



Minerva Neurosciences Reports Third Quarter 2017 Financial Results and Business Updates

November 6, 2017

WALTHAM, Mass., Nov. 06, 2017 (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, 2017.

"As we approach year-end, we are completing the final steps prior to the initiation of a number of advanced-stage clinical efficacy trials with multiple compounds targeting significant unmet needs in CNS, highlighted by our lead product candidate, MIN-101 for the treatment of negative symptoms in schizophrenia," said Dr. Remy Luthringer, president and chief executive officer of Minerva. "Our objective is to ensure rigorously conducted clinical trials that support well-defined product profiles, timely data readouts and a smooth transition to future regulatory review and commercialization."

MIN-101:

- The Company is on schedule to initiate a pivotal Phase 3 trial of MIN-101 to treat negative symptoms in patients diagnosed with schizophrenia in the fourth quarter of 2017. Top-line results from the three-month double blind phase of this trial are expected in the first half of 2019.
- The final protocol for the Phase 3 trial has been submitted to the Investigational New Drug application (IND), and the first Institutional Review Board (IRB) approval has been received for the study in the U.S. The trial will be a 12-week, double-blind, randomized, placebo-controlled, monotherapy study testing two doses of MIN-101 in schizophrenic patients with negative symptoms. These are the same two doses as those employed in the Phase 2b trial. After the double-blind phase, patients may enter a 40-week open label extension phase in which all will receive active treatment. This multi-center, international trial is expected to enroll approximately 500 patients at approximately 60 clinical sites across the U.S. and Europe, with 30 percent of patients coming from the U.S.
- The Chemistry, Manufacturing and Controls (CMC) program has been initiated to ensure consistency between drug batches and its timely inclusion with the potential submission of a New Drug Application (NDA) pending a successful Phase 3 trial.

SELTOREXANT (MIN-202 OR JNJ-42847922):

- The first patient has been enrolled in a Phase 2b clinical trial of seltorexant as adjunctive therapy to antidepressants in adult patients with major depressive disorder (MDD) who have responded inadequately to antidepressant therapy. Approximately 280 patients are planned to be enrolled at more than 85 clinical sites in the U.S., Europe, Russia and Japan. Two additional clinical trials of seltorexant are planned for initiation in the fourth quarter of 2017. These include a second Phase 2b trial in MDD and a Phase 2b trial in insomnia.
- An amendment to the Company's co-development and license agreement with Janssen became effective on August 29, 2017 following approval of its terms by the European Commission.

MIN-117:

- The Company plans to initiate patient recruitment in a Phase 2b clinical trial with MIN-117 in MDD in early 2018. This trial is expected to include patients with MDD who also have symptoms of anxiety, building upon previous Phase 2a clinical results that showed effects in both depressive symptomatology and anxiety.
- In preparation for the Phase 2b trial, a food-effect study is currently ongoing with MIN-117 under the Company's IND.

MIN-301:

- The Company is continuing to conduct pre-clinical, toxicology and other IND-enabling studies with MIN-301 as a prelude to advancing this compound into the initial stage of clinical development.
- MIN-301 is a recombinant protein with the extra-cellular domain of neuregulin-1 beta primarily activating the ErbB4 receptor. Dysregulation of the NRG-1 signaling pathway has been linked to neurodevelopmental and neurodegenerative disorders including and beyond Parkinson's disease.

Third Quarter 2017 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities as of September 30, 2017 were approximately \$143.3 million, compared to \$83.0 million as of December 31, 2016. As previously stated, Minerva expects that its cash, cash equivalents and marketable securities will be sufficient to fund its operations for at least the next 12 months.
- **R&D Expenses:** Research and development (R&D) expenses were \$9.0 million in the third quarter of 2017, compared to \$5.9 million in the third quarter of 2016. R&D expense in the three months ended September 30, 2017 and 2016 included non-cash stock-based compensation expenses of \$0.5 million and \$0.3 million, respectively. This increase in R&D expenses primarily reflects higher development expenses under the MIN-202 program for the Phase 2 clinical trials, increased expenses for the MIN-101 program and an increase in non-cash stock-based compensation expenses.

For the nine months ended September 30, 2017, R&D expenses were \$23.7 million, compared to \$13.9 million for the nine months ended September 30, 2016. R&D expense in the nine months ended September 30, 2017 and 2016 included non-cash stock-based compensation expenses of \$1.5 million and \$0.7 million, respectively. This increase in R&D expenses primarily reflects higher development expenses under the MIN-202 program for the Phase 2 clinical trial, increased expenses for the MIN-101 program, an increase in personnel costs and an increase in non-cash stock-based compensation expenses. These amounts were partially offset by lower costs due to the completion of the Phase 2a clinical trial of MIN-117.

- **G&A Expenses:** General and administrative (G&A) expenses were \$2.5 million in the third quarter of 2017, compared to \$2.4 million in the third quarter of 2016. G&A expense in the three months ended September 30, 2017 and 2016 included non-cash stock-based compensation expenses of \$0.8 million and \$0.7 million, respectively. This increase was primarily due to an increase in professional fees during the three months ended September 30, 2017.

For the nine months ended September 30, 2017, G&A expenses were \$7.9 million, compared to \$7.0 million for the same period in 2016. G&A expense in the nine months ended September 30, 2017 and 2016 included non-cash stock-based compensation expenses of \$2.3 million and \$1.8 million, respectively. This increase was primarily due to an increase in professional fees and an increase in non-cash stock-based compensation expenses during the nine months ended September 30, 2017.

- **Net Loss:** Net loss was \$11.3 million for the third quarter of 2017, or a loss per share of \$0.28 (basic and diluted), as compared to a net loss of \$8.4 million, or a loss per share of \$0.24 (basic and diluted) for the third quarter of 2016. Net loss was \$31.7 million for the first nine months of 2017, or a loss per share of \$0.84 (basic and diluted), as compared to a net loss of \$21.6 million, or a loss per share of \$0.71 (basic and diluted) for the first nine months of 2016.

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 90294475.

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 products to treat CNS diseases. Minerva's proprietary compounds include: MIN-101, in clinical development for schizophrenia; seltorexant (MIN-202 or JNJ-42847922), in clinical development for insomnia and major depressive disorder (MDD); MIN-117, in clinical development for 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 future clinical trials and results of clinical trials with MIN-101, seltorexant, MIN-117 and MIN-301. 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 MIN-101, seltorexant, MIN-117 and MIN-301 will advance further in the clinical trials process; 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, 2017, filed with the Securities and Exchange Commission on November 6, 2017. 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, 2017	December 31, 2016
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 36,255	\$ 82,981
Marketable securities	96,675	-
Restricted cash	80	80
Prepaid expenses and other current assets	1,073	803
Total current assets	134,083	83,864
Marketable securities - noncurrent	10,355	-
Equipment, net	-	10
In-process research and development	34,200	34,200
Goodwill	14,869	14,869
Total Assets	\$ 193,507	\$ 132,943
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Notes payable - current portion	\$ 5,194	\$ 4,854
Accounts payable	1,504	1,467
Accrued expenses and other current liabilities	2,022	816
Accrued collaborative expenses	-	2,548
Total current liabilities	8,720	9,685
Long-Term Liabilities:		
Notes payable - noncurrent	-	3,841
Deferred taxes	13,434	13,434
Deferred revenue	41,176	-
Total liabilities	63,330	26,960
Stockholders' Equity:		
Common stock	4	4
Additional paid-in capital	294,717	238,837
Accumulated deficit	(164,544)	(132,858)
Total stockholders' equity	130,177	105,983
Total Liabilities and Stockholders' Equity	\$ 193,507	\$ 132,943

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)	
	2017	2016	2017	2016
Revenues	\$ -	\$ -	\$ -	\$ -
Operating expenses:				
Research and development	8,956	5,852	23,715	13,941
General and administrative	2,451	2,380	7,923	7,012
Total operating expenses	11,407	8,232	31,638	20,953
Foreign exchange losses	(9)	(3)	(46)	(28)
Investment income	294	70	508	137

Interest expense	(138)	(259)	(510)	(797)
Net loss	<u>\$ (11,260)</u>	<u>\$ (8,424)</u>	<u>\$ (31,686)</u>	<u>\$ (21,641)</u>
Loss per share:				
Basic and diluted	<u>\$ (0.28)</u>	<u>\$ (0.24)</u>	<u>\$ (0.84)</u>	<u>\$ (0.71)</u>
Weighted average shares:				
Basic and diluted	<u>40,880</u>	<u>34,806</u>	<u>37,677</u>	<u>30,393</u>

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