



Minerva Neurosciences Reports Second Quarter 2021 Financial Results and Business Updates

August 2, 2021

WALTHAM, Mass., Aug. 02, 2021 (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 key business updates and financial results for the quarter ended June 30, 2021.

Roluperidone Update

Following the completion of the open-label portion of the Phase 3 trial with roluperidone in schizophrenia and the Type C meeting with the U.S. Food and Drug Administration (FDA), the Company continues to work towards the submission of a New Drug Application (NDA) in the first half of 2022. On June 29, 2021, the Company completed the enrollment of 48 subjects in a pivotal bioequivalence study with roluperidone in healthy volunteers. The objective of this study is to compare the formulations employed in the Phase 2b and Phase 3 trials with roluperidone, as well as at least one new formulation designed in conjunction with the Company's commercial supplier to facilitate large scale manufacturing. Top line results from this study are expected in the third quarter of 2021.

"Demonstration of bioequivalence between the formulations used in our late-stage studies with roluperidone will be an important step toward advancing our NDA package," said Dr. Luthringer. "We are working in parallel on additional activities to support the submission of the NDA that were informed by interactions we have had since the Type C meeting with the FDA. We continue to view roluperidone as a significant innovative agent for the treatment of negative symptoms of schizophrenia, a key unmet need among patients with this disease."

Second Quarter 2021 Financial Results

- **Net Income/Loss:** Net loss was \$10.6 million for the second quarter of 2021, or net loss per share of \$0.25 basic and diluted, as compared to net income of \$29.5 million, or net income per share of \$0.75 basic and \$0.73 diluted, for the second quarter of 2020. Net loss was \$19.4 million for the six months ended June 30, 2021, or net loss per share of \$0.45 basic and diluted, as compared to net income of \$17.4 million, or net income per share of \$0.44 basic and \$0.43 diluted for the six months ended June 30, 2020.

The decreases in net income for both the three and six month periods ended June 30, 2021 were primarily due to the Company's opting out of its joint development agreement with Janssen Pharmaceutica for seltorexant during the second quarter of 2020. As a result of opting out of the agreement, the Company immediately recognized \$41.2 million in collaborative revenue which had previously been included on the balance sheet under deferred revenue.

Net loss during the three and six month periods ended June 30, 2021 included non-cash interest expense of \$1.6 million and \$2.9 million, respectively, versus zero expense for both periods during 2020. The non-cash interest is incurred in connection with the Liability related to the sale of future royalties to Royalty Pharma in January of this year, which is included on the Company's balance sheet.

- **R&D Expense:** For the three months ended June 30, 2021 and 2020, research and development (R&D) expense was \$5.5 million and \$5.8 million, respectively, a decrease of approximately \$0.3 million. For the three months ended June 30, 2021 and 2020, non-cash stock compensation expense included in R&D was \$0.6 million and \$0.7 million, respectively.

For the six months ended June 30, 2021 and 2020, R&D expense was \$8.8 million and \$13.8 million, respectively, a decrease of approximately \$5.0 million. For the six months ended June 30, 2021 and 2020, non-cash stock compensation expense included in R&D was \$1.3 million and \$1.4 million, respectively.

The decrease in R&D expense for both the three and six month periods ended June 30, 2021 versus the same periods in 2020 was primarily due to lower costs for the Phase 3 clinical trial of roluperidone, for which the three-month core study portion of the trial was completed in May 2020.

- **G&A Expense:** For the three months ended June 30, 2021 and 2020, general and administrative (G&A) expense was \$3.4 million and \$5.9 million, respectively, a decrease of approximately \$2.5 million. For the three months ended June 30, 2021 and 2020, non-cash stock compensation expense included in G&A was \$0.7 million and \$2.8 million, respectively.

For the six months ended June 30, 2021 and 2020, G&A expense was \$7.7 million and \$10.1 million, respectively, a decrease of approximately \$2.4 million. For the six months ended June 30, 2021 and June 30, 2020, non-cash stock compensation expense included in G&A was \$1.6 million and \$4.3 million, respectively.

The decrease in G&A expense for both the three and six month periods ended June 30, 2021 was primarily due to a decrease in non-cash stock-based compensation. Stock-based compensation charges were higher in 2020 primarily due to the approval of certain stock option grants and certain severance related benefits.

- **Cash Position:** Cash, cash equivalents, restricted cash and marketable securities as of June 30, 2021 were approximately \$74.3 million, compared to \$25.5 million as of December 31, 2020.

Conference Call Information:

Minerva Neurosciences will host a conference call and live audio webcast today at 8:30 a.m. Eastern Time to discuss the quarter and recent business activities. To participate, please dial (877) 312-5845 (domestic) or (765) 507-2618 (international) and refer to conference ID 4327209.

The live webcast can be accessed under "Events and Presentations" in the Investors and Media section of Minerva's website at ir.minervaneurosciences.com. The archived webcast will be available on the website beginning approximately two hours after the event for 90 days.

About Minerva Neurosciences

Minerva's portfolio of compounds includes: roluperidone (MIN-101), in clinical development for schizophrenia, and MIN-301, in pre-clinical development for Parkinson's disease. Minerva's common stock is listed on the Nasdaq Global Market under the symbol "NERV." For more information, please visit www.minervaneurosciences.com.

Forward-Looking Safe Harbor Statement

This press release contains forward-looking statements. 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 timing and scope of clinical trials and regulatory review and results and outcomes of such clinical trials and regulatory review with roluperidone (MIN-101); the clinical and therapeutic potential of this compound; the likelihood of successful clinical trials, regulatory review, commercialization, and future sales of and potential royalty stream from seltorexant; the timing and outcomes of future interactions with U.S. and foreign regulatory bodies, including the U.S. Food and Drug Administration; our ability to successfully develop and commercialize our therapeutic products; the sufficiency of our current cash position to fund our operations; and management's ability to successfully achieve its goals. 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 roluperidone will advance further in the clinical trials process and whether and when, if at all, it will receive final approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies and for which indications; whether any of our therapeutic products or seltorexant will be successfully marketed if approved; whether any of our therapeutic product discovery and development efforts will be successful; management's ability to successfully achieve its goals; our ability to raise additional capital to fund our operations on terms acceptable to us; changes in expected or existing competition; unexpected litigation or other disputes; the impacts of the COVID-19 pandemic on our business; and general economic conditions. These and other potential risks and uncertainties that could cause actual results to differ from the results predicted are more fully detailed under the caption "Risk Factors" in our filings with the Securities and Exchange Commission, including our Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, filed with the Securities and Exchange Commission on August 2, 2021. Copies of reports filed with the SEC are posted on our website at www.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.

CONDENSED CONSOLIDATED BALANCE SHEET DATA

(Unaudited)

	June 30, 2021	December 31, 2020
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 74,215	\$ 25,357
Marketable securities	-	-
Restricted cash	100	100
Prepaid expenses and other current assets	910	1,983
Total current assets	75,225	27,440
Equipment, net	-	-
Other noncurrent assets	15	15
Operating lease right-of-use assets	15	102
In-process research and development	15,200	15,200
Goodwill	14,869	14,869
Total Assets	\$ 105,324	\$ 57,626
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 1,594	\$ 996
Accrued expenses and other current liabilities	2,834	2,053
Operating leases	16	111
Total current liabilities	4,444	3,160
Long-Term Liabilities:		
Deferred taxes	1,803	1,803
Deferred revenue	-	-
Liability related to the sale of future royalties	62,908	-
Noncurrent operating leases	-	-
Total liabilities	69,155	4,963
Stockholders' Equity:		
Common stock	4	4

Additional paid-in capital	340,354	337,454
Accumulated deficit	(304,189)	(284,795)
Total stockholders' equity	36,169	52,663
Total Liabilities and Stockholders' Equity	\$ 105,324	\$ 57,626

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)	
	2021	2020	2021	2020
Collaborative revenue	\$ -	\$ 41,176	\$ -	\$ 41,176
Operating expenses:				
Research and development	5,521	5,767	8,780	13,849
General and administrative	3,442	5,901	7,691	10,090
Total operating expenses	8,963	11,668	16,471	23,939
Loss from operations	(8,963)	29,508	(16,471)	17,237
Foreign exchange losses	(19)	(4)	(24)	(13)
Investment income	5	25	9	154
Non-cash interest expense for the sale of future royalties	(1,612)	-	(2,908)	-
Loss before income taxes	(10,589)	29,529	(19,394)	17,378
Net income (loss) per share, basic	\$ (0.25)	\$ 0.75	\$ (0.45)	\$ 0.44
Weighted average shares outstanding, basic	42,722	39,483	42,722	39,330
Net income (loss) per share, diluted	\$ (0.25)	\$ 0.73	\$ (0.45)	\$ 0.43
Weighted average shares outstanding, diluted	42,722	40,278	42,722	40,145

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Source: Minerva Neurosciences, Inc