Minerva Neurosciences Reports Fiscal 2018 Fourth Quarter and Year End Financial Results and Business Updates

March 12, 2019

Recruitment active in five late-stage trials with three compounds directed toward significant unmet medical needs

Target indications include schizophrenia, major depressive disorder and insomnia disorder

Five key data readouts expected in 2019

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

WALTHAM, Mass., March 12, 2019 (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, 2018.

“Minerva is on track for the completion of patient enrollment and subsequent top-line data readouts in 2019 from five clinical trials with a diversified pipeline of product candidates, led by the Phase 3 trial with roluperidone for negative symptoms in patients with schizophrenia,” said Dr. Remy Luthringer, executive chairman and chief executive officer of Minerva. “During the past year we have also published additional clinical data with roluperidone, expanded our understanding of its pharmacological effect through new pre-clinical studies, completed further safety testing, and initiated strategic development, market research and pre-commercialization activities. These activities will be further informed by the data expected following the completion of the Phase 3 trial.”

Roluperidone (MIN-101):

- Enrollment continues in the Phase 3 clinical trial (ClinicalTrials.gov Identifier: NCT03397134) of roluperidone as monotherapy for negative symptoms in patients diagnosed with schizophrenia. This multicenter, randomized, double-blind, parallel-group, placebo-controlled, 12-week trial is being followed by a 40-week, open-label extension period. Approximately 500 patients are expected to be enrolled in the U.S. and Europe. The Company expects completion of enrollment during the first half of 2019 and top-line results from the 12-week, double blind period in mid-2019.

- Results announced on November 19, 2018 from a dose escalation study of roluperidone administered at supra-therapeutic doses in healthy volunteers suggest an expanded therapeutic window and significantly improved cardiovascular safety margin for the drug. The data from this study also suggest the potential for future testing of roluperidone in schizophrenic patients with an exacerbation of psychosis at higher doses than those being used in the Phase 3 trial.

- On August 22, 2018, pre-clinical findings with roluperidone were announced, providing evidence of its effect on Brain-Derived Neurotrophic Factor (BDNF). BDNF has been associated with neurogenesis, neuroplasticity, neuroprotection, synapse regulation, learning and memory. Its involvement in schizophrenia has also been described. These findings, along with the previously announced Phase 2b results with roluperidone, suggest the potential of this compound to change the overall course of the disease.

- On May 17, 2018, the Company announced that the Journal of Clinical Psychiatry had published online results showing cognitive improvements in patients with schizophrenia treated with roluperidone. These improvements correlated with improvements in negative symptoms. Currently available dopamine-blocking antipsychotic drugs have little impact on cognitive impairment, and these data suggest that roluperidone, which combines $5HT_{2A}$ and $sigma_2$ antagonism without dopamine blockade, may improve cognitive deficits in these patients.

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

- Three Phase 2b clinical trials are ongoing with seltorexant, including two in major depressive disorder (MDD) and one in insomnia disorder. Enrollment in the MDD trial designated as the 2001 trial (ClinicalTrials.gov Identifier: NCT03227224) has been completed, with 287 patients enrolled at sites in the U.S., Europe, Russia and Japan. The Company expects top-line results in the second quarter of 2019.

- In the MDD trial designated as the 2002 trial (ClinicalTrials.gov Identifier: NCT03321526), approximately 100 patients have been enrolled at clinical sites in the U.S. The Company expects top-line results in mid-2019.

- The insomnia trial, designated as the 2005 trial, (ClinicalTrials.gov Identifier: NCT03375203) is expected to enroll

approximately 360 patients at sites in the U.S., Europe and Japan. The Company expects top-line results in mid-2019.

MIN-117:

- Patients with MDD who also have symptoms of anxiety are being enrolled in a Phase 2b trial of MIN-117 (ClinicalTrials.gov Identifier: NCT03446846). A total of approximately 324 patients are expected to be enrolled at clinical sites in the U.S. and Europe. The Company expects top-line results in the first half of 2019.

- The Company expanded the patent estate for MIN-117 with the filing of a U.S. patent application for the use of MIN-117 to treat pain. The pre-clinical data supporting this application suggest that this compound may be investigated beyond mood and anxiety disorders to include chronic pain, which is often a symptom of several neuro-psychiatric disorders.

Fourth Quarter and Year Ended 2018 Financial Results

- **Net (Loss) Income:** Net loss was $13.2 million for the fourth quarter of 2018, or loss per share of $0.34 (basic and diluted), compared to net income of $0.2 million for the fourth quarter of 2017, or income per share of $0.00 (basic and diluted). Net loss was $50.2 million for the year ended December 31, 2018, or loss per share of $1.29 (basic and diluted), compared to a net loss of $31.5 million, or loss per share of $0.83 (basic and diluted) for the year ended December 31, 2017.

- **R&D Expenses:** Research and development (R&D) expenses were $9.0 million in the fourth quarter of 2018, compared to $6.5 million in the fourth quarter of 2017. R&D expenses were $34.9 million for the year ended December 31, 2018, compared to $30.3 million for the year ended December 31, 2017. The increase in R&D expenses during the fourth quarter and year ended December 31, 2018 primarily reflects higher development expenses for the Phase 3 clinical trial of roluperidone and the Phase 2b clinical trial of MIN-117. During the year ended December 31, 2018, these amounts were partially offset by lower development expenses for the seltorexant program due to the Amendment to our Co-Development and License Agreement with Janssen.

- **G&A Expenses:** General and administrative (G&A) expenses were $4.6 million in the fourth quarter of 2018, compared to $3.0 million in the fourth quarter of 2017. G&A expenses were $16.8 million for the year ended December 31, 2018, compared to $10.9 million for the year ended December 31, 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.

- **Cash Position:** Cash, cash equivalents, restricted cash and marketable securities as of December 31, 2018 were approximately $88.1 million, compared to $133.2 million as of December 31, 2017. 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 these results and recent business activities. To participate, please dial (877) 312-5845 (domestic) or (765) 507-2618 (international) and refer to conference ID 4598906.

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, 2018, filed with the Securities and Exchange Commission on March 12, 2019. 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, 2018	December 31, 2017
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 50,235	$ 26,052
Marketable securities	37,763	102,109
Restricted cash	100	80
Prepaid expenses and other current assets	1,921	1,299
Total current assets	90,019	129,540
Marketable securities - noncurrent	-	5,023
Equipment, net	33	51
Other noncurrent assets	15	15
In-process research and development	34,200	34,200
Goodwill	14,869	14,869
Total Assets	$ 139,136	$ 183,698
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Notes payable	$ -	$ 3,962
Accounts payable	1,799	1,436
Accrued expenses and other current liabilities	1,810	1,439
Total current liabilities	3,609	6,837
Long-Term Liabilities:		
Deferred taxes	4,057	4,057
Deferred revenue	41,176	41,176
Other noncurrent liabilities	29	30
Total liabilities	48,871	52,100
Stockholders' Equity:		
Common stock	4	4
Additional paid-in capital	304,814	295,975
Accumulated deficit	(214,553)	(164,381)
Total stockholders' equity	90,265	131,598
Total Liabilities and Stockholders' Equity	$ 139,136	$ 183,698

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)	
	2018	2017	2018	2017
Revenues	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	9,008	6,541	34,889	30,256
General and administrative	4,620	2,991	16,841	10,914

Total operating expenses	13,628	9,532	51,730	41,170
Foreign exchange losses	(5)	(11)	(5)	(57)
Investment income	430	434	1,674	942
Interest expense	-	(105)	(110)	(614)
Loss before income taxes	(13,203)	(9,214)	(50,171)	(40,899)
Benefit for income taxes	-	(9,376)	-	(9,376)
Net (loss) income	$ (13,203)	$ 162	$ (50,171)	$ (31,523)
Loss per share:				
Basic and diluted	$ (0.34)	$ 0.00	$ (1.29)	$ (0.83)
Weighted average shares:				
Basic and diluted	38,888	38,710	38,793	37,937

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Source: Minerva Neurosciences, Inc