



Minerva Neurosciences Reports 2023 Third Quarter Financial Results and Business Updates

November 7, 2023

BURLINGTON, Mass., Nov. 07, 2023 (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 business updates and financial results for the third quarter ended September 30, 2023.

The Company continues to work with the U.S. Food and Drug Administration (FDA) during its review of its New Drug Application (NDA) for roluperidone for the treatment of negative symptoms of schizophrenia, in advance of the February 26, 2024 PDUFA date.

"We remain committed to bringing roluperidone to patients and physicians as we believe it addresses a significant unmet clinical need and has the potential to improve patients' quality of life and expand treatment options available to physicians. If approved, roluperidone would be the first medication for negative symptoms of schizophrenia to receive regulatory approval," said **Dr. Remy Luthringer, Executive Chairman and Chief Executive Officer of Minerva.**

Third Quarter 2023 Financial Results

- **Research and development (R&D) expense:** For the three months ended September 30, 2023 and 2022, R&D expense was \$3.4 million and \$2.4 million, respectively. R&D expense was higher versus the prior year primarily due to costs associated with the FDA's review of the Company's NDA. For the nine months ended September 30, 2023 and 2022, R&D expense was \$8.0 million and \$11.5 million, respectively. The decrease in R&D expense versus the prior year was primarily due to higher costs in 2022 related to the preparation of the NDA for roluperidone, which was submitted in August 2022.
- **General and administrative (G&A) expense:** For the three months ended September 30, 2023 and 2022, G&A expense was \$2.6 million and \$2.8 million, respectively. For the nine months ended September 30, 2023 and 2022, G&A expense was \$8.0 million and \$8.7 million, respectively. The decrease in G&A expense for the three and nine-months ended September 30, 2023 versus the prior year was primarily due to lower non-cash stock compensation costs.
- **Non-cash interest expense:** For the three months ended September 30, 2023 and 2022, non-cash interest expense for the sale of future royalties was \$2.1 million and \$1.9 million, respectively. For the nine months ended September 30, 2023 and 2022, non-cash interest expense was \$6.1 million and \$5.5 million, respectively. The Company amortizes non-cash interest expense for the difference between the balance of the liability related to the sale of future royalties and the estimated amount future royalties to be received over the royalty period.
- **Net loss:** Net loss was \$7.8 million for the three months ended September 30, 2023, or net loss per share of \$1.03 basic and diluted, as compared to net loss of \$6.9 million, or net loss per share of \$1.29 basic and diluted, for the three months ended September 30, 2022. Net loss was \$21.0 million for the nine months ended September 30, 2023, or net loss per share of \$3.41 basic and diluted, as compared to net loss of \$25.4 million, or net loss per share of \$4.75 basic and diluted for the nine months ended September 30, 2022.
- **Cash Position:** Cash, cash equivalents and restricted cash at September 30, 2023, were approximately \$47.0 million, as compared to \$36.2 million at December 31, 2022.

About Minerva Neurosciences

Minerva Neurosciences, Inc. (Nasdaq: NERV) is a clinical-stage biopharmaceutical company focused on developing product candidates to treat central nervous system (CNS) diseases. Our goal is to transform the lives of patients with improved therapeutic options. Minerva's portfolio of compounds includes roluperidone (f/k/a MIN-101), for negative symptoms of schizophrenia, and MIN-301, for Parkinson's disease. For more information, please visit our [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

the regulatory progress and therapeutic potential of roluperidone for the treatment of negative symptoms in patients with schizophrenia. 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 FDA will require additional trials or data which may significantly delay and put at risk our efforts to obtain regulatory approval; whether the FDA may meet expected review timelines for our NDA; whether roluperidone will be successfully marketed if approved; management's ability to successfully achieve its goals; our ability to raise additional capital to fund our operations and corporate objectives on terms acceptable to us; general economic conditions; and other factors that are described under the caption "Risk Factors" in our filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission on March 8, 2023, as updated by our Quarterly Report on Form 10-Q for the quarter ended September 30, 2023. Copies of reports filed with the SEC are posted on our website at <http://ir.minervaneurosciences.com/>. The forward-looking statements in this press release are based on information available to us as of the date hereof, and we disclaim 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, 2023		December 31, 2022	
	(in thousands)			
ASSETS				
Current Assets:				
Cash and cash equivalents	\$	46,904	\$	36,094
Restricted cash		100		100
Refundable regulatory fee		-		3,117
Prepaid expenses and other current assets		1,221		848
Total current assets		48,225		40,159
Equipment & capitalized software, net		36		59
Goodwill		14,869		14,869
Total Assets	\$	63,130	\$	55,087
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY				
Current Liabilities:				
Accounts payable	\$	1,395	\$	969
Accrued expenses and other current liabilities		1,955		408
Total current liabilities		3,350		1,377
Long-Term Liabilities:				
Liability related to the sale of future royalties		79,826		73,734
Total liabilities		83,176		75,111
Stockholders' (Deficit) Equity:				
Common stock		1		1
Additional paid-in capital		367,746		346,785
Accumulated deficit		(387,793)		(366,810)
Total stockholders' (deficit) equity		(20,046)		(20,024)
Total Liabilities and Stockholders' (Deficit) Equity	\$	63,130	\$	55,087

**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)	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 3,444	\$ 2,367	\$ 7,985	\$ 11,459
General and administrative	2,635	2,840	7,963	8,703

Total operating expenses	6,079	5,207	15,948	20,162
Loss from operations	(6,079)	(5,207)	(15,948)	(20,162)
Foreign exchange (losses) gains	(5)	2	(21)	-
Investment income	349	180	1,079	260
Non-cash interest expense for the sale of future royalties	(2,085)	(1,875)	(6,093)	(5,481)
Net loss	\$ (7,820)	\$ (6,900)	\$ (20,983)	\$ (25,383)
Net loss per share, basic and diluted	\$ (1.03)	\$ (1.29)	\$ (3.41)	\$ (4.75)
Weighted average shares outstanding, basic and diluted	7,569	5,340	6,148	5,340