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

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CONDENSED CONSOLIDATED BALANCE SHEET DATA
(Unaudited)

	December 31, 2023	December 31, 2022
	(in thousands)	
ASSETS		
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
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
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	7,172	5,070	23,119	25,231
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	$ (9,022)	$ (6,726)	$ (30,005)	$ (32,109)
Net loss per share, basic and diluted	$ (1.19)	$ (1.26)	$ (4.61)	$ (6.01)
Weighted average shares outstanding, basic and diluted	7,569	5,340	6,506	5,340