Minerva Neurosciences Reports First Quarter 2024 Financial Results and Business Updates

May 1, 2024

BURLINGTON, Mass., May 01, 2024 (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 business updates and financial results for the first quarter of 2024 ending March 31, 2024.

Roluperidone NDA Update

On February 27, 2024, the Company announced that the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) to its New Drug Application (NDA) for roluperidone (f/k/a MIN-101) for the treatment of negative symptoms in patients with schizophrenia. The Company is in discussions with the FDA regarding the issues and clinical deficiencies raised in the CRL.

Phase 1b Clinical Trial (MIN-101C18)

In the first quarter of 2024, the Company completed a clinical trial initiated in October 2023 to evaluate the safety, tolerability, pharmacodynamics and pharmacokinetics of the co-administration of roluperidone and olanzapine in adult subjects with moderate to severe negative symptoms of schizophrenia. This clinical trial (NCT06107803) was designed to investigate the pharmacodynamic and pharmacokinetic effects and safety of the concomitant therapy of roluperidone with an established and widely used antipsychotic. Of the 17 patients enrolled, 13 completed all 17 days of daily dosing of roluperidone at 64 mg. No new safety signals were observed during the study with few treatment-emergent adverse events (TEAEs), most of which were mild and all resolved without sequelae. No emergent clinically significant electrocardiogram or laboratory abnormalities were observed during the study. There was no symptomatic worsening during the administration of roluperidone alone (7 days) or when administered in combination with olanzapine at 10 mg (10 days).

The study demonstrated that pharmacokinetic interactions between the two drugs were not relevant.

First Quarter 2024 Financial Results

- **Research and development (R&D) expense**: For the three months ended March 31, 2024 and 2023, R&D expense was $4.2 million and $2.7 million, respectively. R&D expense was higher versus the prior year period primarily due to costs associated with the FDA's review of the Company's NDA and the conduct of the MIN-101C18 study.
- **General and administrative (G&A) expense:** For the three months ended March 31, 2024 and 2023, G&A expense was $2.5 million and $2.7 million, respectively. G&A expense was lower versus the prior year period primarily due to lower professional service fees.
- **Non-cash interest expense**: For the three months ended March 31, 2024 and 2023, non-cash interest expense for the sale of future royalties was $2.3 million and $2.0 million, respectively. The increase versus the prior year period was primarily due to the amortization of non-cash interest expense for the difference between the balance of the liability related to the sale of future royalties and the estimated amount of future royalties to be received over the royalty period.
- **Net loss:** Net loss was $8.6 million for the three months ended March 31, 2024, or net loss per share of $1.13 basic and diluted, as compared to net loss of $7.0 million for the three months ended March 31, 2023, or net loss per share of $1.31 basic and diluted.
- **Cash Position:** Cash, cash equivalents and restricted cash at March 31, 2024 were approximately $34.9 million, as compared to $41.0 million at December 31, 2023.

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 and MIN-301 for Parkinson's disease. 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 expectations concerning Minerva's ability to remediate or otherwise resolve issues and deficiencies identified in the CRL. 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, Minerva's ability to address FDA's feedback and timing thereof; uncertainties associated with regulatory processes, including the content and timing of decisions by the FDA; general risks associated with developing biopharmaceutical product candidates; management's ability to successfully achieve its goals; our ability to raise additional capital to fund its operations and corporate objectives on terms acceptable to Minerva; 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, 2023, filed with the Securities and Exchange Commission on February 22, 2024, as updated by its Quarterly Report on Form 10-Q for the quarter ended March 31, 2024. 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)

	March 31, 2024	December 31, 2023
	(in thousands)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 34,818	$ 40,913
Restricted cash	100	100
Refundable regulatory fee	-	-
Prepaid expenses and other current assets	703	989
Total current assets	35,621	42,002
Equipment and capitalized software, net	20	29
Goodwill	14,869	14,869
Total assets	$ 50,510	$ 56,900
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 1,435	$ 1,805
Accrued expenses and other current liabilities	1,395	1,535
Total current liabilities	2,830	3,340
Long-term liabilities:		
Liability related to the sale of future royalties	84,267	82,017
Total liabilities	87,097	85,357
Stockholders' deficit:		
Common stock	1	1
Additional paid-in capital	368,796	368,357
Accumulated deficit	(405,384)	(396,815)
Total stockholders' deficit	(36,587)	(28,457)
Total liabilities and stockholders' deficit	$ 50,510	$ 56,900

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31, (in thousands, except per share amounts)	
	2024	2023
Operating expenses:		
Research and development	$ 4,167	$ 2,653
General and administrative	2,515	2,695
Total operating expenses	6,682	5,348
Loss from operations	(6,682)	(5,348)
Foreign exchange gains (losses)	5	(9)

Investment income	358	364
Non-cash interest expense for the sale of future royalties	(2,250)	(1,977)
Net loss	$ (8,569)	$ (6,970)
Net loss per share, basic and diluted	$ (1.13)	$ (1.31)
Weighted average shares outstanding, basic and diluted	7,569	5,340