



## Minerva Neurosciences Reports Fourth Quarter and Fiscal Year 2023 Financial Results and Business Updates

February 22, 2024

BURLINGTON, Mass., Feb. 22, 2024 (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 fourth quarter and year ended December 31, 2023.

### Corporate Update

On May 8 2023, the U.S. Food and Drug Administration (FDA) confirmed acceptance for filing of Minerva's New Drug Application (NDA) for roluperidone for the treatment of negative symptoms of schizophrenia. The Company was advised of a Prescription Drug User Fee Act (PDUFA) goal date of February 26, 2024 and has continued to work with the FDA during its review of the NDA.

"Minerva achieved a significant milestone in 2023, with the acceptance of our NDA for roluperidone, which if approved will be the first ever medication for negative symptoms of schizophrenia to receive regulatory approval. This milestone also brings hope to the patients, families and physicians caring for those experiencing negative symptoms of schizophrenia who currently have no treatment options," said Dr. Remy Luthringer, Executive Chairman and Chief Executive Officer of Minerva.

### Fourth Quarter and Year End Financial Results

- **Research and development (R&D) expense:** For the three months ended December 31, 2023 and 2022, R&D expense was \$4.7 million and \$3.2 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 higher compensation expenses. For the years ended December 31, 2023 and 2022, R&D expense was \$12.7 million and \$14.6 million, respectively. The decrease in R&D expense versus the prior year was primarily due to lower costs related to the preparation of our NDA for roluperidone, which was submitted during 2022, and lower non-cash stock compensation costs, partially offset by higher compensation expenses.
- **General and administrative (G&A) expense:** For the three months ended December 31, 2023 and 2022, G&A expense was \$2.5 million and \$1.9 million, respectively. G&A expense was higher versus the prior year period primarily due to higher compensation expenses and professional service fees. For the years ended December 31, 2023 and 2022, G&A expense was \$10.4 million and \$10.6 million, respectively. The decrease in G&A expense versus the prior year was primarily due to lower non-cash stock compensation costs and insurance costs, partially offset by higher professional service fees and compensation expenses.
- **Non-cash interest expense:** For the three months ended December 31, 2023 and 2022, non-cash interest expense for the sale of future royalties was \$2.2 million and \$1.9 million, respectively. For the years ended December 31, 2023 and 2022, non-cash interest expense was \$8.3 million and \$7.4 million, respectively. The increase for both the fourth quarter and year ended December 31, 2023 versus the prior year periods 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 \$9.0 million for the three months ended December 31, 2023, or net loss per share of \$1.19 basic and diluted, as compared to net loss of \$6.7 million, or net loss per share of \$1.26 basic and diluted, for the three months ended December 31, 2022. Net loss was \$30.0 million for the year ended December 31, 2023, or net loss per share of \$4.61 basic and diluted, as compared to net loss of \$32.1 million, or net loss per share of \$6.01 basic and diluted for the year ended December 31, 2022.
- **Cash Position:** Cash, cash equivalents and restricted cash at December 31, 2023, were approximately \$41.0 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, 2023, filed with the Securities and Exchange Commission on February 22, 2024. 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.

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**CONDENSED CONSOLIDATED BALANCE SHEET DATA  
(Unaudited)**

	December 31, 2023	December 31, 2022
	(in thousands)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 40,913	\$ 36,094
Restricted cash	100	100
Refundable regulatory fee	-	3,117
Prepaid expenses and other current assets	989	848
Total current assets	42,002	40,159
Equipment and capitalized software, net	29	59
Goodwill	14,869	14,869
Total assets	\$ 56,900	\$ 55,087
<b>LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,805	\$ 969
Accrued expenses and other current liabilities	1,535	408
Total current liabilities	3,340	1,377
Long-term liabilities:		
Liability related to the sale of future royalties	82,017	73,734
Total liabilities	85,357	75,111
Stockholders' (deficit) equity:		
Common stock	1	1
Additional paid-in capital	368,357	346,785
Accumulated deficit	(396,815)	(366,810)
Total stockholders' (deficit) equity	(28,457)	(20,024)
Total liabilities and stockholders' (deficit) equity	\$ 56,900	\$ 55,087

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
(Unaudited)**

	Three Months Ended December 31, (in thousands, except per share amounts)		Twelve Months Ended December 31, (in thousands, except per share amounts)	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 4,721	\$ 3,190	\$ 12,705	\$ 14,649
General and administrative	2,451	1,880	10,414	10,582
Total operating expenses	<u>7,172</u>	<u>5,070</u>	<u>23,119</u>	<u>25,231</u>
Loss from operations	(7,172)	(5,070)	(23,119)	(25,231)
Foreign exchange (losses) gains	(19)	(28)	(40)	(28)
Investment income	359	297	1,437	557
Non-cash interest expense for the sale of future royalties	(2,190)	(1,925)	(8,283)	(7,407)
Net loss	<u>\$ (9,022)</u>	<u>\$ (6,726)</u>	<u>\$ (30,005)</u>	<u>\$ (32,109)</u>
Net loss per share, basic and diluted	<u>\$ (1.19)</u>	<u>\$ (1.26)</u>	<u>\$ (4.61)</u>	<u>\$ (6.01)</u>
Weighted average shares outstanding, basic and diluted	<u>7,569</u>	<u>5,340</u>	<u>6,506</u>	<u>5,340</u>