# Minerva Neurosciences Reports Third Quarter 2019 Financial Results and Business Updates

November 4, 2019

WALTHAM, Mass., Nov. 04, 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 September 30, 2019.

Clinical program updates

Roluperidone

The Company is currently enrolling patients in the U.S. and Europe into a Phase 3 trial of roluperidone for the treatment of negative symptoms in schizophrenia. The Company expects to complete patient enrollment at approximately year-end 2019, and top line results from the 12-week, double-blind part of the trial are expected to be available in the first half of 2020. Following the most recent meeting of the Data Safety Monitoring Board (DSMB) in July, the DSMB recommended continuation of the study with no changes to the protocol.

This trial is a multicenter, randomized, double-blind, parallel group, placebo-controlled, 12-week trial to evaluate the efficacy and safety of 32 mg and 64 mg doses of roluperidone as measured by the Positive and Negative Syndrome Scale (PANSS) Marder negative symptoms factor score. The core 12-week study is followed by a 40-week, open-label extension period during which patients on the drug continue receiving their original dose and patients on placebo receive one of the two doses of roluperidone.

In September, 2019, the Company entered into a long-term commercial supply agreement with Catalent under which Catalent will manufacture and package the finished dose form of the drug. The Company is working with Catalent to enable the tech transfer from pilot to commercial-scale production.

MIN-117

Enrollment has been completed in a Phase 2b trial of MIN-117 in the U.S. and Europe, with a total of 360 adult patients enrolled with moderate or severe major depressive disorder (MDD) with anxious distress and without psychotic features. The Company expects top-line results from this trial in the fourth quarter of 2019.

This trial is a 6-week, 3-arm, randomized, double-blind, placebo-controlled study to investigate the safety and efficacy of MIN-117. The primary efficacy endpoint is the change in the Montgomery-Asberg Depression Rating Scale (MADRS) total score from baseline (the start of double-blind treatment) to the end of the double-blind treatment period (week 6), and the key secondary endpoint is the change in the Hamilton-Anxiety Rating Scale (HAM-A) over the same period.

Seltorexant

During 2019, the Company completed and announced top-line results from three Phase 2b trials and one Phase 1b trial with seltorexant (MIN-202). Three of these trials were in MDD and one was in insomnia disorder.

Key conclusions following data analyses from these trials include the following.

- Seltorexant shows clinically meaningful and consistent improvements in mood and sleep symptoms.
- In depressed patients, seltorexant shows improvement in mood as monotherapy and as add-on therapy to SSRIs or SNRIs, and its effect on mood is stronger in patients with insomnia.
- Among the doses of seltorexant tested, 20 mg shows the most robust and consistent effect on mood.
- In both adult and elderly subjects, seltorexant improves both sleep induction and sleep maintenance compared to zolpidem.
- Seltorexant shows a safety and tolerability profile similar to placebo.

These findings are expected to help define a Phase 3 clinical development program for seltorexant that potentially will encompass both MDD and insomnia.

**Third Quarter 2019 Financial Results**

- **Cash Position:** Cash, cash equivalents, marketable securities and restricted cash as of September 30, 2019 were approximately $60.0 million, compared to $88.1 million as of December 31, 2018.

- **R&D Expenses:** Research and development (R&D) expenses for the three and nine months ended September 30, 2019 were $9.7 million and $29.6 million, respectively, compared to $8.4 million and $25.9 million for the same periods in 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.

- **G&A Expenses:** General and administrative (G&A) expenses for the three and nine months ended September 30, 2019 were $4.6 million and $13.9 million, respectively, compared to $4.1 million and $12.2 million for the same periods in 2018. The increase in G&A expenses during the three-month period was primarily due to higher professional fees to support pre-commercial activities. The increase in G&A expenses during the nine-month period was primarily due to an increase in non-cash stock-based compensation expenses, increased salary costs and professional fees to support pre-commercial activities.

- **Net Loss:** The Company reported a net loss for the three and nine months ended September 30, 2019 of $14.0 million and $42.3 million respectively, or $0.36 and $1.08 per share, respectively, compared to $12.0 million and $37.0 million, respectively, or $0.31and $0.95 per share, respectively, for the same period in 2018.

**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 5277094.

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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, filed with the Securities and Exchange Commission on November 4, 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)**

| | September 30, 2019 | December 31, 2018 |
|---|---|---|
| | (in thousands) | |
| **ASSETS** | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 37,906 | $ 50,235 |
| Marketable securities | 22,027 | 37,763 |
| Restricted cash | 100 | 100 |
| Prepaid expenses and other current assets | 1,377 | 1,921 |
| Total current assets | 61,410 | 90,019 |
| Equipment, net | 20 | 33 |
| Other noncurrent assets | 15 | 15 |
| Operating lease right-of-use assets | 299 | - |
| In-process research and development | 34,200 | 34,200 |
| Goodwill | 14,869 | 14,869 |

| | | |
|---|---|---|
| Total Assets | $ 110,813 | $ 139,136 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current Liabilities: | | |
| Accounts payable | $ 5,330 | $ 1,799 |
| Accrued expenses and other current liabilities | 4,398 | 1,810 |
| Operating leases | 167 | - |
| Total current liabilities | 9,895 | 3,609 |
| Long-Term Liabilities: | | |
| Deferred taxes | 4,057 | 4,057 |
| Deferred revenue | 41,176 | 41,176 |
| Other noncurrent liabilities | - | 29 |
| Noncurrent operating leases | 157 | - |
| Total liabilities | 55,285 | 48,871 |
| Stockholders' Equity: | | |
| Common stock | 4 | 4 |
| Additional paid-in capital | 312,342 | 304,814 |
| Accumulated deficit | (256,818) | (214,553) |
| Total stockholders' equity | 55,528 | 90,265 |
| Total Liabilities and Stockholders' Equity | $ 110,813 | $ 139,136 |

**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) | |
|---|---|---|---|---|
| | **2019** | **2018** | **2019** | **2018** |
| Revenues | $ - | $ - | $ - | $ - |
| Operating expenses: | | | | |
| Research and development | 9,674 | 8,369 | 29,600 | 25,881 |
| General and administrative | 4,608 | 4,055 | 13,898 | 12,221 |
| Total operating expenses | 14,282 | 12,424 | 43,498 | 38,102 |
| Foreign exchange losses | (5) | (11) | (18) | - |
| Investment income | 325 | 418 | 1,250 | 1,244 |
| Interest expense | - | (4) | - | (110) |
| Loss before income taxes | (13,962) | (12,021) | (42,266) | (36,968) |
| Benefit for income taxes | - | - | - | - |
| Net (loss) income | $ (13,962) | $ (12,021) | $ (42,266) | $ (36,968) |
| Loss per share: | | | | |
| Basic and diluted | $ (0.36) | $ (0.31) | $ (1.08) | $ (0.95) |
| Weighted average shares: | | | | |
| Basic and diluted | 39,025 | 38,782 | 39,007 | 38,760 |

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