Minerva Neurosciences Provides First Quarter 2026 Financial Results and Business Updates

May 5, 2026

Confirmatory Phase 3 trial of roluperidone for negative symptoms of schizophrenia initiated and first patient screened

Previous open label trial data presented at SIRS 2026 showed no safety or drug–drug interaction concerns with roluperidone and olanzapine

Roluperidone remains the only late-stage drug candidate for this high-need population

BURLINGTON, Mass., May 05, 2026 (GLOBE NEWSWIRE) -- Minerva Neurosciences, Inc. (Nasdaq: NERV), a clinical-stage biopharmaceutical company focused on the development of therapies to treat central nervous system disorders, today reported financial and business updates for the first quarter ended March 31, 2026.

Business Updates

Roluperidone - potentially the First Treatment for Negative Symptoms of Schizophrenia

- Minerva initiated its global confirmatory Phase 3 clinical trial of roluperidone for the treatment of negative symptoms of schizophrenia during the first quarter of 2026 with efficacy topline data expected 2H 2027.
- The Company screened the first patient in March 2026, marking an important operational milestone for the program.
- The Phase 3 trial will enroll approximately 380 patients across roughly 40 clinical sites worldwide, including the United States (US) and multiple European countries.
- This confirmatory Phase 3 trial follows productive discussions with the FDA on the overall design and efficacy assessments and builds directly on Minerva's clinical success in the prior pivotal Phase 2b and Phase 3 trials (C03 and C07).
- The trial will evaluate roluperidone 64 mg versus placebo to confirm the effect of roluperidone on primary negative symptoms at 12 weeks.
- The trial will also evaluate on an informational basis the longer-term relapse rate of positive symptoms for roluperidone as compared with several commonly prescribed antipsychotic medications for an additional 40 weeks.
- See "About the Phase 3 MIN-101C19 Trial" below for more information.
- Roluperidone remains the only late-stage drug candidate for this high-need population.

Scientific presentations - further supporting the roluperidone program and reinforcing real world applicability

- In March 2026, Minerva presented data from its open-label safety trial evaluating roluperidone co-administered with olanzapine at the Schizophrenia International Research Society (SIRS) 2026 Annual Congress.
- The data demonstrated no clinically meaningful safety concerns, no significant pharmacokinetic interactions, and no pharmacodynamic effects when roluperidone was administered with olanzapine. This supports the continued development of roluperidone in patients receiving background antipsychotic therapy.
- The presentation is available on Minerva's website under the presentation tab: https://ir.minervaneurosciences.com/static-files/49dcf8af-fa88-428d-89c7-c35491745374
- In February 2026, Minerva hosted a live key opinion leader (KOL) webcast, "Roluperidone: From Unmet Need to Reality," featuring Greg Strauss, PhD, Franklin Professor of Psychology at the University of Georgia, and Brian Kirkpatrick, MD, MSPH, Peters Professor of Psychiatry at the University of Arkansas for Medical Sciences.
- The discussion addressed the burden and assessment of negative symptoms, limitations of existing treatment approaches, and the rationale and design of the ongoing confirmatory Phase 3 trial. The presentation is available at: https://bit.ly/48YzdNK and the replay is also available: https://lifescievents.com/event/pkv02859/

“The initiation of our confirmatory Phase 3 trial and the screening of the first patient represent meaningful milestones for Minerva that underscore the progress of our lead program,” said Dr. Remy Luthringer, Executive Chairman and CEO of Minerva Neurosciences. “With no approved treatments for negative symptoms of schizophrenia in the United States or Europe, roluperidone remains the only late-stage candidate specifically targeting this substantial unmet medical need. Patients often live with persistent negative symptoms such as avolition and anhedonia that remain even when positive symptoms of schizophrenia are controlled, driving long-term disability and functional impairment. Building directly on consistent late-stage clinical results, this confirmatory Phase 3 trial is designed to evaluate roluperidone’s potential to improve these core drivers of disability while laying the groundwork for a broader treatment strategy.”

Corporate Updates

- During the first quarter of 2026, Minerva announced a leadership transition with the appointment of Jim O’Connor as Chief Business Officer and General Counsel, effective April 21, 2026, as Geoff Race, the Company’s President, elected to leave the company. Mr. Race will continue to be involved with Minerva as a consultant.

- During the quarter, one investor from the October private placement elected to exercise a portion of their warrants to purchase Series A preferred stock, resulting in additional proceeds to Minerva of $1.2 million.

First Quarter Financial Results

Research and Development (R&D) Expenses: R&D expenses were $5.3 million, compared to $1.4 million in the prior-year period. The increase was primarily due to expenses related to the initiation of the C19 trial as well as higher compensation costs.

General and Administrative (G&A) Expenses: G&A expenses were $11.4 million, compared to $2.5 million in the prior-year period. The increase of $8.9 million was primarily due to non-cash stock compensation expense of $8.0 million, as well as higher professional service fees and compensation costs. Non-cash stock compensation expense included a one-time charge of $6.6 million for the modification of the terms of previously granted stock options related to Mr. Race’s settlement agreement.

Change in Fair Value of Warrant Liability: For the three months ended March 31, 2026, the Company recorded a non-cash expense of $109.4 million for both the change in the fair value of the warrant liability and losses recognized upon the exercise of warrants during 2026.

Total Liabilities: Under U.S. Generally Accepted Accounting Principles (“GAAP”), for the periods ended March 31, 2026 and December 31, 2025, total liabilities were $343.1 million and $233.8 million, respectively. Excluding the warrant liability and liability related to the sale of future royalties, non-GAAP total liabilities* were $4.5 million and $2.3 million for the periods ended March 31, 2026 and December 31, 2025, respectively.

Net loss: Under GAAP, Net loss for the three months ended March 31, 2026 was $125.4 million, or $2.86 per basic and diluted share, compared to a net loss of $3.8 million, or $0.50 per basic and diluted share, for the three months ended March 31, 2025. On a non-GAAP basis, adjusted net loss* was $7.3 million, or an adjusted net loss per share* of $0.17, compared to a non-GAAP adjusted net loss* of $3.5 million, or an adjusted net loss per share* of $0.46 per share, in the prior-year period.

Cash Position: As of March 31, 2026, Minerva had approximately $78.2 million in cash, cash equivalents, marketable securities and restricted cash, compared to $82.4 million at December 31, 2025.

** Definitions of the non-GAAP measures used by Minerva and a reconciliation of such measures to the related GAAP financial measure can be found under the sections below titled “Non-GAAP Financial Measures” and “Reconciliation of GAAP Financial Measures to Non-GAAP Financial Measures.”*

About the Phase 3 MIN-101C19 Trial

The global Phase 3 MIN-101C19 trial will enroll approximately 380 adults aged 18–55 with moderate to severe negative symptoms of schizophrenia, confirmed by a Positive and Negative Syndrome Scale (PANSS) negative subscale score greater than 20 and stable positive symptoms for at least six months. The trial utilizes a two-part design. The overall objective of the study is to confirm the effect of roluperidone on primary negative symptoms at 12 weeks compared to placebo and to evaluate longer-term relapse of positive symptoms compared with commonly prescribed antipsychotic medications for an additional 40 weeks.

The trial is designed to minimize variability and maximize sensitivity to treatment effect, including standardized assessments, and comprehensive caregiver engagement. Topline data from the 12-week Phase A portion (i.e., primary efficacy endpoint) of the trial are expected in the second half of 2027. The trial’s operational model includes intensive rater training, real-time monitoring of scoring data, and structured caregiver outreach to support safety tracking, functional assessments, and adherence.

Phase A is a12-week, randomized, double-blind, placebo-controlled phase during which patients will receive 64 mg of roluperidone or placebo to evaluate the primary endpoint: change from baseline in the Marder Negative Symptoms Factor Score (NSFS), which is a factor-analytic composite created from selected PANSS items. The sole key secondary endpoint is the change from baseline in the Personal and Social Performance (PSP) total score. Other secondary endpoints include a broad set of additional clinical measures, including PANSS subscales, Clinical Global Impression – Severity (CGI-S), Clinical Global Impression – Improvement (CGI-I), the Calgary Depression Scale, avolition-specific analyses, and patient and caregiver treatment-satisfaction ratings.

Phase B extends the trial for 40 weeks using a double-dummy, active-controlled, randomized design comparing continued roluperidone with three commonly prescribed antipsychotic medications (risperidone, aripiprazole, or olanzapine). This phase is designed to compare relapse rates between treatment groups. Relapses of positive symptoms will be evaluated using a rigorous, multi-component definition incorporating psychometric endpoints based on PANSS score worsening, and clinically meaningful events such as hospitalization or dangerous behavior.

About Minerva Neurosciences

Minerva Neurosciences, Inc. is a clinical-stage biopharmaceutical company focused on developing product candidates to treat CNS diseases. Minerva is initiating a confirmatory Phase 3 trial with roluperidone for negative symptoms of schizophrenia. For more information, please visit the Company's website.

Non-GAAP Financial Measures

In addition to the financial information presented in this release in accordance with accounting principles generally accepted in the United States of America (GAAP), Minerva also presents adjusted non-GAAP financial measures.

Non-GAAP financial measures are included with the intent of providing investors with an understanding of Minerva's historical financial results and trends and to facilitate comparisons between periods. In addition, these non-GAAP financial measures are among the indicators that Minerva's management uses for planning and forecasting purposes and measuring Minerva's performance. Minerva believes that these non-GAAP financial measures, when considered together with U.S. GAAP measures, can enhance the understanding of its 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 Minerva's results of operations without including all events during a period and may not provide a comparable view of Minerva's 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 the business.

Non-GAAP total liabilities is defined as GAAP total liabilities, excluding warrant liability and liability related to the sale of future royalties.

Non-GAAP adjusted net loss is defined as GAAP net loss, adjusted to exclude non-cash items related to: (i) stock-based compensation expense and (ii) changes in fair value of the warrant liability.

Non-GAAP adjusted net loss per share, basic and diluted, is defined as GAAP net loss per share, basic and diluted, adjusted to exclude non-cash items related to: (i) stock-based compensation expense and (ii) changes in fair value of the warrant liability.

Forward-Looking Safe Harbor Statement

This press release contains forward-looking statements which are subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts, reflect management's expectations as of the date of this press release, and involve certain risks and uncertainties. Forward-looking statements include, but are not limited to, statements herein with respect to implied or express statements regarding the expected timeline, design and conduct of Minerva's confirmatory Phase 3 trial of roluperidone for the treatment of negative symptoms of schizophrenia, including the timing of its results; the therapeutic and regulatory potential of roluperidone in the United States and Europe; market opportunities; and Minerva's plans and objectives with respect to the roluperidone program. These forward-looking statements are based on our current expectations and may differ materially from actual results due to a variety of factors including, without limitation, the inability to predict with certainty the level of expenditures and resources required for the confirmatory Phase 3 trial for roluperidone and other operational matters following Minerva's plans to refocus efforts on the successful execution of the Phase 3 trial; Minerva's future financial performance and position may not improve, resulting in difficulties in implementing Minerva's business strategy, and plans and objectives for future operations; the expected sufficiency of Minerva's existing cash resources and runway may not be accurate resulting in the need for additional financing sooner than anticipated or unexpected liquidity constraints; the internal and external costs required for Minerva's ongoing and planned activities, and the resulting impact on expense and use of cash, may be higher than expected, which may cause Minerva to use cash more quickly than expected or to change or curtail some of Minerva's plans or both; trials and studies may be delayed and may not have satisfactory outcomes, and earlier trials and studies may not be predictive of later trials and studies; the design and rate of enrollment for clinical trials, including the current design of the Phase 3 confirmatory trial evaluating roluperidone may not enable successful completion of the trial(s); the commercial opportunity for roluperidone in negative symptoms of Schizophrenia may be smaller than anticipated; Minerva may be unable to obtain and maintain regulatory approvals, including uncertainties associated with the development and timing of Minerva's interactions with the FDA; Minerva may experience uncertainties inherent in the initiation and completion of clinical trials and clinical development; the need to align with collaborators or partners may hamper or delay development and regulatory efforts or increase costs; uncertainties of patent protection and litigation; general economic conditions; and other factors that are described under the caption "Risk Factors" in Minerva's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2025, filed with the Securities and Exchange Commission (the "SEC") on March 11, 2026, as supplemented by Minerva's Form 10-Q for the quarter ended March 31, 2026, filed with the SEC on May 5, 2026. Copies of reports filed with the SEC are posted on Minerva's website at http://ir.minervaneurosciences.com/. The forward-looking statements in this press release are based on information available to Minerva as of the date hereof, and Minerva disclaims any obligation to update any forward-looking statements, except as required by law.

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CONDENSED CONSOLIDATED BALANCE SHEET DATA
(Unaudited)

	March 31, 2026	December 31, 2025
	(in thousands)	

ASSETS

Current assets:		
Cash and cash equivalents	$ 32,660	$ 82,302
Marketable securities	45,405	-
Restricted cash	100	100
Prepaid expenses and other current assets	942	698
Total current assets	79,107	83,100
Goodwill	14,869	14,869
Deferred offering costs	51	-
Total assets	$ 94,027	$ 97,969

LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

Current liabilities:		
Accounts payable	$ 2,118	$ 639
Accrued expenses and other current liabilities	2,364	1,651
Total current liabilities	4,482	2,290
Long-term liabilities:		
Warrant liability	278,597	171,465
Liability related to the sale of future royalties	60,000	60,000
Total liabilities	343,079	233,755
Redeemable preferred stock:		
Series A convertible preferred stock	4,962	4,962
Stockholders' deficit:		
Common stock	4	4
Additional paid-in capital	560,186	548,047
Accumulated deficit	(814,204)	(688,799)
Total stockholders' deficit	(254,014)	(140,748)
Total liabilities, redeemable preferred stock and stockholders' deficit	$ 94,027	$ 97,969

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31, (in thousands, except per share amounts)	
	2026	**2025**
Operating expenses:		
Research and development	$ 5,255	$ 1,362
General and administrative	11,417	2,541
Total operating expenses	16,672	3,903
Loss from operations	(16,672)	(3,903)
Foreign exchange losses	(2)	(8)
Investment income	630	158
Changes in fair value of the warrant liability	(109,360)	-
Net loss	$ (125,404)	$ (3,753)
Net loss per share, basic and diluted	$ (2.86)	$ (0.50)
Weighted average shares outstanding, basic and diluted	43,900	7,569

Reconciliation of GAAP Financial Measures to Non-GAAP Financial Measures

RECONCILIATION OF TOTAL LIABILITIES - NON-GAAP
(Unaudited)

	March 31, 2026	December 31, 2025
	(in thousands)	
Current liabilities:		
Accounts payable	$ 2,118	$ 639
Accrued expenses and other current liabilities	2,364	1,651

Total current liabilities	4,482	2,290
Long-term liabilities:		
Warrant liability	278,597	171,465
Liability related to the sale of future royalties	60,000	60,000
Total liabilities - GAAP	343,079	233,755
Reconciling items:		
Warrant liability	(278,597)	(171,465)
Liability related to the sale of future royalties	(60,000)	(60,000)
Total liabilities - non-GAAP	$ 4,482	$ 2,290

RECONCILIATION OF ADJUSTED NET LOSS - NON-GAAP
(Unaudited)

	Three Months Ended March 31, (in thousands, except per share amounts)	
	2026	**2025**
Net loss – GAAP	$ (125,404)	$ (3,753)
Reconciling items:		
Stock-based compensation expense	8,710	297
Changes in fair value of the warrant liability	109,360	-
Adjusted net loss – non-GAAP	$ (7,334)	$ (3,456)
Net loss per share, basic and diluted – GAAP	$ (2.86)	$ (0.50)
Weighted average shares outstanding, basic and diluted	43,900	7,569
Reconciling items:		
Stock-based compensation expense	0.20	0.04
Changes in fair value of the warrant liability	2.49	-
Net loss per share, basic and diluted – non-GAAP	$ (0.17)	$ (0.46)
Weighted average shares outstanding, basic and diluted	43,900	7,569