



Minerva Neurosciences Reports Third Quarter 2020 Financial Results And Business Updates

November 2, 2020

WALTHAM, Mass., Nov. 02, 2020 (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 September 30, 2020.

Clinical program update

Roluperidone

The U.S. Food and Drug Administration (FDA) has granted Minerva a Type C meeting scheduled to take place via teleconference on November 10, 2020. This meeting will provide an opportunity for the Company to review clinical data generated to date with roluperidone, including the recently completed double-blind part of the Phase 3 trial for the treatment of negative symptoms in schizophrenia, and to solicit recommendations from the FDA regarding these data and the readiness of the roluperidone data package to support a New Drug Application submission. The Company expects to provide an update in mid-late December 2020 following receipt of the official minutes of the meeting.

"The objective of our upcoming meeting with the FDA is to discuss and define a path forward for roluperidone, Minerva's lead product," said Dr. Remy Lühringer, Executive Chairman and Chief Executive Officer of Minerva. "Negative symptoms continue to represent the leading unmet need in the treatment of schizophrenia, as well as significant symptoms in a number of other psychiatric disorders. Our analyses of the recently announced Phase 3 trial top line results, in conjunction with the database we have generated to date, support our confidence in roluperidone's potential to be a novel treatment in this space."

Third Quarter 2019 Financial Results

- **Cash Position:** Cash, cash equivalents and restricted cash as of September 30, 2020 were approximately \$32.6 million.
- **R&D Expenses:** Research and development (R&D) expenses for the three and nine months ended September 30, 2020 were \$4.6 million and \$18.5 million, respectively, compared to \$9.7 million and \$29.6 million for the same periods in 2019. The decreases in R&D expenses primarily reflect lower development expenses for the Phase 3 clinical trial of roluperidone and the completion of the Phase 2b clinical trial of MIN-117 in December 2019. The Company expects R&D expenses to decrease during 2020 as compared to 2019 following the completion of the MIN-117 clinical trial as well as the 12-week, double-blind portion of the Phase 3 clinical trial of roluperidone.
- **G&A Expenses:** General and administrative (G&A) expenses for the three and nine months ended September 30, 2020 were \$3.5 million and \$13.5 million, respectively, compared to \$4.6 million and \$13.9 million for the same periods in 2019. The decrease in G&A expenses in the three-month period was primarily due to a decrease in non-cash stock-based compensation expenses and lower commercial expenses, and the decrease in G&A expenses in the nine-month period was primarily due to lower commercial expenses.
- **Net Loss/Income:** Net loss for the three months ended September 30, 2020 was \$8.1 million, or a loss per share of \$0.19 basic and diluted, compared to a net loss of \$14.0 million, or a loss per share of \$0.36 basic and diluted for the three months ended September 30, 2019. For the nine months ended September 30, 2020, net income was \$9.3 million, or \$0.23 basic and diluted, compared to a net loss of \$42.3 million, or net loss per share of \$1.08 basic and diluted for the nine months ended September 30, 2019.

Collaborative revenue was \$41.2 million for the nine months ended September 30, 2020 compared to zero for the same period in 2019, an increase of \$41.2 million. The increase in collaborative revenue was the result of the Company's opting out of its co-development and license agreement with Janssen for seltorexant. That revenue was recognized during the second quarter of 2020 as there are no future performance obligations under the agreement.

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 number 9459728.

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; a potential royalty stream from seltorexant (MIN-202 or JNJ-42847922), in clinical development for insomnia and major depressive disorder; 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 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 statements herein with respect to the timing and scope of future clinical trials and results of clinical trials with roluperidone (MIN-101); the clinical and therapeutic potential of this compound; the likelihood of future sales and a royalty stream from seltorexant; the timing and outcomes of future interactions with U.S. and foreign regulatory bodies; 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 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; 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 September 30, 2020, filed with the Securities and Exchange Commission on November 2, 2020. 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)

	September 30,	December 31,
	2020	2019
(in thousands)		
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 32,516	\$ 21,413
Marketable securities	-	24,442
Restricted cash	100	100
Prepaid expenses and other current assets	2,374	1,182
Total current assets	<u>34,990</u>	<u>47,137</u>
Equipment, net	3	16
Other noncurrent assets	15	15
Operating lease right-of-use assets	143	262
In-process research and development	15,200	15,200
Goodwill	14,869	14,869
Total Assets	<u>\$ 65,220</u>	<u>\$ 77,499</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 702	\$ 2,317
Accrued expenses and other current liabilities	4,536	4,139
Operating leases	157	173
Total current liabilities	<u>5,395</u>	<u>6,629</u>
Long-Term Liabilities:		
Deferred taxes	1,803	1,803
Deferred revenue	-	41,176
Noncurrent operating leases	-	111
Total liabilities	<u>7,198</u>	<u>49,719</u>
Stockholders' Equity:		
Common stock	4	4
Additional paid-in capital	335,489	314,512
Accumulated deficit	(277,471)	(286,736)
Total stockholders' equity	<u>58,022</u>	<u>27,780</u>
Total Liabilities and Stockholders' Equity	<u>\$ 65,220</u>	<u>\$ 77,499</u>

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30	
	(in thousands, except per share amounts)	2020	(in thousands, except per share amounts)	2020
	2019		2019	
Collaborative revenue	\$ -	\$ -	\$ 41,176	\$ -
Operating expenses:				
Research and development	4,639	9,674	18,488	29,600
General and administrative	3,452	4,608	13,541	13,898
Total operating expenses	8,091	14,282	32,029	43,498
Gain (loss) from operations	(8,091)	14,282	9,147	43,498
Foreign exchange losses	(27)	(5)	(41)	(18)
Investment income	5	325	159	1,250
Income loss before income taxes	(8,113)	(13,962)	9,265	(42,266)
Net income (loss) per share, basic	\$ (0.19)	\$ (0.36)	\$ 0.23	\$ (1.08)
Weighted average shares outstanding, basic	41,918	39,025	40,199	39,007
Net income (loss) per share, diluted	\$ (0.19)	\$ (0.36)	\$ 0.23	\$ (1.08)
Weighted average shares outstanding, diluted	41,918	39,025	40,478	39,007

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Source: Minerva Neurosciences, Inc