Minerva Neurosciences Reports Second Quarter 2020 Financial Results and Business Updates

August 3, 2020

WALTHAM, Mass., Aug. 03, 2020 (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, 2020.

Clinical Pipeline Update

Roluperidone

On May 29, 2020, the Company announced that the Phase 3 trial of roluperidone to treat negative symptoms in schizophrenia did not meet its primary (reduction in PANSS Marder Negative Symptoms Factor Score or NSFS) and key secondary (improvement in the Personal and Social Performance Scale Total Score or PSP) endpoints.

Although limited inferences can be drawn from these data, unadjusted statistically significant separations from placebo were observed in NSFS at Week 4 for both doses and at Week 8 for the 64 mg dose. The 64 mg dose was statistically significantly different from placebo as measured by change in PSP at all other assessment timepoints.

The patients receiving active treatment showed numerically superior improvements in NSFS to placebo, and a higher number of responders as measured by NSFS and total PANSS scores was observed in the roluperidone treatment groups. The reduction in negative symptoms scores in the 64 mg arm of roluperidone translated into functional improvement as measured by PSP.

Roluperidone was generally well tolerated, and Phase 3 safety data were consistent with such data from the Phase 2b trial.

“We continue our in-depth analyses of the Phase 3 trial with roluperidone and will be contacting the U.S. Food and Drug Administration to request a meeting to discuss our plans regarding the next steps in the clinical development of roluperidone,” said Dr. Remy Luthringer, Executive Chairman and Chief Executive Officer of Minerva. “Although the trial did not meet its primary endpoint due, we believe, to an unexpected high placebo response, we are encouraged by the study results. The consistency of reduction in overall negative symptoms and in the most important subtypes of these symptoms is similar to that observed in the previous Phase 2b study.”

“The integrated analysis of the Phase 2b and Phase 3 data show a highly significant separation between the two doses of roluperidone and placebo throughout the treatment period,” said Dr. Luthringer. “We believe the improvement in negative symptoms and the resulting functional improvement support the potential of roluperidone. This finding will help guide our discussions with the FDA regarding this potential treatment for negative symptoms, which remain one of the most important causes of everyday disability and a critical unmet need for patients with this disease.”

Seltorexant

On July 1, 2020, the Company announced that it exercised its right to opt out of its agreement with Janssen Pharmaceutica NV (Janssen) for the future development of seltorexant (MIN-202). As a result, the Company will collect a royalty on worldwide sales of seltorexant in all indications in the mid-single digits, with no financial obligations to Janssen.

“With respect to seltorexant, the decision to opt out of our agreement with Janssen at this stage of the program enables us to retain a meaningful financial interest in the future revenue stream of a compound with significant commercial potential while eliminating the Company’s financial obligations to a substantial Phase 3 program encompassing major depressive disorder and insomnia,” said Dr. Luthringer. “Furthermore, opting out will help align our human and financial resources with our primary focus on defining a path to approval of our lead compound, roluperidone.”

Second Quarter 2020 Financial Results

- **Cash Position:** Cash, cash equivalents, restricted cash and marketable securities as of June 30, 2020 were approximately $35.3 million.

- **R&D Expenses:** Research and development (R&D) expenses were $5.8 million in the second quarter of 2020, compared to $8.3 million in the second quarter of 2019, a decrease of approximately $2.5 million.

  For the six months ended June 30, 2020, R&D expenses were $13.8 million, compared to $19.9 million for the six months ended June 30, 2019, a decrease of approximately $6.1 million.

  The decreases in R&D expenses during the quarter and six months ended June 30, 2020 primarily reflect lower 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 decrease during 2020, as it has completed the MIN-117 clinical trial and the 12-week, double-blind portion of the Phase 3 clinical trial of roluperidone.

- **G&A Expenses**: General and administrative (G&A) expenses were $5.9 million in the second quarter of 2020, compared to $4.6 million in the second quarter of 2019, an increase of approximately $1.3 million.

  For the six months ended June 30, 2020, G&A expenses were $10.1 million, compared to $9.3 million for the same period in 2019, an increase of approximately $0.8 million.

  The increases in G&A expenses during the quarter and six months ended June 30, 2020 were primarily due to increases in non-cash stock-based compensation expenses and severance benefits.

- **Net Income/Loss:** Net income was $29.5 million for the second quarter of 2020, or net income per share of $0.75 and $0.73 basic and diluted, respectively, 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 2019. Net income was $17.4 million for the first six months of 2020, or net income per share of $0.44 and $0.43 basic and diluted, respectively, as compared to a net loss of $28.3 million, or a loss per share of $0.73 basic and diluted for the first six months of 2019.

  As a result of opting out of the agreement with Janssen, the Company recognized $41.2 million in collaborative revenue during the second quarter of 2020 which had previously been included on the balance sheet under deferred revenue. This amount represents the $30 million payment made by Janssen in 2017 and $11.2 million in previously accrued collaborative expenses forgiven by Janssen upon the effective date of the Amendment. The Company does not have any future performance obligations under the agreement and will recognize any future royalty revenues in the periods of the sale of products related to the Agreement.

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 8687621.

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’s portfolio of compounds includes: roluperidone (MIN-101), in clinical development for schizophrenia; a potential royalty stream from 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 (MIN-101); the clinical and therapeutic potential of this compound; the likelihood of future sales and a royalty stream from seltorexant; 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 will advance further in the clinical trials process and whether and when, if at all, it 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 June 30, 2020, filed with the Securities and Exchange Commission on August 3, 2020. 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, 2020	December 31, 2019
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 32,252	$ 21,413
Marketable securities	2,996	24,442
Restricted cash	100	100

Prepaid expenses and other current assets	543	1,182
Total current assets	35,891	47,137
Equipment, net	7	16
Other noncurrent assets	15	15
Operating lease right-of-use assets	184	262
In-process research and development	15,200	15,200
Goodwill	14,869	14,869
Total Assets	$ 66,166	$ 77,499
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 3,138	$ 2,317
Accrued expenses and other current liabilities	4,080	4,139
Operating leases	185	173
Total current liabilities	7,403	6,629
Long-Term Liabilities:		
Deferred taxes	1,803	1,803
Deferred revenue	-	41,176
Noncurrent operating leases	16	111
Total liabilities	9,222	49,719
Stockholders' Equity:		
Common stock	4	4
Additional paid-in capital	326,298	314,512
Accumulated deficit	(269,358)	(286,736)
Total stockholders' equity	56,944	27,780
Total Liabilities and Stockholders' Equity	$ 66,166	$ 77,499

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)**	
	2020	**2019**	**2020**	**2019**
Collaborative revenue	$ 41,176	$ -	$ 41,176	$ -
Operating expenses:				
Research and development	5,767	8,320	13,849	19,926
General and administrative	5,901	4,584	10,090	9,290
Total operating expenses	11,668	12,904	23,939	29,216
Gain (loss) from operations	29,508	12,904	17,237	29,216
Foreign exchange losses	(4)	(7)	(13)	(13)
Investment income	25	434	154	925
Net income (loss)	29,529	(12,477)	17,378	(28,304)
Net income (loss) per share, basic	$ 0.75	$ (0.32)	$ 0.44	$ (0.73)
Weighted average shares outstanding, basic	39,483	39,025	39,330	38,997
Net income (loss) per share, diluted	$ 0.73	$ (0.32)	$ 0.43	$ (0.73)
Weighted average shares outstanding, diluted	40,278	39,025	40,145	38,997

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