Minerva Neurosciences Reports Fiscal 2017 Fourth Quarter and Year End Financial Results and Business Updates

March 12, 2018

Four late-stage trials underway, targeting schizophrenia, major depressive disorder and insomnia disorder

Planning for commercialization moves forward

Management to host conference call today at 8:30 a.m. Eastern Time

WALTHAM, Mass., March 12, 2018 (GLOBE NEWSWIRE) -- Minerva Neurosciences, Inc. (NASDAQ:NERV), a clinical-stage biopharmaceutical company focused on the development of innovative therapies to treat unmet medical needs of central nervous system (CNS) disorders, today reported key business updates and financial results for the fourth quarter and fiscal year ended December 31, 2017.

“We have initiated four late-stage clinical efficacy trials with two compounds during late 2017, and we are planning to initiate a fifth with a third compound in the near future,” said Dr. Remy Luthringer, executive chairman and chief executive officer of Minerva. “We have also expanded our internal capabilities in the areas of strategic development, market research and commercial expertise as we plan for the transition from late-stage clinical development to the market for our product candidates,” said Dr. Luthringer. “This evolution supports our corporate strategy to develop and commercialize first-in-class products with novel mechanisms of action that address critical needs in targeted CNS areas, led by roluperidone (MIN-101) for negative symptoms in patients with schizophrenia.”

Roluperidone (MIN-101):

- In December 2017, the first patient was screened in the pivotal Phase 3 clinical trial of roluperidone as monotherapy for negative symptoms in patients diagnosed with schizophrenia. This multicenter, randomized, double-blind, parallel-group, placebo-controlled, 12-week trial will evaluate the efficacy and safety of 32 milligrams (mg) and 64 mg of roluperidone in adult patients with negative symptoms of schizophrenia. The 12-week study will be followed by a 40-week, open-label extension period during which patients on drug will continue receiving their original dose and patients on placebo will receive either 32 mg or 64 mg of roluperidone.

- The effect of roluperidone as compared to placebo will be determined with respect to the primary endpoint, the change from baseline in negative symptoms using the Positive and Negative Syndrome Scale (PANSS) Marder’s negative symptoms factor score (NSFS) over the 12-week double-blind treatment period. The key secondary endpoint is the effect of roluperidone compared to placebo as measured by the change from baseline in the Personal and Social Performance (PSP) total score over the same period. Additional secondary endpoints will be the Clinical Global Impression of Severity (CGI-S) score and safety and tolerability.

- Approximately 500 patients are expected to be enrolled at approximately 60 clinical sites in the U.S. and Europe, with about 30 percent of patients coming from the U.S. Top-line results from the 12-week double blind phase of this trial are expected in the first half of 2019.

Seltorexant (MIN-202 or JNJ-42847922), under joint development with Janssen Pharmaceutica NV (Janssen):

- In September 2017, the first patient was enrolled in a Phase 2b multi-center, double-blind, randomized, parallel-group, placebo-controlled, adaptive-dose finding clinical trial of seltorexant as adjunctive therapy to antidepressants in adult patients with major depressive disorder (MDD) who have responded inadequately to antidepressant therapy. The primary objectives of this study are: (1) to assess the dose-response relationship and augmentation of antidepressant effect of up to three doses of seltorexant (10 mg, 20 mg, and 40 mg), and (2) to assess the safety and tolerability of seltorexant compared to placebo. Approximately 280 patients are planned to be enrolled at more than 85 clinical sites in the U.S., Europe, Russia and Japan.

- In December 2017, the first patient was enrolled in a Phase 2b multi-center, double-blind, randomized, parallel-group, active- and placebo-controlled dose finding clinical trial of seltorexant in patients with insomnia disorder. The primary objective is to assess the dose-response of three doses of seltorexant (5, 10 and 20 milligrams daily) compared to placebo on sleep onset as measured by the latency to persistent sleep using polysomnography (PSG). The key secondary objective is to assess the dose-response of these three doses compared to placebo on wake after sleep onset over the first six hours using PSG. In addition, the effects of seltorexant on sleep and cognition will be compared to those effects of zolpidem to determine potential differences between the compounds. Approximately 360 patients are planned to be randomized at clinical sites in the U.S., European Union and Japan.

- In December 2017, the first patient was enrolled in a Phase 2b multi-center, double-blind, randomized, flexible-dose, parallel-group study to assess the efficacy of flexibly dosed seltorexant compared to flexibly dosed quetiapine as adjunctive therapy to a baseline antidepressant drug in delaying time to all-cause discontinuation of study drug over a 6-month treatment period. Approximately 100 patients are planned to be randomized at approximately 34 sites in the U.S. to receive either flexibly dosed seltorexant, 20 mg or 40 mg, or flexibly dosed quetiapine XR, 150 mg or 300 mg.

- Under the amended agreement with Janssen that became effective in August, 2017, Janssen has waived its right to royalties on seltorexant insomnia sales in the Minerva territory (the European Union, Switzerland, Liechtenstein, Iceland and Norway). Minerva retains all of its rights to seltorexant, including commercialization for the treatment of insomnia and as an adjunctive therapy for MDD, which includes an exclusive license in the Minerva Territory. Minerva has also assumed strategic control for the clinical development of seltorexant in insomnia but has no further financial obligations until the Phase 2b development milestone is complete, which is expected to occur in the second half of 2019.

MIN-117:

- Building upon the results of an earlier Phase 2a trial with MIN-117 in Europe, the Company is planning to initiate a Phase 2b trial in MDD in the U.S. and Europe in early 2018. The Company expects to enroll patients with MDD who also have symptoms of anxiety. In preparation for this trial, a food effect study was recently completed, and no food effect was observed on the PK exposure parameters, therefore allowing dosing with or without food.

MIN-301:

- The Company is continuing the pre-clinical development of MIN-301, a soluble recombinant form of the Neuregulin-1b1 protein, for the treatment of Parkinson's disease and potentially for other neurodegenerative disorders. The next planned steps in this program include the completion of the pre-clinical package to enable the filing of an Investigational New Drug application (IND) in the U.S. and/or an Investigational Medicinal Product Dossier in Europe, and pending acceptance by regulatory authorities, the initiation of Phase 1 clinical testing thereafter.

Fourth Quarter and Year Ended 2017 Financial Results

- **Net Income (Loss):** Net income was $0.2 million for the fourth quarter of 2017, or income per share of $0.00 (basic and diluted), compared to a net loss of $9.4 million for the fourth quarter of 2016, or a loss per share of $0.27 (basic and diluted). Net loss was $31.5 million for the year ended December 31, 2017, or a loss per share of $0.83 (basic and diluted), compared to a net loss of $31.0 million, or a loss per share of $0.99 (basic and diluted), for the year ended December 31, 2016.

- **R&D Expenses:** Research and development (R&D) expenses were $6.5 million in the fourth quarter of 2017 and 2016. R&D expenses were $30.3 million for the year ended December 31, 2017, compared to $20.4 million for the year ended December 31 , 2016. This increase in R&D expenses primarily reflects higher development expenses under the seltorexant program, 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 $3.0 million in the fourth quarter of 2017, compared to $2.7 million in the fourth quarter of 2016. G&A expenses were $10.9 million for the year ended December 31, 2017, compared to $9.8 million for the year ended December 31, 2016. The increase in general and administrative expenses was primarily due to an increase in professional fees and an increase in non-cash stock-based compensation expenses.

- **Benefit for income taxes:** Benefit for income taxes was $9.4 million in the fourth quarter of 2017, compared to zero in the fourth quarter of 2016. Benefit for income taxes was $9.4 million for the year ended December 31, 2017, compared to zero for the year ended December 31, 2016. On December 22, 2017, the United States enacted tax reform legislation commonly known as the Tax Cuts and Jobs Act (the "Act"), resulting in significant modifications to existing law. In the year ended December 31, 2017, these tax reforms resulted in a benefit of $9.4 million related to future implications of indefinite lived deferred tax positions.

- **Cash Position:** Cash, cash equivalents and marketable securities as of December 31, 2017 were approximately $133.2 million, compared to $83.0 million as of December 31, 2016. During 2017, the Company received approximately $41.6 million in net proceeds from a July 2017 public offering of common stock, proceeds from the exercise of common stock warrants of $9.4 million, proceeds from the exercise of common stock options of $1.1 million, and $30 million in an upfront payment in connection with the amendment to the Company's Co-Development and License Agreement with Janssen for seltorexant. Minerva presently expects that its existing cash and cash equivalents will be sufficient to meet its anticipated capital requirements for at least the next 12 months from today. The assumptions upon which this estimate is based are routinely evaluated and may be subject to change.

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 1581007.

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 Phase 3 clinical development for schizophrenia; seltorexant (MIN-202 or JNJ-42847922) in Phase 2b 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 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; 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, 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 Annual Report on Form 10-K for the year ended December 31, 2017, filed with the Securities and Exchange Commission on March 12, 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)

	December 31, 2017	December 31, 2016
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 26,052	$ 82,981
Marketable securities	102,109	-
Restricted cash	80	80
Prepaid expenses and other current assets	1,299	803
Total current assets	129,540	83,864
Marketable securities - noncurrent	5,023	-
Equipment, net	51	10
Other non-current assets	15	-
In-process research and development	34,200	34,200
Goodwill	14,869	14,869
Total Assets	$ 183,698	$ 132,943
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Notes payable - current portion	$ 3,962	$ 4,854
Accounts payable	1,436	1,467
Accrued expenses and other current liabilities	1,439	816
Accrued collaborative expenses	-	2,548
Total current liabilities	6,837	9,685
Long-Term Liabilities:		
Notes payable - noncurrent	-	3,841
Deferred taxes	4,057	13,434
Deferred revenue	41,176	-
Other non-current liabilities	30	-
Total liabilities	52,100	26,960
Stockholders' Equity:		
Common stock	4	4
Additional paid-in capital	295,975	238,837
Accumulated deficit	(164,381)	(132,858)
Total stockholders' equity	131,598	105,983
Total Liabilities and Stockholders' Equity	$ 183,698	$ 132,943

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended December 31, (in thousands, except per share amounts)		Twelve Months Ended December 31, (in thousands, except per share amounts)	
	2017	**2016**	**2017**	**2016**
Revenues	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	6,541	6,499	30,256	20,440
General and administrative	2,991	2,739	10,914	9,751
Total operating expenses	9,532	9,238	41,170	30,191
Foreign exchange losses	(11)	4	(57)	(23)
Investment income	434	61	942	198
Interest expense	(105)	(232)	(614)	(1,030)
Loss before income taxes	(9,214)	(9,405)	(40,899)	(31,046)
Benefit for income taxes	(9,376)	-	(9,376)	-
Net income (loss)	$ 162	$ (9,405)	$ (31,523)	$ (31,046)
Loss per share:				
Basic and diluted	$ 0.00	$ (0.27)	$ (0.83)	$ (0.99)
Weighted average shares:				
Basic and diluted	38,710	34,852	37,937	31,514

Contact:

William B. Boni
VP, Investor Relations/
Corp. Communications
Minerva Neurosciences, Inc.
(617) 600-7376

Primary Logo

Source: Minerva Neurosciences, Inc