Minerva Neurosciences Provides Third Quarter 2026 Financial Results and Business Updates

November 6, 2026

Confirmatory Phase 3 trial of roluperidone (MIN-101C19) ongoing with topline efficacy data expected 2H 2027

Recent Schizophrenia Research article describes need to expand basic science beyond dopaminergic mechanisms and to improve clinical trial methodology for negative symptoms

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

Company to host in-person and virtual KOL event on November 12, 2026 at 10:00 AM ET

BURLINGTON, Mass., Nov. 06, 2026 (GLOBE NEWSWIRE) -- Minerva Neurosciences, Inc. (Nasdaq: NERV), a clinical-stage biopharmaceutical company focused on the development of therapies to treat central nervous system (CNS) disorders, today reported financial and business updates for the third quarter ended September 30, 2026.

"The recent publication in Schizophrenia Research lays out the approach we are taking at Minerva: developing treatments for negative symptoms beyond dopaminergic mechanisms and testing them in trials designed to separate signal from noise," said Remy Luthringer, Ph.D., Chief Executive Officer of Minerva Neurosciences. "The psychiatry field has increasingly recognized the importance of finding non-dopaminergic mechanisms in the treatment of schizophrenia, particularly for negative symptoms. Roluperidone is the only late-stage candidate targeting negative symptoms directly. The C19 study, our ongoing Phase 3 trial, is designed to confirm the effect we saw in our prior trials. We remain focused on execution and on track for topline efficacy data in the second half of 2027."

In-Person and Virtual KOL Event

The Company will host a KOL event in New York on Thursday, November 12, 2026, at 10:00 AM ET featuring several key opinion leaders and company management focused on the opportunity for roluperidone in treating the negative symptoms of schizophrenia.

For more details and to register for the event, click here.

Corporate Updates

Roluperidone - potentially the first treatment for negative symptoms of schizophrenia

- Minerva's ongoing global Phase 3 clinical trial of roluperidone for the treatment of negative symptoms of schizophrenia (the C19 Study) is designed to enroll 380 patients across approximately 40 clinical sites worldwide, including the United States (US) and multiple European countries.
- The C19 Study follows discussions with the FDA on the overall design and efficacy assessments and builds directly on Minerva's prior Phase 2b and Phase 3 trials (C03 and C07).
- Phase A of the C19 Study is evaluating roluperidone 64 mg versus placebo to confirm the effect of roluperidone on primary negative symptoms at 12 weeks. The topline data from Phase A is expected in 2H 2027.
- Phase B of the C19 Study is evaluating longer-term relapse of positive symptoms for roluperidone versus commonly prescribed antipsychotic medications for an additional 52-week period. The topline data from Phase B is expected in 2H 2028.
- 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 Publication – development of non-dopamine active drugs for negative symptoms

- Remy Luthringer, Ph.D. (Chief Executive Officer) and Michael Davidson, MD (Chief Medical Officer) published "Development of non-dopamine active drugs for negative symptoms" in Schizophrenia Research.
- The article describes the need for basic science to expand beyond attempts to interfere with brain dopaminergic activity and for clinical science to improve trial methodology in negative symptoms of schizophrenia.
- The article describes roluperidone as an antagonist with high affinity for σ-2, 5-HT2A and α1A receptors and very weak

affinity for dopamine receptors.

- The article also discusses trial design considerations for negative symptoms, including the distinction between primary and secondary negative symptoms, patient selection, placebo response, add-on and targeted treatment designs, assessment instruments, and Bayesian analysis.

Third Quarter and Nine Months 2026 Financial Results

Research and development (R&D) expense: For the three months ended September 30, 2026 and 2025, R&D expense was $5.2 million and $0.9 million, respectively. For the nine months ended September 30, 2026 and 2025, R&D expense was $17.6 million and $3.6 million, respectively. R&D expense was higher versus the prior year period in both the three and nine months ended September 30 primarily due to expenses related to the C19 trial as well as higher compensation costs.

General and administrative (G&A) expense: For the three months ended September 30, 2026 and 2025, G&A expense was $4.3 million and $1.9 million, respectively. G&A expense was higher versus the prior year period primarily due to higher professional service fees and compensation costs. For the nine months ended September 30, 2026 and 2025, G&A expense was $19.1 million and $6.5 million, respectively. G&A expense was higher versus the prior year period 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.

Other income and expense: For the three months ended September 30, 2026 and 2025, investment income was $0.6 million and $0.1 million, respectively. For the nine months ended September 30, 2026 and 2025, investment income was $1.8 million and $0.4 million, respectively. The increase is primarily due to higher cash equivalents and marketable securities balances.

Changes in Fair Value of the Warrant Liability[1]: For the three months ended September 30, 2026, the Company recorded a non-cash gain of $109.6 million related to the change in fair value of the warrant liability. For the nine months ended September 30, 2026, the Company recorded a non-cash gain of $27.8 million related to the change in fair value of the warrant liability. The gain on the changes in fair value of the warrant liability is related to the warrants issued in conjunction with the October 2025 private placement.

Total Liabilities: Under U.S. Generally Accepted Accounting Principles (“GAAP”), for the periods ended September 30, 2026 and December 31, 2025, total liabilities were $184.1 million and $233.8 million, respectively. Excluding the warrant liability and liability related to the sale of future royalties, non-GAAP total liabilities[2] were $2.5 million and $2.3 million for the periods ended September 30, 2026 and December 31, 2025, respectively.

Net Income (Loss): For the three months ended September 30, 2026, Minerva recorded GAAP net income of $100.7 million, or $1.94 per basic share and $(0.19) per diluted share, compared to a net loss of $2.7 million, or $(0.36) per basic and diluted share, for the three months ended September 30, 2025. The quarter’s GAAP net income was driven by a $109.6 million non-cash gain on the changes in fair value of the warrant liability [1]; excluding that gain and stock-based compensation expense, adjusted (non-GAAP) net loss[2] for the quarter was $5.6 million, compared to an adjusted net loss[2] of $2.5 million in the prior-year period.

For the nine months ended September 30, 2026, Minerva recorded a GAAP net loss of $7.2 million, or $(0.15) per basic share and $(0.45) per diluted share, compared to a net loss of $9.8 million, or $(1.29) per basic and diluted share, for the nine months ended September 30, 2025. Excluding the $27.8 million non-cash gain on the changes in fair value of the warrant liability[1] and stock-based compensation expense, adjusted (non-GAAP) net loss[2] for the nine months was $20.8 million, compared to an adjusted net loss[2] of $8.9 million in the prior year period.

Cash Position: Cash, cash equivalents, marketable securities and restricted cash at September 30, 2026 was approximately $77.0 million, as compared to $82.4 million at December 31, 2025.

About the Phase 3 MIN-101C19 Trial

Minerva’s Phase 3 MIN-101C19 trial (the C19 Study) is designed to enroll 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 C19 Study 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 (Phase A) and to evaluate longer-term relapse of positive symptoms compared with commonly prescribed antipsychotic medications for an additional 52 weeks (Phase B).

The trial is designed to minimize variability and maximize sensitivity to treatment effect, including standardized assessments, and comprehensive caregiver engagement. 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 a 12-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. Topline data from Phase A of the trial is expected in the second half of 2027.

Phase B extends the trial for an additional 52 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 multi-component definition incorporating psychometric endpoints based on PANSS score worsening, and clinically meaningful events such as hospitalization or dangerous behavior. Topline data from Phase B of the trial is expected in the second half of 2028.

About Minerva Neurosciences

Minerva Neurosciences, Inc. is a clinical-stage biopharmaceutical company focused on developing product candidates to treat CNS diseases. Minerva is conducting 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 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.

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, enrollment 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 regulatory and therapeutic potential of roluperidone; clinical adoption of treatments focused on negative symptoms of schizophrenia; 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 September 30, 2026, filed with the SEC on November 6, 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)

	September 30, 2026	December 31, 2025
	(in thousands)	
ASSETS		

Current assets:		
Cash and cash equivalents	$ 20,216	$ 82,302
Marketable securities	56,729	-
Restricted cash	100	100
Prepaid expenses and other current assets	6,364	698
Total current assets	**83,409**	**83,100**
Goodwill	14,869	14,869
Total assets	**$ 98,278**	**$ 97,969**
LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 653	$ 639
Accrued expenses and other current liabilities	1,873	1,651
Total current liabilities	**2,526**	**2,290**
Long-term liabilities:		
Warrant liability	121,535	171,465
Liability related to the sale of future royalties	60,000	60,000
Total liabilities	**184,061**	**233,755**
Redeemable preferred stock:		
Series A convertible preferred stock	11,741	4,962
Stockholders' deficit:		
Common stock	5	4
Additional paid-in capital	598,462	548,047
Accumulated deficit	(695,991)	(688,799)
Total stockholders' deficit	**(97,524)**	**(140,748)**
Total liabilities, redeemable preferred stock and stockholders' deficit	**$ 98,278**	**$ 97,969**

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	$ 5,156	$ 925	$ 17,598	$ 3,586
General and administrative	4,278	1,919	19,149	6,535
Total operating expenses	**9,434**	**2,844**	**36,747**	**10,121**
Loss from operations	**(9,434)**	**(2,844)**	**(36,747)**	**(10,121)**
Foreign exchange losses	(8)	(6)	(25)	(36)
Investment income	587	106	1,786	401
Changes in fair value of the warrant liability	109,602	-	27,794	-
Net income (loss)	**$ 100,747**	**$ (2,744)**	**$ (7,192)**	**$ (9,756)**
Undistributed earnings attributable to participating preferred stock	(5,085)	-	-	-
Net income (loss) attributable to common stockholders	**$ 95,662**	**$ (2,744)**	**$ (7,192)**	**$ (9,756)**
Net income (loss) per share, basic	$ 1.94	$ (0.36)	$ (0.15)	$ (1.29)
Weighted average shares outstanding, basic	49,293	7,569	46,617	7,569
Net income (loss) per share, diluted	$ (0.19)	$ (0.36)	$ (0.45)	$ (1.29)
Weighted average shares outstanding, diluted	75,251	7,569	78,223	7,569

RECONCILIATION OF TOTAL LIABILITIES - NON-GAAP

(Unaudited)

	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**
Long-term liabilities:		
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**

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

(Unaudited)

	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)**

[1] The warrant liability is a non-cash, mark-to-market obligation revalued each period based on Minerva's stock price and other inputs; its fluctuation does not reflect the Company's operating performance or cash position.

[2] 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.”