

Minerva Neurosciences Reports 2023 Second Quarter Financial Results and Business Updates

August 1, 2023

BURLINGTON, Mass., Aug. 01, 2023 (GLOBE NEWSWIRE) -- <u>Minerva Neurosciences. Inc.</u> (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 second quarter ended June 30, 2023.

"In the second quarter, we completed an equity financing of \$20.0 million, further strengthening our cash position. This investment from Boehringer Ingelheim and Federated Hermes Kaufman Funds comes as we continue to interact with the FDA in support of their review of our New Drug Application (NDA) for roluperidone for the treatment of negative symptoms of schizophrenia."

"We remain committed to bringing roluperidone to patients and physicians, as we believe it has the potential to improve patients' quality of life and expand the treatment options physicians can offer their patients. Roluperidone, if approved, would be the first medication for negative symptoms of schizophrenia, a recognized unmet clinical need," said Dr. Remy Luthringer, Executive Chairman and Chief Executive Officer of Minerva.

Q2 2023 Business Highlights

- On <u>June 30, 2023</u>, the Company completed a private investment in public equity financing of \$20 million in gross proceeds from Boehringer Ingelheim, a global biopharmaceutical company with a growing mental health pipeline that includes schizophrenia, and Federated Hermes Kaufmann Funds.
- On May 8, 2023, the FDA confirmed that they had assigned a Prescription Drug User Fee Act (PDUFA) goal date of February 26, 2024.
- On <u>April 27, 2023</u>, the FDA confirmed the filing of Minerva's NDA for roluperidone for the treatment of negative symptoms in patients with schizophrenia.

Second Quarter 2023 Financial Results

- Research and development ("R&D") expense: R&D expense was \$1.9 million and \$4.5 million for the three and six months ended June 30, 2023, respectively, as compared to \$4.1 million and \$9.1 million for the three and six months ended June 30, 2022, respectively. The decrease of \$2.2 million and \$4.6 million in R&D expense for the three and six months ended June 30, 2023 versus the prior year periods was primarily due to lower non-cash stock compensation costs and lower consultant fees related to the preparation of the Company's NDA for roluperidone, which was submitted during 2022, partially offset by higher professional service fees and staffing related expenses during 2023. Non-cash stock compensation costs included in R&D expense was \$0.3 million and \$0.5 million for the three and six months ended June 30, 2023, respectively, as compared to \$0.5 million and \$1.0 million for the three and six months ended June 30, 2022, respectively.
- General and administrative (G&A) expense: G&A expense was \$2.6 million and \$5.3 million for the three and six months ended June 30, 2023, respectively, as compared to \$2.8 million and \$5.9 million for the three and six months ended June 30, 2022, respectively. The decrease of approximately \$0.2 million and \$0.6 million for the three and six months ended June 30, 2023 versus the prior year periods was primarily due to lower non-cash stock compensation expense and insurance costs, partially offset by higher staffing related expenses during 2023. Non-cash stock compensation costs included in G&A expense was \$0.3 million and \$0.5 million for the three and six months ended June 30, 2023, respectively, as compared to \$0.6 million and \$1.1 million for the three and six month periods ended June 30, 2022, respectively.
- Non-cash interest expense: For the three and six months ended June 30, 2023, we recognized non-cash interest expense of \$2.0 million and \$4.0 million, respectively, as compared to \$1.8 million and \$3.6 million for the three and six months ended June 30, 2022, respectively. The increase in non-cash interest expense for both periods was primarily due to an increase in the carrying value of the liability related to the sale of future royalties for seltorexant to Royalty Pharma, for which upfront milestone payments are being amortized under the interest method over the estimated life of the agreement.
- Net loss: Basic and diluted net loss for the three and six months ended June 30, 2023 was \$6.2 million and \$13.2 million, or a loss per share of \$1.12 and \$2.43, respectively, as compared to a net loss for the three and six months ended June 30, 2022 of \$8.7 million and \$18.5 million or a loss per share of \$1.63 and \$3.46, respectively.

• Cash Position: Cash, cash equivalents, and restricted cash as of June 30, 2023, were approximately \$51.9 million, as compared to \$36.2 million as of December 31, 2022. In June 2023, we issued approximately 1.4 million shares of common stock and approximately 0.6 million pre-funded warrants to purchase common shares to two investors for gross proceeds to the Company of \$20.0 million.

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 (MIN-101), for negative symptoms of schizophrenia, and MIN-301, for Parkinson's disease. For more information, please visit our <u>website</u>.

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 June 30, 2023. Copies of reports filed with the SEC are posted on our website at <u>http://ir.minervaneurosciences.com/</u>. 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, in thousands)

(onaddied, in mousands)	Ju	une 30, 2023	December	31, 2022
ASSETS				
Current Assets:				
Cash and cash equivalents	\$	51,797	\$	36,094
Restricted cash		100		100
Refundable regulatory fee		-		3,117
Prepaid expenses and other current assets		329		848
Total current assets		52,226		40,159
Equipment & capitalized software, net		44		59
Goodwill		14,869		14,869
Total Assets	\$	67,139	\$	55,087
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY				
Current Liabilities:				
Accounts payable	\$	298	\$	969
Accrued expenses and other current liabilities		1,610		408
Total current liabilities		1,908		1,377
Long-Term Liabilities:				
Liability related to the sale of future royalties		77,742		73,734
Total liabilities		79,650		75,111
Stockholders' (Deficit) Equity:				
Common stock		1		1

Additional paid-in capital	367,461	346,785
Accumulated deficit	 (379,973)	(366,810)
Total stockholders' (deficit) equity	 (12,511)	(20,024)
Total Liabilities and Stockholders' (Deficit) Equity	\$ 67,139 \$	55,087

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)			
		2023	2022		2023	2022	
Operating expenses:							
Research and development	\$	1,887 \$	4,132	\$	4,541 \$	9,092	
General and administrative		2,633	2,833		5,327	5,862	
Total operating expenses		4,520	6,965		9,868	14,954	
Loss from operations		(4,520)	(6,965)		(9,868)	(14,954)	
Foreign exchange (losses) gains		(7)	2		(16)	(2)	
Investment income		365	72		730	80	
Non-cash interest expense for the sale of future royalties		(2,030)	(1,827)		(4,008)	(3,606)	
Net loss	\$	(6,192) \$	(8,718)	\$	(13,162) \$	(18,482)	
Net loss per share, basic and diluted	\$	(1.12) \$	(1.63)	\$	(2.43) \$	(3.46)	
Weighted average shares outstanding, basic and diluted		5,511	5,340		5,426	5,340	