



Minerva Neurosciences Reports Third Quarter 2024 Financial Results and Business Updates

November 5, 2024

BURLINGTON, Mass., Nov. 05, 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 third quarter of 2024 ending September 30, 2024.

Roluperidone NDA Update

As [announced](#) in February 2024, the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) to our New Drug Application (NDA) for roluperidone (f/k/a MIN-101) for the treatment of negative symptoms in patients with schizophrenia. Interactions with the FDA continue with the goal of addressing questions raised in the CRL.

Third Quarter 2024 Financial Results

Research and development (R&D) expense: For the three months ended September 30, 2024 and 2023, R&D expense was \$1.9 million and \$3.4 million, respectively. R&D expense was lower versus the prior year period primarily due to lower costs associated with the FDA's review of our NDA for roluperidone and lower compensation expenses. For the nine months ended September 30, 2024 and 2023, R&D expense was \$9.9 million and \$8.0 million, respectively. R&D expense was higher versus the prior year period primarily due to higher subcontractor fees related to costs associated with our drug substance validation campaign and the conduct of the MIN-101C18 study, partially offset by lower compensation expenses.

General and administrative (G&A) expense: For the three months ended September 30, 2024 and 2023, G&A expense was \$2.5 million and \$2.6 million, respectively. G&A expense was lower versus the prior year period primarily due to lower compensation expenses. For the nine months ended September 30, 2024 and 2023, G&A expense was \$7.4 million and \$8.0 million, respectively. G&A expense was lower versus the prior year period primarily due to lower compensation expenses and professional service fees.

Non-cash interest expense: For the three and nine months ended September 30, 2024, non-cash interest expense for the sale of future royalties was zero and \$4.6 million, respectively, as compared to \$2.1 million and \$6.1 million for the three and nine months ended September 30, 2023, respectively. The non-cash interest expense was lower versus the prior year periods primarily due to the change in the effective annual interest rate of the liability related to the sale of future royalties, whereby we no longer recognize interest on the liability as the effective annual interest rate is negative.

Other income: For the three and nine months ended September 30, 2024 and 2023, other income was \$26.6 million and zero, respectively. Other income was higher versus the prior year periods due to the gain associated with the adjustment to the carrying amount of the liability related to the sale of future royalties.

Net income (loss): Net income for the three and nine months ended September 30, 2024 was \$22.5 million and \$5.7 million, or a basic and diluted net income per share of \$2.97 and \$0.75, respectively, as compared to a net loss for the three and nine months ended September 30, 2023 of \$7.8 million and \$21.0 million or a basic and diluted net loss per share of \$1.03 and \$3.41, respectively.

Cash Position: Cash, cash equivalents and restricted cash at September 30, 2024 were approximately \$26.6 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 and the timing and outcome of its interactions with the FDA. 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 September 30, 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.

Contact:

Investor inquiries:

Frederick Ahlholm
 Chief Financial Officer
 Minerva Neurosciences, Inc.
info@minervaneurosciences.com

Media inquiries:

Helen Shik
 Principal
 Shik Communications LLC
helen@shikcommunications.com

CONDENSED CONSOLIDATED BALANCE SHEET DATA
(Unaudited)

	September 30, 2024	December 31, 2023
	(in thousands)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 26,529	\$ 40,913
Restricted cash	100	100
Prepaid expenses and other current assets	1,307	989
Total current assets	27,936	42,002
Equipment and capitalized software, net	7	29
Goodwill	14,869	14,869
Total assets	\$ 42,812	\$ 56,900
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 553	\$ 1,805
Accrued expenses and other current liabilities	3,930	1,535
Total current liabilities	4,483	3,340
Long-term liabilities:		
Liability related to the sale of future royalties	60,000	82,017
Total liabilities	64,483	85,357
Stockholders' deficit:		
Common stock	1	1
Additional paid-in capital	369,433	368,357
Accumulated deficit	(391,105)	(396,815)
Total stockholders' deficit	(21,671)	(28,457)
Total liabilities and stockholders' deficit	\$ 42,812	\$ 56,900

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30, (in thousands, except per share amounts)		Nine Months Ended September 30, (in thousands, except per share amounts)	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ 1,888	\$ 3,444	\$ 9,916	\$ 7,985
General and administrative	2,479	2,635	7,410	7,963
Total operating expenses	4,367	6,079	17,326	15,948
Loss from operations	(4,367)	(6,079)	(17,326)	(15,948)
Foreign exchange losses	(13)	(5)	(12)	(21)
Investment income	314	349	1,032	1,079
Non-cash interest expense for the sale of future royalties	-	(2,085)	(4,562)	(6,093)
Other income	26,579	-	26,579	-
Net income (loss)	\$ 22,513	\$ (7,820)	\$ 5,711	\$ (20,983)

Net income (loss) per share, basic	\$	2.97	\$	(1.03)	\$	0.75	\$	(3.41)
Weighted average shares outstanding, basic		7,569		7,569		7,569		6,148
Net income (loss) per share, diluted	\$	2.97	\$	(1.03)	\$	0.75	\$	(3.41)
Weighted average shares outstanding, diluted		7,569		7,569		7,578		6,148