



Minerva Neurosciences Reports Second Quarter 2024 Financial Results and Business Updates

August 6, 2024

BURLINGTON, Mass., Aug. 06, 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 second quarter of 2024 ending June 30, 2024.

Roluperidone NDA Update

During the first quarter of this year, the Company [announced](#) that the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) to its New Drug Application (NDA) for roluperidone (f/k/a MIN-101) for the treatment of negative symptoms in patients with schizophrenia. Since receiving the CRL, the Company has continued to have interactions with the FDA with the goal of addressing questions raised in the CRL.

Second Quarter 2024 Financial Results

Research and development (R&D) expense: For the three months ended June 30, 2024 and 2023, R&D expense was \$3.9 million and \$1.9 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, partially offset by lower compensation expenses. For the six months ended June 30, 2024 and 2023, R&D expense was \$8.0 million and \$4.5 million, respectively. R&D expense was higher versus the prior year period primarily due to costs associated with our drug substance validation campaign and the conduct of the MIN-101C18 study.

General and administrative (G&A) expense: For the three months ended June 30, 2024 and 2023, G&A expense was \$2.4 million and \$2.6 million, respectively. G&A expense was lower versus the prior year period primarily due to lower compensation expenses. For the six months ended June 30, 2024 and 2023, G&A expense was \$4.9 million and \$5.3 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 six months ended June 30, 2024, non-cash interest expense for the sale of future royalties was \$2.3 million and \$4.6 million, respectively, as compared to \$2.0 million and \$4.0 million for the three and six months ended June 30, 2023, respectively. The increase versus the prior year period 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 for the three and six months ended June 30, 2024 was \$8.2 million and \$16.8 million, or a basic and diluted net loss per share of \$1.09 and \$2.22, respectively, as compared to a net loss for the three and six months ended June 30, 2023 of \$6.2 million and \$13.2 million or a basic and diluted net loss per share of \$1.12 and \$2.43, respectively.

Cash Position: Cash, cash equivalents and restricted cash at June 30, 2024 were approximately \$31.0 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 June 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.

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CONDENSED CONSOLIDATED BALANCE SHEET DATA
(Unaudited)

| | June 30, 2024 | December 31, 2023 |
|---|----------------|-------------------|
| | (in thousands) | |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 30,881 | \$ 40,913 |
| Restricted cash | 100 | 100 |
| Prepaid expenses and other current assets | 428 | 989 |
| Total current assets | 31,409 | 42,002 |
| Equipment and capitalized software, net | 13 | 29 |
| Goodwill | 14,869 | 14,869 |
| Total assets | \$ 46,291 | \$ 56,900 |
| LIABILITIES AND STOCKHOLDERS' DEFICIT | | |
| Current liabilities: | | |
| Accounts payable | \$ 829 | \$ 1,805 |
| Accrued expenses and other current liabilities | 3,375 | 1,535 |
| Total current liabilities | 4,204 | 3,340 |
| Long-term liabilities: | | |
| Liability related to the sale of future royalties | 86,579 | 82,017 |
| Total liabilities | 90,783 | 85,357 |
| Stockholders' deficit: | | |
| Common stock | 1 | 1 |
| Additional paid-in capital | 369,125 | 368,357 |
| Accumulated deficit | (413,618) | (396,815) |
| Total stockholders' deficit | (44,492) | (28,457) |
| Total liabilities and stockholders' deficit | \$ 46,291 | \$ 56,900 |

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) | |
|--|--|------------|--|-------------|
| | 2024 | 2023 | 2024 | 2023 |
| Operating expenses: | | | | |
| Research and development | \$ 3,860 | \$ 1,887 | \$ 8,028 | \$ 4,541 |
| General and administrative | 2,417 | 2,633 | 4,932 | 5,327 |
| Total operating expenses | 6,277 | 4,520 | 12,960 | 9,868 |
| Loss from operations | (6,277) | (4,520) | (12,960) | (9,868) |
| Foreign exchange (losses) gains | (5) | (7) | 1 | (16) |
| Investment income | 361 | 365 | 719 | 730 |
| Non-cash interest expense for the sale of future royalties | (2,312) | (2,030) | (4,562) | (4,008) |
| Net loss | \$ (8,233) | \$ (6,192) | \$ (16,802) | \$ (13,162) |
| Net loss per share, basic and diluted | \$ (1.09) | \$ (1.12) | \$ (2.22) | \$ (2.43) |
| Weighted average shares outstanding, basic and diluted | 7,569 | 5,511 | 7,569 | 5,426 |