Minerva Neurosciences Reports Second Quarter 2019 Financial Results and Business Updates

August 5, 2019

During the Second Quarter, Minerva announced several important clinical advancements, including positive top line results from two Phase 2b studies of seltorexant (MIN-202) in major depressive disorder (MDD) and insomnia

Patient enrollment progresses in pivotal Phase 3 trial of roluperidone (MIN-101) in schizophrenia, Phase 2 trial of seltorexant in MDD and Phase 2b trial of MIN-117 in MDD

WALTHAM, Mass., Aug. 05, 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 June 30, 2019.

“In the first half of 2019, we presented positive data from two Phase 2b clinical trials with seltorexant,” said Dr. Remy Luthringer, Executive Chairman and Chief Executive Officer of Minerva. “In addition, in a recent biomarker study with seltorexant, we demonstrated mood improvements in MDD patients when seltorexant was given as monotherapy. Taken together, the data from these studies point to the unique ability of seltorexant to address unmet medical needs in both depression and insomnia as an adjunctive treatment or in monotherapy.”

Key data reported in the Second Quarter and today include:

- Statistically significant and clinically meaningful improvement in symptoms of depression in MDD patients not responding adequately to first line anti-depressant therapies (MDD2001);
- Statistically significant and clinically meaningful improvement in symptoms of depression in MDD patients treated with seltorexant administered as monotherapy (MDD1009);
- In both studies the improvement in mood was greater in patients with associated insomnia;
- Statistically significant and clinically meaningful effect in adult and elderly patients suffering from insomnia, with a favorable tolerability profile (ISM2005);
- Primary and multiple secondary endpoints were also improved versus zolpidem (ISM2005).

Clinical Pipeline Update

Seltorexant

Seltorexant is a novel, oral, investigational highly selective Orexin-2 antagonist that is currently being evaluated in major depressive disorder (MDD) and insomnia. Minerva is co-developing seltorexant with Janssen Pharmaceutica NV (Janssen).

- Study MDD1009: The Company recently analyzed data from an exploratory, biomarker, multicenter, placebo-controlled, randomized, double-blind Phase 1b trial of seltorexant, administered at doses of 20 and 40 milligrams (mg) as monotherapy in 128 subjects with moderate to severe MDD. The primary objective of this study was to analyze the treatment effect of seltorexant versus placebo on symptoms of depression as measured by the Hamilton Rating Scale for Depression ($HDRS_{17}$) . The presence of subjective sleep disturbance (subjective sleep assessment, Insomnia Severity Index (ISI), and Ruminative Response Scale [RRS]) as a possible indicator of hyper-arousal was used as a stratification factor in patient randomization.

  The primary endpoint analysis showed a significant treatment effect at week 5 for seltorexant versus placebo. The efficacy signal for the 20 mg dose was statistically significant (p=0.0049) and more pronounced in the MDD population with sleep disorder, measured as having an ISI >15 and subjective sleep onset latency >30 min during at least 3 nights over 7 recorded days and in MDD patients with higher rumination (RRS ≥ 50).

  Seltorexant 40 mg dose did not show a statistically significant effect at week 5, although the efficacy signal was also more pronounced in the subgroups (MDD patients with presence of subjective sleep disorder, ISI >15 or RRS ≥50).

  These new findings show that seltorexant administered as monotherapy improves depressive symptoms and that the improvement is more pronounced when patients present with insomnia. Importantly, they also support the relationship between mood disorders, insomnia, hyper-arousal, clinical efficacy and the mechanism of action of seltorexant.

- Study MDD2001: On May 13, 2019, Minerva announced positive top line results from a Phase 2b clinical trial of seltorexant as adjunctive therapy to antidepressants in adult patients with MDD who are not responding adequately to selective serotonin reuptake inhibitors (SSRIs) and/or serotonin-norepinephrine reuptake inhibitors (SNRIs).

In this dose finding study, the 20 mg dose of seltorexant showed a statistically significant improvement in the Montgomery-Asberg Depression Rating Scale (MADRS) score compared to placebo at week 6. Seltorexant was also observed to have even greater improvement over placebo in patients with clinically significant insomnia and a favorable tolerability profile.

- Study ISM2005: On June 24, 2019, the Company announced positive top line results from a Phase 2b clinical trial of seltorexant in patients with insomnia disorder that demonstrated highly statistically significant and clinically meaningful improvement in the primary endpoint, Latency to Persistent Sleep (LPS) at Night 1 after treatment with 10 and 20 mg doses of seltorexant.

  In addition to the primary endpoint, multiple secondary endpoints were improved with seltorexant versus placebo and standard of care zolpidem, available under the brand name Ambien. Furthermore, the beneficial effects of seltorexant on elderly patients, in conjunction with a favorable safety profile, suggest its potential benefit in the large and growing population of elderly patients whose prevalence of insomnia is higher than in younger patients.

Roluperidone

Roluperidone is a novel, oral, investigational 5-HT_{2A} and $Sigma_2$ receptor antagonist that is currently being evaluated in patients diagnosed with schizophrenia presenting with negative symptoms.

Minerva is currently enrolling a pivotal Phase 3 clinical trial of roluperidone (Study MIN-101C07) as monotherapy for negative symptoms in patients diagnosed with schizophrenia. The trial is a multicenter, randomized, double-blind, parallel-group, placebo-controlled, 12-week study to evaluate the efficacy and safety of 32 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 500 patients expected to be enrolled in this trial at clinical sites in the U.S. and Europe will be initially randomized equally to receive one of the two doses of roluperidone or placebo for 12 weeks. Thereafter, all patients will continue treatment with roluperidone for the 40-week extension period. Top-line results from the 12-week double blind phase of this trial are expected in the fourth quarter of 2019.

The primary endpoint of this trial will be improvement in negative symptoms in patients treated with roluperidone compared to placebo as measured by the change in the Positive and Negative Syndrome Scale, or PANSS, Marder negative symptoms factor score, or NSFS, over the 12-week double-blind treatment period. The key secondary endpoint will be the effect of roluperidone compared to placebo as measured by the Personal and Social Performance, or PSP, total score over the same period. Additional secondary endpoints will be the effect of roluperidone compared to placebo on the Clinical Global Impression of Severity, or CGI-S, score and safety and tolerability.

MIN-117

MIN-117 is a novel, oral, investigational drug with a multimodal mechanism of action in development for the treatment of MDD and specifically for patients suffering with MDD and anxiety.

Minerva is currently enrolling a Phase 2b trial in MDD in the U.S. and Europe. The primary objective of the trial is to evaluate the efficacy of two fixed doses of MIN-117, 5.0 mg and 2.5 mg, compared with placebo in reducing the symptoms of major depression as measured by the change in the MADRS total score over six weeks of treatment. Secondary objectives include: (1) assessment of the change from baseline in symptoms of anxiety using the Hamilton Anxiety Scale (HAM-A); (2) the change in severity of illness using the CGI-S and the Clinical Global Impression of Improvement Scale (CGI-I); and (3) safety over six weeks of treatment.

Approximately 324 patients are expected to be enrolled at approximately 40 sites in the U.S. and Europe. Patients will be randomized to one of three arms, including placebo and the two dosage arms, in a 2:1:1 ratio, resulting in approximately 162 patients in the placebo group and 81 patients in each of the two MIN-117 treatment groups.

Second Quarter 2019 Financial Results

- **Cash Position:** Cash, cash equivalents, restricted cash and marketable securities as of June 30, 2019 were approximately $69.4 million, compared to $88.1 million as of December 31, 2018.

- **R&D Expenses:** Research and development (R&D) expenses were $8.3 million in the second quarter of 2019, compared to $9.1 million in the second quarter of 2018, a decrease of $0.8 million. This decrease primarily reflects decreased non-clinical and clinical pharmacology expenses, partially offset by increased costs for the Phase 3 clinical trial of roluperidone and the Phase 2b clinical trial of MIN-117.

  For the six months ended June 30, 2019, R&D expenses were $19.9 million, compared to $17.5 million for the six months ended June 30, 2018, an increase of $2.4 million. This increase primarily reflects higher development expenses for the Phase 3 clinical trial of roluperidone and the Phase 2b clinical trial of MIN-117.

  The Company expects R&D expenses to increase during 2019 associated with patient enrollment and related support activities for the roluperidone and MIN-117 clinical trials.

- **G&A Expenses:** General and administrative (G&A) expenses were $4.6 million in the second quarter of 2019, compared

to $3.9 million in the second quarter of 2018, an increase of approximately $0.7 million.

For the six months ended June 30, 2019, G&A expenses were $9.3 million, compared to $8.2 million for the same period in 2018, an increase of approximately $1.1 million.

These increases in G&A expenses were primarily due to an increase in non-cash stock-based compensation expenses and salary costs from increased staffing to support pre-commercial activities. The Company expects G&A expenses to increase during 2019 as it prepares for the transition of roluperidone from clinical development to commercialization.

- **Net Loss:** Net loss was $12.5 million for the second quarter of 2019, or a loss per share of $0.32 (basic and diluted), as compared to a net loss of $12.5 million, or a loss per share of $0.32 (basic and diluted) for the second quarter of 2018. Net loss was $28.3 million for the first six months of 2019, or a loss per share of $0.73 (basic and diluted), as compared to a net loss of $24.9 million, or a loss per share of $0.64 (basic and diluted) for the first six months of 2018.

Anticipated Clinical Milestones

Roluperidone: Phase 3 trial to treat negative symptoms in patients diagnosed with schizophrenia (monotherapy); completion of enrollment in this trial is expected during the second half of 2019, with top line results from the 12-week double blind phase of this trial expected in the fourth quarter of 2019.

Seltorexant: Phase 2 positive-controlled MDD2002 trial to treat patients with MDD (adjunctive therapy); enrollment has been completed, with top-line results expected in the third quarter of 2019.

MIN-117: Phase 2b trial to treat patients with MDD who also have symptoms of anxiety (monotherapy); completion of enrollment in this trial is expected in the third quarter of 2019, with top-line results expected in the fourth quarter of 2019.

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 7559419.

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 future clinical trials and results of clinical trials with roluperidone, seltorexant, MIN-117 and MIN-301; 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 June 30, 2019, filed with the Securities and Exchange Commission on August 5, 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)

	June 30, 2019	December 31, 2018
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 27,845	$ 50,235

Marketable securities	41,449	37,763
Restricted cash	100	100
Prepaid expenses and other current assets	1,453	1,921
Total current assets	70,847	90,019
Marketable securities - noncurrent	-	-
Equipment, net	25	33
Other noncurrent assets	15	15
Operating lease right-of-use assets	336	-
In-process research and development	34,200	34,200
Goodwill	14,869	14,869
Total Assets	$ 120,292	$ 139,136
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Notes payable	$ -	$ -
Accounts payable	2,941	1,799
Accrued expenses and other current liabilities	4,486	1,810
Operating leases	162	-
Total current liabilities	7,589	3,609
Long-Term Liabilities:		
Deferred taxes	4,057	4,057
Deferred revenue	41,176	41,176
Other noncurrent liabilities	-	29
Noncurrent operating leases	201	-
Total liabilities	53,023	48,871
Stockholders' Equity:		
Common stock	4	4
Additional paid-in capital	310,121	304,814
Accumulated deficit	(242,856)	(214,553)
Total stockholders' equity	67,269	90,265
Total Liabilities and Stockholders' Equity	$ 120,292	$ 139,136

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30, (in thousands, except per share amounts)		**Six Months Ended June 30, (in thousands, except per share amounts)**	
	2019	**2018**	**2019**	**2018**
Revenues	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	8,320	9,062	19,926	17,512
General and administrative	4,584	3,873	9,290	8,167
Total operating expenses	12,904	12,935	29,216	25,679
Foreign exchange losses	(7)	29	(13)	11
Investment income	434	412	925	826
Interest expense	-	(36)	-	(106)
Loss before income taxes	(12,477)	(12,530)	(28,304)	(24,948)
Benefit for income taxes	-	-	-	-
Net (loss) income	$ (12,477)	$ (12,530)	$ (28,304)	$ (24,948)
Loss per share:				
Basic and diluted	$ (0.32)	$ (0.32)	$ (0.73)	$ (0.64)
Weighted average shares:				
Basic and diluted	39,025	38,749	38,997	38,749

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