs, resulting in net proceeds of approximately $74.3 million. $3.1 million of the offering costs were allocated to the Preferred Warrants, which are classified as liabilities, and expensed as incurred. $2.6 million of the offering costs attributable to the issuance of Series A Preferred Stock were recorded as a reduction of the carrying value of the Preferred Stock. On the Closing Date, the Company recorded a loss on issuance of convertible preferred stock and warrants of $321.5 million, reflecting the initial fair values of the Series A Preferred Stock of $184.6 million and the warrants of $216.9 million, offset by $80.0 million in gross proceeds received from investors. The value of the Series A Preferred Stock at issuance was determined based on the contractual conversion ratio multiplied by the closing price of the Company's common stock on the Closing Date. See Note 7 for additional information regarding the warrant liability and related valuation assumptions.

On December 23, 2025, following the announcement of the stockholders' approval of the issuance of common stock issuable upon conversion of the Series A Preferred Stock, the Company issued an aggregate of 36,280,992 shares of common stock upon the automatic conversion of an aggregate of 76,704 shares of Series A Preferred Stock in accordance with the terms set forth in the Certificate of Designation of Preferences, Rights and Limitations of the Series A Convertible Voting Preferred Stock (the "Certificate of Designation"). As of September 30, 2026, an aggregate of 3,296 shares of Series A Preferred Stock remain outstanding after the automatic conversion in December 2025, which are convertible into an aggregate of 1,559,008 shares of common stock, subject to the limitations on conversion set forth in the Certificate of Designation. Each share of Series A Preferred Stock automatically converted 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% (the "Beneficial Ownership Limitation") of the Company's outstanding shares of common stock as of the applicable conversion date. By written notice to the Company, the holder may from time to time increase or decrease the Beneficial Ownership Limitation to any other percentage not in excess of 19.99% specified in such notice; provided, that any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company.

During the nine months ended September 30, 2026, an additional 2,243 shares of Series A Preferred Stock became outstanding upon the exercise of Preferred Tranche A Warrants, which are convertible into an aggregate of 1,060,939 shares of common stock, subject to the limitations on conversion set forth in the Certificate of Designation.

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 upon issuance for an aggregate of 80,000 shares of Series A Preferred Stock for an aggregate cash exercise price of up to $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"). As of September 30, 2026, an aggregate of 68,300 Preferred Tranche A Warrants remained outstanding.

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 up to $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. As of September 30, 2026, an aggregate of 40,000 Preferred Tranche B Warrants remained outstanding.

The Preferred Warrants are subject to forfeiture in the event the applicable holder engages in any Short Sales (as defined in the Securities Purchase Agreement) involving the Company's securities during the 48-months period following the Closing Date. In addition, the shares of common stock and/or Series A Preferred Stock, as applicable, underlying the Preferred Tranche B Warrants are subject to reduction if the applicable holder sells or transfers any shares of Series A Preferred Stock purchased on the Closing Date or shares of common stock received upon conversion of the Series A Preferred Stock purchased on the Closing Date, in either case before the Exercisability Date (as defined therein), except to affiliates for no consideration.

Pursuant to the Certificate of Designation, no fractional shares or scrip representing fractional shares of common stock shall be issued upon the conversion of the Series A Preferred Stock. All fractional shares shall be rounded down to the nearest whole shares of common stock. Holders of Series A Preferred Stock are not entitled to receive any dividends except to the extent that dividends are paid on the Company's common stock. If dividends are paid on shares of common stock, holders of Series A Preferred Stock are entitled to participate in such dividends on an as-converted basis. Upon the liquidation, dissolution, or winding up of the Company, each holder of Series A Preferred Stock will participate pari passu with any distribution of proceeds to holders of common stock. Holders of the Series A Preferred Stock are entitled to vote together with the holders of common stock on an as-if-converted basis on all matters submitted to a vote of stockholders.

Pursuant to the Securities Purchase Agreement, the Company filed a registration statement on Form S-3 (File No. 333-292410), which was declared effective by the SEC on January 6, 2026, covering the resale of the Registrable Securities (as such term is defined in the Securities Purchase Agreement). The Company has agreed to take all steps necessary to keep such registration statement effective at all times until all Registrable Shares have been resold, or there remains no Registrable Shares.

Series A Convertible Preferred Stock

In accordance with ASC 480, *Distinguishing Liabilities from Equity,* and ASC 815, *Derivatives and Hedging*, the Series A Preferred Stock was classified as temporary equity. Pursuant to the Certificate of Designation, in the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, including a change of control transaction, or Deemed Liquidation Event (any such event, a "Liquidation"), the assets of the Company available for distribution to its stockholders shall be distributed among the holders of the shares of Series A Preferred Stock and common stock, pro rata based on the number of shares held by each such holder, treating for this purpose all shares of Series A Preferred Stock as if they had been converted to common stock pursuant to the terms of the Certificate of Designation immediately prior to such Liquidation, without regard to any limitations on conversion set forth in the Certificate of Designation or otherwise. However, there will be no Liquidation Preference on the shares of Series A Preferred Stock.

Warrant Exercises

During the three months ended September 30, 2026, an aggregate of 1,100 Preferred Tranche A Warrants were exercised at an exercise price of $1,000 per share, resulting in total proceeds of $1,100,000 to the Company. Upon exercise, 1,100 shares of Series A Preferred Stock were issued and immediately converted into an aggregate of 520,300 shares of the Company's common stock.

During the nine months ended September 30, 2026, an aggregate of 11,700 Preferred Tranche A Warrants were exercised at an exercise price of $1,000 per share, resulting in total proceeds of $11,700,000 to the Company. Upon exercise, 11,700 shares of Series A Preferred Stock were issued. Of these, 9,457 shares were immediately converted into an aggregate of 4,473,161 shares of the Company's common stock, and the remaining 2,243 shares of Series A Preferred Stock remained outstanding.

No Preferred Tranche A Warrants were exercised during the three or nine months ended September 30, 2025.

Preferred Stock

The Company is authorized to issue 100,000,000 shares of preferred stock, $0.0001 par value per share, including 200,000 shares of Series A Preferred Stock, $0.0001 par value per share. No preferred shares were issued or outstanding as of September 30, 2026 and December 31, 2025, other than shares of the Series A Preferred Stock.

NOTE 7 — WARRANT LIABILITY

In conjunction with the issuance of Series A Preferred Stock and Preferred Tranche A and Tranche B Warrants (the "Warrants") as described in Note 6, the Company established a warrant liability.

The Warrants meet the definition of freestanding instruments and are classified as liabilities in accordance with ASC 480, *Distinguishing Liabilities from Equity*. The Warrants were initially recognized at fair value and are subject to remeasurement at each

balance sheet date after issuance. Any change in fair value is recognized as a component of other income (expense) in the statements of operations in the period of change. For the three and nine months ended September 30, 2026, the Company recognized a $109.6 million gain and a $27.8 million gain, respectively, related to changes in the fair value of the warrant liability, which were included in other income (expense) in the statements of operations. No gain or loss was recognized for the three and nine months ended September 30, 2025 related to changes in the fair value of the liability. In addition to the valuation inputs described below, there is an indirect relationship between the Company's share price and the fair value of the warrant liability, whereby changes in the share price influence the valuation model used to determine fair value.

The fair value of the warrants is estimated using a binomial 2-node model in combination with the Black-Scholes Option Pricing Model using unobservable (Level 3) inputs that reflect the Company's own assumptions, as described in Note 2. The significant unobservable inputs include the expected timing of the Milestone Event, the probability of the Milestone Event being successfully achieved, and the value of the Series A Preferred Stock upon the success or failure of the Milestone Event. Significant increases (decreases) in any of the inputs in isolation would result in a significantly higher (lower) fair value measurement.

The table below summarizes the valuation inputs used in the binomial model for the liability associated with the Warrants at September 30, 2026:

	September 30, 2026	
	Tranche A Warrants	Tranche B Warrants
Scenario 1: Milestone Successfully Achieved		
Discount rate	4.60%	4.60%
Time period between valuation date and Milestone Event	1.25	1.25
Risk-neutral probability of Milestone Event achievement	47.00%	47.00%
Probability-weighted present value of the Series A Preferred Warrants	$ 1,027.50	$ 1,187.80
Scenario 2: Milestone Not Achieved		
Discount rate	4.60%	4.60%
Time period between valuation date and Milestone Event	1.25	1.25
Risk-neutral probability of Milestone Event failure	53.00%	53.00%
Probability-weighted present value of the Series A Preferred Warrants	$ 35.50	$ 35.50
Fair Value of Series A Warrants	$ 1,063.00	$ 1,223.30

The table below summarizes the valuation inputs used in the binomial model for the liability associated with the Warrants at December 31, 2025:

	December 31, 2025	
	Tranche A Warrants	Tranche B Warrants
Scenario 1: Milestone Successfully Achieved		
Discount rate	3.52%	3.52%
Time period between valuation date and Milestone Event	2.00	2.00
Risk-neutral probability of Milestone Event achievement	49.00%	49.00%
Probability-weighted present value of the Series A Preferred Warrants	$ 1,360.60	$ 1,500.60
Scenario 2: Milestone Not Achieved		
Discount rate	3.52%	3.52%
Time period between valuation date and Milestone Event	2.00	2.00
Risk-neutral probability of Milestone Event failure	51.00%	51.00%
Probability-weighted present value of the Series A Preferred Warrants	$ 21.60	$ 21.60
Fair Value of Series A Warrants	$ 1,382.20	$ 1,522.20

The table below summarizes the valuation inputs used in the Black-Scholes Option Pricing Model for the Warrants at September 30, 2026 and December 31, 2025.

	September 30, 2026	December 31, 2025
Term to expiration	1.81	1.81
Risk-free interest rate	4.73%	3.51%
Volatility	120.00%	117.50%
Dividend yield	0.00%	0.00%

The Company estimated the fair value of the Tranche A Warrants and Tranche B Warrants to be approximately $72.6 million and $48.9 million, respectively, as of September 30, 2026, and $110.6 million and $60.9 million, respectively, as of December 31, 2025. The Preferred Tranche A warrants were remeasured to fair value immediately prior to exercise, and the resulting difference between the carrying amount and the fair value at the date of exercise was recognized as a change in fair value of the warrant liability. The Series A Preferred Stock, and common shares that were issued upon conversion, were recorded at their fair value at the exercise date based upon the underlying price of the common stock at that date. These changes represent additional non-cash gains or expenses included in changes in fair value of the warrant liability in the Company's consolidated statements of operations during the reporting period. Such amounts are presented in the tables below as "reduction of warrant liability upon exercise of warrants".

The following table provides a summary of the Company's warrant liability fair value estimates and the changes in Level 3 fair value measurements during the three months ended September 30, 2026:

	Three Months Ended September 30, 2026
Fair value, June 30, 2026	$ 232,690,185
Reduction of warrant liability upon exercise of warrants	(1,553,529)
Changes in fair value of the warrant liability	(109,601,827)
Fair value, September 30, 2026	$ 121,534,829

The following table provides a summary of the Company's warrant liability fair value estimates and the changes in Level 3 fair value measurements during the nine months ended September 30, 2026:

	Nine Months Ended September 30, 2026
Fair value, January 1, 2026	$ 171,464,575
Reduction of warrant liability upon exercise of warrants	(22,135,345)
Changes in fair value of the warrant liability	(27,794,401)
Fair value, September 30, 2026	$ 121,534,829

NOTE 8 — 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, 2026, the total shares authorized for issuance under the Plan were 14,578,917.

Stock Option Awards

Stock option activity for employees and non-employees for the nine months ended September 30, 2026 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, 2026	8,173,509	$ 4.73	9.5	$ 1,270
Granted	5,300,816	$ 5.10		
Exercised	—	$ —		
Cancelled/Forfeited	(34,375)	$ 41.24		
Expired	(4,686)	$ 81.60		
Outstanding September 30, 2026	13,435,264	$ 4.75	8.4	$ 575
Exercisable September 30, 2026	2,816,691	$ 5.61	4.6	$ 376
Available for future grant	812,540			

The weighted average grant-date fair value of stock options outstanding on September 30, 2026 and 2025 was $4.17 per share and $6.20 per share, respectively. Total unrecognized compensation costs related to non-vested stock options at September 30, 2026 were approximately $35.9 million and are expected to be recognized within future operating results over a weighted-average period of 3.3

years. Generally, stock options are granted using exercise prices equal to the market price at the date of grant, vest over four years for employees and one year for directors, and are exercisable over a maximum period of 10 years from their grant dates.

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

The Company uses the Black-Scholes model to estimate the fair value of stock options granted. There were no stock options granted during the nine months ended September 30, 2025. For stock options granted during the nine months ended September 30, 2026, the Company utilized the following assumptions:

	Nine Months Ended September 30, 2026
Expected term (years)	5.14 - 6.25
Risk free interest rate	3.75% - 4.47%
Volatility	117% - 133%
Dividend yield	0%
Weighted-average fair value of options granted during the period	$4.53

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.

As of September 30, 2026, 228,213 PRSUs have vested, 48,646 have been cancelled, and the remaining 199,781 expired during August 2026.

The following table presents stock-based compensation expense included in the Company's consolidated statements of operations, including $6.6 million recognized in connection with the modification of stock options granted to Mr. Race pursuant to the settlement agreement described in Note 10.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 1,216,667	$ 74,376	$ 2,950,817	$ 274,205
General and administrative	1,991,895	198,521	11,240,887	594,139
Total	$ 3,208,562	$ 272,897	$ 14,191,704	$ 868,344

NOTE 9 — COMMITMENTS AND CONTINGENCIES

Legal Proceedings

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

Leases

On October 11, 2022, the Company entered into an office lease agreement with Regus to lease office space located at 1500 District Avenue, Burlington, MA 01803. In May 2026, the Company amended its month-to-month lease agreement to increase the rentable office space, commencing on June 15, 2026, with a monthly payment of $1,643. The Company has elected to not recognize the lease agreement on the balance sheet as the term of the agreement is 12 months or less.

NOTE 10 — RELATED PARTY TRANSACTIONS

Settlement Agreement and Consulting Agreement with Geoffrey Race

On March 30, 2026, the Company, Mind-NRG SARL ("Mind-NRG"), and Mr. Geoffrey Race entered into the Settlement Agreement, pursuant to which Mr. Race resigned from his role as President of the Company and as a Director of Mind-NRG, effective March 31, 2026. Under the Settlement Agreement, the Company agreed to make a payment to Mr. Race, in lieu of the 12-month notice entitlement provided by Mr. Race's Employment Agreement with Mind-NRG, dated as of August 1, 2016 (as amended by that certain First Amendment to Employment Agreement, effective October 11, 2020), which payment consists of (i) a one-time payment in the amount of his annual salary, (ii) 12-months' pension contributions and (iii) a pro-rated portion of his 2026 bonus-entitlement. In addition, in consideration of Mr. Race's execution of a general release of claims and his compliance with the other terms of the Settlement Agreement, the Company agreed to provide Mr. Race with the following separation benefits: (x) a one-time severance payment of £30,000; (y) payments in lieu of 12-months' private medical insurance contributions and life assurance contributions and (z) reimbursement of Mr. Race's reasonable legal fees incurred in connection with obtaining advice on the termination of his employment and the terms of the Settlement Agreement, up to a maximum of £15,000 plus VAT. With respect to Mr. Race's outstanding stock options to purchase shares of common stock granted pursuant to the 2013 Plan, the Company agreed to treat all such options as fully vested effective as of March 31, 2026, and to extend the period during which Mr. Race may exercise such options until midnight U.S. Eastern Time on January 1, 2030, after which time the options will lapse and cease to be exercisable.

Also on March 30, 2026, the Company entered into a consultancy agreement (the "Consultancy Agreement") with Mr. Race. The Consultancy Agreement commenced on April 15, 2026 and continues until April 14, 2027 (the "Consulting Period"), unless earlier terminated by either party upon one month's prior written notice, or by the Company upon the occurrence of certain termination events, including gross misconduct or material breach by Mr. Race. During the Consulting Period, Mr. Race is entitled to receive consulting fees in amounts of £333 per hour, for a minimum of 35 hours per month. At the discretion of the Company's Compensation Committee, Mr. Race may be eligible to receive options to acquire shares of common stock under the 2013 Plan.

On July 31, 2026, the Company provided Mr. Race with written notice, pursuant to Section 2.2 of the Consultancy Agreement, terminating the consultancy engagement effective August 31, 2026. Following such termination, the Company has no further obligations to Mr. Race under the Consultancy Agreement other than with respect to amounts accrued prior to the termination date.

NOTE 11 — SUBSEQUENT EVENT

None.

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, 2025 as filed with the Securities and Exchange Commission ("SEC") on March 11, 2026. 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 certain proprietary product candidates to treat patients suffering from central nervous system ("CNS") diseases.

Our lead product candidate, roluperidone, is in development for the treatment of negative symptoms in patients diagnosed with schizophrenia. In August 2022, we 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. On February 26, 2024, the FDA issued a Complete Response Letter ("CRL") regarding our NDA for roluperidone. Subsequent to the CRL, we have had multiple interactions with the FDA to confirm the design of an additional Phase 3 confirmatory clinical trial to address the deficiencies cited in the CRL and resubmit the NDA.

In connection with our interactions with the FDA subsequent to the CRL, the FDA 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. The FDA also 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 or antipsychotics. We informed the FDA that best efforts will be made to secure 25-30% of patients from the United States, subject to competitive recruitment.

We submitted the protocol for the new Phase 3 confirmatory trial, which we refer to as the C19 trial, to the FDA on December 3, 2025. Consistent with the previous Phase 2b (C03) and Phase 3 (C07) clinical trials of roluperidone, the C19 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 trial is designed to enroll 380 patients, randomized on a 1:1 basis to receive either placebo or a double-blinded single daily 64 mg dose of roluperidone.

The primary efficacy endpoint of the C19 trial is expected to be the change from baseline in the PANSS Marder negative symptoms factor score ("NSFS") at 12 weeks of treatment with roluperidone compared to placebo. Following the initial 12-week treatment period, patients are expected to enter a 52-week relapse assessment phase, during which patients will crossover to receive either a daily 64 mg dose of roluperidone or antipsychotics. On March 31, 2026, we announced that the first patient had been screened in the C19 trial. We currently expect topline efficacy results in the second half of 2027 and relapse assessment data in the second half of 2028.

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 certain regulatory approvals and commercial milestones. To our knowledge, Janssen is currently conducting two Phase 3 trials with seltorexant.

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, 2026 and December 31, 2025, we had an accumulated deficit of $696.0 million and $688.8 million, respectively. For the nine months ended September 30, 2026 and 2025, we recorded net loss of $7.2 million and $9.8 million, respectively. We expect our clinical and administrative costs will increase as we incur clinical trial costs related to the Phase 3 trial of roluperidone.

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 Gains (Losses)

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

Investment Income

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

Changes in fair value of the warrant liability

Changes in fair value of the warrant liability consist of the gain (loss) associated with the adjustment to the carrying amount of the warrant liability.

Results of Operations

Comparison of Three Months Ended September 30, 2026 versus September 30, 2025

Research and Development Expenses

Research and development expenses were $5.2 million and $0.9 million for the three months ended September 30, 2026 and 2025, respectively, an increase of approximately $4.3 million. The increase in research and development expenses was primarily due to expenses related to the C19 trial as well as higher compensation costs. Non-cash stock compensation costs included in research and development expenses were $1.2 million and $0.1 million for the three months ended September 30, 2026 and 2025, respectively.

General and Administrative Expenses

General and administrative expenses were $4.3 million and $1.9 million for the three months ended September 30, 2026 and 2025, respectively, an increase of approximately $2.4 million. The increase in general and administrative expenses was primarily due to higher professional service fees and compensation costs. Non-cash stock compensation costs included in general and administrative expenses were $2.0 million and $0.2 million for the three months ended September 30, 2026 and 2025, respectively.

Foreign Exchange Losses

Foreign exchange losses were $9 thousand and $6 thousand for the three months ended September 30, 2026 and 2025, respectively, an increase of $3 thousand, primarily due to currency movements.

Investment Income

Investment income was $0.6 million and $0.1 million for the three months ended September 30, 2026 and 2025, respectively, an increase of approximately $0.5 million, primarily due to higher cash equivalents and marketable securities balances.

Changes in fair value of the warrant liability

Changes in fair value of the warrant liability were a gain of $109.6 million and zero for the three months ended September 30, 2026 and 2025, respectively, an increase of $109.6 million. The gain on the change in fair value of the warrant liability is related to the warrants issued in conjunction with the October 2025 private placement. The fair value of the non-cash warrant liability at September 30, 2026 was $121.5 million. Accordingly, we recognized a non-cash gain of $109.6 million for the three-month period ended September 30, 2026, reflecting both the decrease in fair value of the warrant liability and losses recognized upon the exercise of warrants during 2026. This non-cash gain was recorded within other income (expense) in the statement of operations.

Comparison of Nine Months Ended September 30, 2026 versus September 30, 2025

Research and Development Expenses

Research and development expenses were $17.6 million and $3.6 million for the nine months ended September 30, 2026 and 2025, respectively, an increase of approximately $14.0 million. The increase in research and development expenses was primarily due to expenses related to the C19 trial as well as higher compensation costs. Non-cash stock compensation costs included in research and development expenses were $3.0 million and $0.3 million for the nine months ended September 30, 2026 and 2025, respectively.

General and Administrative Expenses

General and administrative expenses were $19.1 million and $6.5 million for the nine months ended September 30, 2026 and 2025, respectively, an increase of approximately $12.6 million. The increase in general and administrative expenses was primarily due to higher professional service fees and compensation costs as well as costs related to a severance agreement in the first quarter, which included a $6.6 million one-time, non-cash charge for the modification of the terms of previously granted stock options. Non-cash stock compensation costs included in general and administrative expenses were $11.2 million and $0.6 million for the nine months ended September 30, 2026 and 2025, respectively.

Foreign Exchange Losses

Foreign exchange losses were $25 thousand and $36 thousand for the nine months ended September 30, 2026 and 2025, respectively, a decrease of $11 thousand, primarily due to currency movements.

Investment Income

Investment income was $1.8 million and $0.4 million for the nine months ended September 30, 2026 and 2025, respectively, an increase of approximately $1.4 million, primarily due to higher cash equivalents and marketable securities balances.

Changes in fair value of the warrant liability

Changes in fair value of the warrant liability were a gain of $27.8 million and zero for the nine months ended September 30, 2026 and 2025, respectively, an increase of $27.8 million. The gain on the change in fair value of the warrant liability is related to the warrants issued in conjunction with the October 2025 private placement. The fair value of the non-cash warrant liability at September 30, 2026 was $121.5 million. Accordingly, we recognized a non-cash gain of $27.8 million for the nine-month period ended September 30, 2026, reflecting both the decrease in fair value of the warrant liability and losses recognized upon the exercise of warrants during 2026. This non-cash gain was recorded within other income (expense) in the statement of operations.

Non-GAAP Financial Measures

In addition to our results determined in accordance with U.S. generally accepted accounting principles ("GAAP"), we believe the following non-GAAP measures are useful in evaluating our operating performance and financial condition. Non-GAAP financial measures are included with the intent of providing investors with an understanding of our historical financial results and trends and to facilitate comparisons between periods. In addition, these non-GAAP financial measures are among the indicators our management uses for planning and forecasting purposes and measuring our performance. We believe that these non-GAAP financial measures, when considered together with U.S. GAAP measures, can enhance the understanding of our financial and operating performance. Non-GAAP financial measures have no standardized meaning and investors are cautioned that, unlike financial measures prepared in accordance with U.S. GAAP, non-GAAP measures may not be comparable with the calculation of similar measures for other companies. The limitations of using non-GAAP financial measures as performance measures are that they provide a view of our results of operations without including all events during a period and may not provide a comparable view of our performance to other companies in the biopharmaceutical industry. Investors are encouraged to review the related GAAP financial measures and the reconciliation of these non-GAAP financial measures to their most directly comparable GAAP financial measures, and not to rely on any single financial measure to evaluate our business.

Non-GAAP total liabilities is defined as GAAP total liabilities, excluding warrant liability and liability related to the sale of future royalties. Reconciliations of reported GAAP total liabilities to non-GAAP total liabilities as of September 30, 2026 and December 31, 2025 were as follows (in thousands):

	September 30, 2026	December 31, 2025
Current liabilities		
Accounts payable	$ 653	$ 639
Accrued expenses and other current liabilities	1,873	1,651
Total current liabilities	2,526	2,290
Warrant liability	121,535	171,465
Liability related to the sale of future royalties	60,000	60,000
Total liabilities – GAAP	184,061	233,755
Reconciling items:		
Warrant liability	(121,535)	(171,465)
Liability related to the sale of future royalties	(60,000)	(60,000)
Total liabilities – non-GAAP	$ 2,526	$ 2,290

Non-GAAP adjusted net income (loss) is defined as GAAP net income (loss), adjusted to exclude non-cash items related to: (i) stock-based compensation expense and (ii) changes in fair value of the warrant liability. Reconciliations of reported GAAP net income (loss) to non-GAAP adjusted net income (loss) for the three and nine months ended September 30, 2026 and 2025 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Net income (loss) – GAAP	$ 100,747	$ (2,744)	$ (7,192)	$ (9,756)
Reconciling items:				
Stock-based compensation expense	3,209	273	14,192	868
Changes in fair value of the warrant liability	(109,602)	—	(27,794)	—
Adjusted net income (loss) – non-GAAP	$ (5,646)	$ (2,471)	$ (20,794)	$ (8,888)

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2026, we had an accumulated deficit of approximately $696.0 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, 2026, we had approximately $77.0 million in cash, cash equivalents, marketable securities and restricted cash, which we believe will be sufficient to meet our operating commitments for the next 12 months from the date our interim condensed financial statements are issued. Our cash requirements primarily relate to expenditures to support the development of roluperidone, which includes advancing the program through the regulatory process.

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

At-the-Market Equity Offering Program

On May 27, 2026, we entered into a Sales Agreement (the "Agreement") with Leerink Partners LLC (the "Agent") with respect to an "at-the-market" offering program, pursuant to which we may issue and sell, from time to time, shares of our common stock, par value $0.0001 per share. The issuance and sale, if any, of shares of our common stock under the Agreement will be effected pursuant to our registration statement on Form S-3 (File No. 333-294203), which became effective on March 19, 2026, and the related prospectus supplement dated May 27, 2026 (the "Prospectus Supplement"), in each case filed with the U.S. Securities and Exchange Commission (the "SEC"). In accordance with the terms of the Agreement, under the Prospectus Supplement, we may offer and sell shares of our common stock having an aggregate offering price of up to $75.0 million from time to time through the Agent (such program, the "ATM Offering"). During the three and nine months ended September 30, 2026, we issued and sold 2,087,682 shares of our common stock under the Agreement. The shares were sold at an average price of $4.79 per share for aggregate net proceeds to us of approximately $9.2 million, after deducting sales commissions and offering costs payable by us.

Private Placement of Series A Preferred Stock and Warrants

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 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 Private Placement closed on October 23, 2025 (the "Closing Date"), pursuant to which we received aggregate gross proceeds of $80.0 million, before deducting placement agent fees, financial advisor fees, and other offering expenses. We incurred approximately $5.7 million in offering costs, resulting in net proceeds of approximately $74.3 million. $3.1 million of the offering costs were allocated to the Preferred Warrants, which are classified as

liabilities, and expensed as incurred. $2.6 million of the offering costs attributable to the issuance of Series A Preferred Stock were recorded as a reduction of the carrying value of the Preferred Stock. On the Closing Date, we recorded a loss on issuance of convertible preferred stock and warrants of $321.5 million, reflecting the initial fair values of the Series A Preferred Stock of $184.6 million and the warrants of $216.9 million, offset by $80.0 million in gross proceeds received from investors. The value of the Series A Preferred Stock at issuance was determined based on the contractual conversion ratio multiplied by the closing price of our common stock on the Closing Date. For further discussion regarding the warrant liability and related valuation assumptions, please refer to Note 7, Warrant Liability, to our condensed consolidated financial statements appearing elsewhere in this Form 10-Q.

On December 23, 2025, following the announcement of the stockholders' approval of the issuance of common stock issuable upon conversion of the Series A Preferred Stock, we issued an aggregate of 36,280,992 shares of common stock upon the automatic conversion of an aggregate of 76,704 shares of Series A Preferred Stock in accordance with the terms set forth in the Certificate of Designation of Preferences, Rights and Limitations of the Series A Convertible Voting Preferred Stock (the "Certificate of Designation"). As of September 30, 2026, an aggregate of 3,296 shares of Series A Preferred Stock remain outstanding after the automatic conversion in December 2025, which are convertible into an aggregate of 1,559,008 shares of common stock, subject to the limitations on conversion set forth in the Certificate of Designation. Each share of Series A Preferred Stock automatically converted 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% (the "Beneficial Ownership Limitation") of our outstanding shares of common stock as of the applicable conversion date. By written notice to us, the holder may from time to time increase or decrease the Beneficial Ownership Limitation to any other percentage not in excess of 19.99% specified in such notice; provided, that any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to us.

During the nine months ended September 30, 2026, an additional 2,243 shares of Series A Preferred Stock became outstanding upon the exercise of Preferred Tranche A Warrants, which are convertible into an aggregate of 1,060,939 shares of common stock, subject to the limitations on conversion set forth in the Certificate of Designation.

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 upon issuance for an aggregate of 80,000 shares of Series A Preferred Stock for an aggregate cash exercise price of up to $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"). As of September 30, 2026, an aggregate of 68,300 Preferred Tranche A Warrants remained outstanding.

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 up to $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. As of September 30, 2026, an aggregate of 40,000 Preferred Tranche B Warrants remained outstanding.

The Preferred Warrants are subject to forfeiture in the event the applicable holder engages in any Short Sales (as defined in the Securities Purchase Agreement) involving our securities during the 48-months period following the Closing Date. In addition, the shares of common stock and/or Series A Preferred Stock, as applicable, underlying the Preferred Tranche B Warrants are subject to reduction if the applicable holder sells or transfers any shares of Series A Preferred Stock purchased on the Closing Date or shares of common stock received upon conversion of the Series A Preferred Stock purchased on the Closing Date, in either case before the Exercisability Date (as defined therein), except to affiliates for no consideration.

Pursuant to the Certificate of Designation, no fractional shares or scrip representing fractional shares of common stock shall be issued upon the conversion of the Series A Preferred Stock. All fractional shares shall be rounded down to the nearest whole shares of common stock. Holders of Series A Preferred Stock are not entitled to receive any dividends except to the extent that dividends are paid on our common stock. If dividends are paid on shares of common stock, holders of Series A Preferred Stock are entitled to participate in such dividends on an as-converted basis. Upon the liquidation, dissolution, or winding up of us, each holder of Series A Preferred Stock will participate pari passu with any distribution of proceeds to holders of common stock. Holders of the Series A Preferred Stock are entitled to vote together with the holders of common stock on an as-if-converted basis on all matters submitted to a vote of stockholders.

Pursuant to the Securities Purchase Agreement, we filed a registration statement on Form S-3 (File No. 333-292410), which was declared effective by the SEC on January 6, 2026, covering the resale of the Registrable Securities (as such term is defined in the

Securities Purchase Agreement). We have agreed to take all steps necessary to keep such registration statement effective at all times until all Registrable Shares have been resold, or there remains no Registrable Shares.

Warrant Exercises

During the three months ended September 30, 2026, an aggregate of 1,100 Preferred Tranche A Warrants were exercised at an exercise price of $1,000 per share, resulting in total proceeds of $1,100,000 to us. Upon exercise, 1,100 shares of Series A Preferred Stock were issued and immediately converted into an aggregate of 520,300 shares of our common stock.

During the nine months ended September 30, 2026, an aggregate of 11,700 Preferred Tranche A Warrants were exercised at an exercise price of $1,000 per share, resulting in total proceeds of $11,700,000 to us. Upon exercise, 11,700 shares of Series A Preferred Stock were issued. Of these, 9,457 shares were immediately converted into an aggregate of 4,473,161 shares of our common stock, and the remaining 2,243 shares of Series A Preferred Stock remained outstanding.

No Preferred Tranche A Warrants were exercised during the three or nine months ended September 30, 2025.

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. No royalties or milestone payments were accrued or paid during the three and nine months ended September 30, 2026 or 2025.

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, marketable securities and restricted cash will be sufficient to meet our cash commitments for at least the next 12 months after the date that the financial statements are issued. The timing of future capital requirements depends upon many factors including the size and timing of future clinical trials, the timing and scope of any strategic partnering activity and the progress of other research and development activities.

Cash Flows

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

	Nine Months Ended September 30,	
	2026	2025
	(dollars in millions)	
Net cash (used in) provided by:		
Operating activities	$ (26.9)	$ (9.0)
Investing activities	(55.9)	—
Financing activities	20.7	(0.1)
Net decrease in cash	$ (62.1)	$ (9.1)

Net Cash Used in Operating Activities

Net cash used in operating activities of approximately $26.9 million during the nine months ended September 30, 2026 was primarily due to our net loss of $7.2 million, a $27.8 million decrease in fair value of the warrant liability, a $5.6 million increase in prepaid expenses and $0.9 million in accretion of marketable securities, partially offset by a stock-based compensation expense of $14.2 million.

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 Investing Activities

Net cash used in investing activities of approximately $55.9 million during the nine months ended September 30, 2026 was primarily due to the purchase of marketable securities of $78.4 million, partially offset by the maturity and redemption of marketable securities of $22.5 million.

Net cash used in investing activities was zero during the nine months ended September 30, 2025.

Net Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities of approximately $20.7 million during the nine months ended September 30, 2026 was primarily due to net proceeds of $9.2 million received from the at-the-market offering and proceeds from the exercise of Preferred Tranche A Warrants.

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.

Critical Accounting Policies and Estimates

In our Annual Report on Form 10-K for the fiscal year ended December 31, 2025, 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, 2026.

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, 2025 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 are currently evaluating the impact that recently issued, but not yet adopted, accounting pronouncements will have on the condensed consolidated financial statements or have determined they 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, 2026. Based on the evaluation of our disclosure controls and procedures as of September 30, 2026, 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, 2025, as filed with the Securities and Exchange Commission ("SEC") on March 11, 2026. 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, 2025, 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. Our net loss was $7.2 million and $9.8 million for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, we had an accumulated deficit of approximately $696.0 million.

Our lead product candidate, roluperidone, is in development for the treatment of negative symptoms in patients diagnosed with schizophrenia. In August 2022, we 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. On February 26, 2024, the FDA issued a Complete Response Letter (the "CRL") to our NDA for roluperidone. Subsequent to the CRL, we have had multiple interactions with the FDA to confirm the design of an additional Phase 3 confirmatory clinical trial to address the deficiencies cited in the CRL and resubmit the NDA. While we are advancing plans for an additional confirmatory Phase 3 clinical trial for roluperidone for the treatment of negative symptoms in schizophrenia, which we refer to as the C19 trial, in consultation with the FDA and expect to fund such trial and our resubmission of the NDA in part with net proceeds from our October 2025 private placement, there can be no assurances that we will successfully resubmit the NDA and 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, 2026, we had cash, cash equivalents, marketable securities and restricted cash of $77.0 million. We believe that this amount 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 C19 trial required by the FDA for roluperidone. 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.

Stockholders will be diluted by any conversions of outstanding Series A Preferred Stock and exercises of outstanding warrants.

As of September 30, 2026, there were (i) 2,619,947 shares of common stock issuable upon conversion of outstanding Series A Preferred Stock for no additional consideration, (ii) 32,305,900 shares of common stock issuable upon exercise of outstanding tranche A warrants to purchase Series A Preferred Stock and (iii) 18,920,000 shares of common stock issuable upon exercise of outstanding tranche B warrants to purchase Series A Preferred Stock. The outstanding Series A Preferred Stock is convertible any time at the option of the holder thereof subject to beneficial ownership limitations. The tranche A warrants became exercisable immediately upon issuance. The exercise of such warrants and conversion of the Series A Preferred Stock for shares of our common stock will result in further dilution of our stockholders' investment and could negatively affect the market price of our common stock. In addition, stockholders may experience further dilution if we issue common stock, or securities convertible into common stock, in the future. As a result of this dilution, stockholders may receive significantly less than the full purchase price paid for the shares in the event of liquidation.

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	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant, effective June 17, 2022 (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K (File No. 001-36517) filed with the SEC on June 17, 2022).
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant, effective December 22, 2025 (incorporated by reference to Exhibit 3.3 to the Registrant's registration statement on Form S-3 (File No. 333-292410) filed with the SEC on December 23, 2025).
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Minerva Neurosciences, Inc., effective June 4, 2026 (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K (File No. 001-36517) filed with the SEC on June 4, 2026).
3.5	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's current report on Form 8-K (File No. 001-36517) filed with the SEC on June 4, 2026).
3.6	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 Registrant'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.
+ 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 6, 2026

EXHIBIT 31.1

CERTIFICATION

I, Remy Luthringer, certify that:

1. I have reviewed this quarterly report on 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 6, 2026

/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 quarterly report on 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 6, 2026

/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, 2026, 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 6, 2026

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

/s/ Frederick Ahlholm

Date: November 6, 2026

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.