Minerva Neurosciences Reports First Quarter 2019 Financial Results and Business Updates

May 6, 2019

WALTHAM, Mass., May 06, 2019 (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 March 31, 2019.

Minerva has five late-stage clinical efficacy trials ongoing with three product candidates, including a Phase 3 trial with roluperidone (MIN-101) for negative symptoms in patients with schizophrenia, a Phase 2b trial with MIN-117 for major depressive disorder (MDD) associated with anxiety and three Phase 2b trials with seltorexant (MIN-202) for insomnia disorder and MDD.

“I am very pleased to provide an update and insights into the progress we are making in all of our studies,” said Dr. Remy Luthringer, Executive Chairman and Chief Executive Officer of Minerva. “We have updated forecast timelines for the roluperidone Phase 3 study and the MIN-117 Phase 2b study, both of which we now expect to read out in the fourth quarter of this year.

“Our three seltorexant studies will now read out sooner than anticipated, with patient enrollment completed in all three,” said Dr. Luthringer. “We expect to report top-line results from both our first MDD trial and our insomnia trial in the second quarter of 2019, and we expect top-line results from our second MDD trial in the third quarter of 2019.

“The new timelines reflect the latest information available from our sites, as well as the care that we are taking both in recruiting subjects who meet stringent entry criteria and in engaging well-trained clinical investigators to evaluate the therapeutic benefit of our product candidates,” said Dr. Luthringer. “I am pleased to report that patient selection to date has met these standards and the investigators are performing well. Our focus continues to be on trial conduct and data quality.”

Development Updates

Roluperidone (MIN-101):

- The Company is actively enrolling patients in the pivotal Phase 3 trial with roluperidone (clinicaltrials.gov identifier: NCT03397134). Approximately 60 sites in the U.S. and Europe are participating in this trial, and target enrollment is approximately 500 patients. Completion of full enrollment is now expected in the second half of 2019, and top-line results from the 12-week, double-blind portion of the trial are expected in the fourth quarter of 2019.

- In parallel with advancing its Phase 3 study, Minerva is continuing preparatory work for regulatory filing and commercialization. These activities include clinical pharmacology studies and manufacturing of registration batches.

- Pre-clinical data presented at the 2019 Congress of the Schizophrenia International Research Society suggest a mechanistic role for roluperidone in addressing negative symptoms. Presenters also indicated the potential of roluperidone for disease modification and improved neuroplasticity.

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 MDD and one in insomnia disorder.

- In the first MDD trial, designated as the 2001 trial (Clinicaltrials.gov Identifier: NCT03227224), patient enrollment has been completed, with 287 patients enrolled at clinical sites in the U.S., Europe and Japan. Top-line results from this trial are expected in the second quarter of 2019.

- Enrollment has also been completed in the insomnia trial, designated as the 2005 trial (Clinicaltrials.gov Identifier: NCT03375203), with approximately 360 patients enrolled at clinical sites in the U.S., Europe and Japan. Top-line results are expected in the second quarter of 2019.

- In the second MDD trial, designated as the 2002 trial (Clinicaltrials.gov Identifier NCT03321526), patient enrollment has also been completed, with 100 patients enrolled at clinical sites in the U.S. Top-line results from this trial are expected in the third quarter of 2019.

MIN-117:

- A Phase 2b trial is ongoing with MIN-117 to treat patients diagnosed with MDD and associated anxiety disorders (Clinicaltrials.gov Identifier: NCT03446846). Approximately 324 patients are expected to be enrolled at 40 clinical sites in the U.S. and Europe. Completion of enrollment is now expected in the third quarter of 2019, with top-line results expected

to be available in the fourth quarter of 2019.

First Quarter 2019 Financial Results

- **Net Loss:** Net loss was $15.8 million for the first quarter of 2019, or a loss per share of $0.41 (basic and diluted), compared to a net loss of $12.4 million for the first quarter of 2018, or a loss per share of $0.32 (basic and diluted).

- **R&D Expenses:** Research and development (R&D) expenses were $11.6 million in the first quarter of 2019, compared to $8.4 million in the first quarter of 2018. The increase in R&D expenses primarily reflects 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 2019 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 were $4.7 million in the first quarter of 2019, compared to $4.3 million in the first quarter of 2018. 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 the Company's pre-commercial activities.

- **Cash Position:** Cash, cash equivalents, restricted cash and marketable securities as of March 31, 2019 were approximately $79.3 million.

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 5697837.

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; 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 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-Q for the quarter ended March 31, 2019, filed with the Securities and Exchange Commission on March 6, 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)

	March 31, 2019	December 31, 2018
	(in thousands)	
ASSETS		
Current Assets:		

Cash and cash equivalents	$ 30,608	$ 50,235
Marketable securities	48,557	37,763
Restricted cash	100	100
Prepaid expenses and other current assets	1,054	1,921
Total current assets	80,319	90,019
Marketable securities - noncurrent	-	-
Equipment, net	29	33
Other noncurrent assets	15	15
Operating lease right-of-use assets	371	-
In-process research and development	34,200	34,200
Goodwill	14,869	14,869
Total Assets	$ 129,803	$ 139,136
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Notes payable	$ -	$ -
Accounts payable	3,026	1,799
Accrued expenses and other current liabilities	3,721	1,810
Operating leases	156	-
Total current liabilities	6,903	3,609
Long-Term Liabilities:		
Deferred taxes	4,057	4,057
Deferred revenue	41,176	41,176
Other noncurrent liabilities	-	29
Noncurrent operating leases	243	-
Total liabilities	52,379	48,871
Stockholders' Equity:		
Common stock	4	4
Additional paid-in capital	307,800	304,814
Accumulated deficit	(230,380)	(214,553)
Total stockholders' equity	77,424	90,265
Total Liabilities and Stockholders' Equity	$ 129,803	$ 139,136

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31, (in thousands, except per share amounts)	
	2019	**2018**
Revenues	$ -	$ -
Operating expenses:		
Research and development	11,606	8,449
General and administrative	4,706	4,294
Total operating expenses	16,312	12,743
Foreign exchange losses	(6)	(18)
Investment income	491	414

Interest expense	-	(71)
Loss before income taxes	(15,827)	(12,418)
Benefit for income taxes	-	-
Net (loss) income	$ (15,827)	$ (12,418)
Loss per share:		
Basic and diluted	$ (0.41)	$ (0.32)
Weighted average shares:		
Basic and diluted	38,968	38,749

Contact:

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

Source: Minerva Neurosciences, Inc