Minerva Neurosciences Reports Third Quarter 2018 Financial Results and Business Updates

November 5, 2018

Data readouts from five ongoing late-stage trials expected in 2019

WALTHAM, Mass., Nov. 05, 2018 (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, 2018.

“Over the last quarter, we have continued to enroll patients into five clinical trials with roluperidone (MIN-101), seltorexant (MIN-202) and MIN-117,” said Dr. Remy Luthringer, Executive Chairman and Chief Executive Officer of Minerva. “Momentum continues to build in the enrollment of patients in our Phase 3 trial with roluperidone. We are nearing our target number of clinical sites, including certain sites initiated following the decision by two eastern European countries not to participate in this trial. We expect the completion of enrollment during the first half of 2019 and top-line results in mid-2019.

“All other trials are proceeding on schedule with existing data readout timelines, as we have previously guided,” said Dr. Luthringer. “We believe that each of our clinical-stage product candidates has the potential to have a meaningful impact on the CNS therapeutic landscape and improve the quality of life of patients and their families.”

Summary of ongoing clinical trials with the Company’s products :

- Roluperidone: Phase 3 trial to treat negative symptoms in patients diagnosed with schizophrenia (monotherapy); top line results from the 12-week double blind phase of this trial are expected in mid-2019.
- MIN-117: Phase 2b trial to treat patients with major depressive disorder who also have symptoms of anxiety (monotherapy); top-line results are expected in the first half of 2019.
- Seltorexant (MIN-202): two Phase 2b trials to treat patients with major depressive disorder (adjunctive therapy); results expected in 2019.
- Seltorexant: one Phase 2b trial to treat patients with insomnia disorder (monotherapy); results expected in 2019.

Third Quarter 2018 Financial Results

- **Cash Position:** Cash, cash equivalents, restricted cash and marketable securities as of September 30, 2018 were approximately $97.7 million, compared to $133.3 million as of December 31, 2017.

- **R&D Expenses:** Research and development (R&D) expenses for the three and nine months ended September 30, 2018 were $8.4 million and $25.9 million, respectively, compared to $9.0 million and $23.7 million for the same periods in 2017. This variance in R&D expenses was due to lower development expenses for the seltorexant program due to the Amendment to our Co-Development and License Agreement with Janssen, which was partially offset by higher development expenses for the Phase 3 clinical trial of roluperidone and the Phase 2b clinical trial of MIN-117.

  R&D expenses are expected to increase during 2018 in connection with increased patient enrollment and related support activities for the roluperidone and MIN-117 clinical trials.

- **G&A Expenses:** General and administrative (G&A) expenses for the three and nine months ended September 30, 2018 were $4.1 million and $12.2 million, respectively, compared to $2.5 million and $7.9 million for the same periods in 2017. This increase in G&A expenses was primarily due to an increase in non-cash stock-based compensation expenses and salary costs from increased staffing to support pre-commercial activities.

  G&A expenses are expected to increase during 2018 as the Company begins to invest in the infrastructure necessary to support its growth.

- **Net Loss:** The Company reported a net loss for the three and nine months ended September 30, 2018 of $12.0 million and $37.0 million respectively, or $0.31 and $0.95 per share, respectively, compared to $11.3 million and $31.7 million, respectively, or $0.28 and $0.84 per share, respectively, for the same period in 2017.

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 7429089.

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 Neurosciences, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of a portfolio of product candidates to treat CNS diseases. Minerva's proprietary compounds include: roluperidone (MIN-101), in clinical development for schizophrenia; MIN-117, in clinical development for major depressive disorder (MDD); seltorexant (MIN-202 or JNJ-42847922), in clinical development for insomnia and MDD; 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 current clinical trials and results of clinical trials with roluperidone, seltorexant, MIN-117 and MIN-301; the timing and scope of future clinical trials and results of clinical trials with these compounds; the clinical and therapeutic potential of these compounds; 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, seltorexant, MIN-117 and MIN-301 will advance further in the clinical trials process and whether and when, if at all, they 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, 2018, filed with the Securities and Exchange Commission on November 5, 2018. 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, 2018	December 31, 2017
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 87,296	$ 26,052
Marketable securities	10,309	102,109
Restricted cash	100	80
Prepaid expenses and other current assets	3,700	1,299
Total current assets	101,405	129,540
Marketable securities - noncurrent	-	5,023
Equipment, net	38	51
Other noncurrent assets	15	15
In-process research and development	34,200	34,200
Goodwill	14,869	14,869
Total Assets	$ 150,527	$ 183,698
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Notes payable	$ -	$ 3,962
Accounts payable	875	1,436
Accrued expenses and other current liabilities	2,996	1,439
Total current liabilities	3,871	6,837
Long-Term Liabilities:		
Deferred taxes	4,057	4,057
Deferred revenue	41,176	41,176
Other noncurrent liabilities	30	30
Total liabilities	49,134	52,100
Stockholders' Equity:		
Common stock	4	4
Additional paid-in capital	302,739	295,975
Accumulated deficit	(201,350)	(164,381)
Total stockholders' equity	101,393	131,598
Total Liabilities and Stockholders' Equity	$ 150,527	$ 183,698

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30, (in thousands, except per share amounts)		Nine Months Ended September 30, (in thousands, except per share amounts)	
	2018	**2017**	**2018**	**2017**
Revenues	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	8,369	8,956	25,881	23,715
General and administrative	4,055	2,451	12,221	7,923
Total operating expenses	12,424	11,407	38,102	31,638
Foreign exchange losses	(11)	(9)	-	(46)
Investment income	418	294	1,244	508
Interest expense	(4)	(138)	(110)	(510)
Net income (loss)	$ (12,021)	$ (11,260)	$ (36,968)	$ (31,686)
Loss per share:				
Basic and diluted	$ (0.31)	$ (0.28)	$ (0.95)	$ (0.84)
Weighted average shares:				
Basic and diluted	38,782	40,880	38,760	37,677

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Source: Minerva Neurosciences, Inc