Minerva Neurosciences Provides Business Updates and Second Quarter Financial Results

August 14, 2025

FDA confirms requirement for confirmatory study of roluperidone for the treatment of negative symptoms in schizophrenia

Evaluation of strategic alternatives

BURLINGTON, Mass., Aug. 14, 2025 (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 provided business updates.

FDA Discussions & Roluperidone Update

The Company has had multiple interactions with the FDA following receipt of the Complete Response Letter (CRL) for its New Drug Application (NDA) in February 2024 and the FDA has confirmed the requirement for an additional confirmatory clinical trial to address the deficiencies cited in the CRL and resubmit the NDA.

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

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

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

Second Quarter 2025 Financial Results

***Research and development (R&D) expense*:** For the three months ended June 30, 2025 and 2024, R&D expense was $1.3 million and $3.9 million, respectively. R&D expense was lower versus the prior year period primarily due to lower costs associated with our drug substance validation campaign and lower consultant fees. For the six months ended June 30, 2025 and 2024, R&D expense was $2.7 million and $8.0 million, respectively. R&D expense was lower versus the prior year period primarily due to lower costs associated with our drug substance validation campaign, costs for the C18 study, consultant fees, and lower compensation expenses.

***General and administrative (G&A) expense*:** For the three months ended June 30, 2025 and 2024, G&A expense was $2.1 million and $2.4 million, respectively. For the six months ended June 30, 2025 and 2024, G&A expense was $4.6 million and $4.9 million, respectively. G&A expense was lower versus the prior year periods primarily due to lower professional service fees.

***Non-cash interest expense*:** For the three and six months ended June 30, 2025, non-cash interest expense for the sale of future royalties was zero, as compared to $2.3 million and $4.6 million for the three and six months ended June 30, 2024, respectively. Non-cash interest expense was lower versus the prior year periods due to revising our estimates for the timing and amount of future royalty payments to be received under the royalty arrangement. During the third quarter of 2024, we adjusted the carrying amount of our liability related to the sale of future royalties to the initial payment of $60 million. This adjustment resulted in the recognition of $26.6 million in other income during the third quarter of 2024, representing the amount of non-cash interest expense amortized through June 30, 2024.

Net loss: Net loss for the three and six months ended June 30, 2025 was $3.3 million and $7.0 million, or a basic and diluted net loss per share of $0.43 and $0.93, respectively, as compared to a net loss for the three and six months ended June 30, 2024 of $8.2 million and $16.8 million or a basic and diluted net loss per share of $1.09 and $2.22, respectively.

Cash Position: Cash, cash equivalents and restricted cash at June 30, 2025 were approximately $15.3 million, as compared to $21.5 million at December 31, 2024.

Review of Strategic Alternatives

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

About Minerva Neurosciences

Minerva Neurosciences, Inc. is a clinical-stage biopharmaceutical company focused on developing product candidates to treat CNS diseases. Minerva's goal is to transform the lives of patients with improved therapeutic options, including roluperidone for negative symptoms of schizophrenia. For more information, please visit the Company's website.

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 Minerva's expectations regarding the confirmatory clinical trial of roluperidone and related regulatory developments; and Minerva's cost reduction measures, the exploration of strategic alternatives for the company to maximize value for stockholders, and the outcomes thereof. 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, whether the objectives of the strategic alternative review process will be achieved; the terms, structure, benefits and costs of any strategic transaction; the timing of any transaction and whether any transaction will be consummated at all; the risk of any unexpected costs or expenses resulting from the review; uncertainties associated with regulatory processes; whether Minerva will maintain compliance with Nasdaq's listing standards and will be able to continue its listing on the Nasdaq Capital Market; 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, 2024, filed with the Securities and Exchange Commission on February 25, 2025, as updated by its Quarterly Report on Form 10-Q for the quarter ended June 30, 2025. 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 the Company as of the date hereof, and the Company disclaims any obligation to update any forward-looking statements, except as required by law.

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CONDENSED CONSOLIDATED BALANCE SHEET DATA
(Unaudited)

	June 30, 2025	December 31, 2024
	(in thousands)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,248	$ 21,362
Restricted cash	100	100
Prepaid expenses and other current assets	200	807
Total current assets	15,548	22,269
Equipment, net	3	6
Goodwill	14,869	14,869
Total assets	$ 30,420	$ 37,144
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 897	$ 1,608
Accrued expenses and other current liabilities	1,632	1,229
Total current liabilities	2,529	2,837
Long-term liabilities:		
Liability related to the sale of future royalties	60,000	60,000
Total liabilities	62,529	62,837
Stockholders' deficit:		
Common stock	1	1
Additional paid-in capital	370,278	369,683
Accumulated deficit	(402,388)	(395,377)
Total stockholders' deficit	(32,109)	(25,693)

Total liabilities and stockholders' deficit	$ 30,420	$ 37,144

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30, (in thousands, except per share amounts)		Six Months Ended June 30, (in thousands, except per share amounts)	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 1,298	$ 3,860	$ 2,660	$ 8,028
General and administrative	2,076	2,417	4,617	4,932
Total operating expenses	3,374	6,277	7,277	12,960
Loss from operations	(3,374)	(6,277)	(7,277)	(12,960)
Foreign exchange (losses) gains	(21)	(5)	(30)	1
Investment income	136	361	295	719
Non-cash interest expense for the sale of future royalties	-	(2,312)	-	(4,562)
Net loss	$ (3,259)	$ (8,233)	$ (7,012)	$ (16,802)
Net loss per share, basic and diluted	$ (0.43)	$ (1.09)	$ (0.93)	$ (2.22)
Weighted average shares outstanding, basic and diluted	7,569	7,569	7,569	7,569