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Minerva Neurosciences Reports Second Quarter 2016 Financial Results and Business Updates

Positive clinical data advance development with MIN-101 in schizophrenia and MIN-117 in major depressive disorder

Additional trials also planned with MIN-202 in insomnia disorder and major depressive disorder

WALTHAM, Mass., Aug. 04, 2016 (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, 2016.

"Positive data announced during the second quarter of 2016 reinforced the differentiated product profiles of MIN-101 and MIN-117 that have the potential to address substantial unmet needs in schizophrenia and major depressive disorder (MDD)," said Dr. Remy Luthringer, president and chief executive officer of Minerva. "Minerva is now planning the next steps in the clinical development pathways for both of these product candidates, as well as for MIN-202, under development with Janssen Pharmaceutica NV, for which positive data were announced earlier this year in both insomnia disorder and major depressive disorder."

The Company also completed a public offering of shares of common stock on June 17, 2016 that resulted in net proceeds of approximately $53.7 million. These resources will support the continued clinical development of MIN-101, MIN-117 and MIN-202, as well as the pre-clinical development of MIN-301 for Parkinson's disease.

MIN-101:

- The primary endpoint of improvement in negative symptoms was achieved in a Phase IIb, 12-week, randomized, double-blind, placebo-controlled parallel trial of two daily doses of MIN-101, 32 milligrams (mg) and 64 mg, in 244 patients with schizophrenia.
- Consistent and statistically significant improvements were demonstrated in multiple secondary endpoints, including overall symptomatology and cognition as measured by a number of rating scales. Positive symptoms were observed to remain stable.
- The absence of extra-pyramidal symptoms supports the direct and specific effect of MIN-101 on negative symptoms rather than an indirect effect mediated by improvements of positive symptoms.
- MIN-101 was reported to be well tolerated, and the incidence and types of side effects did not differ significantly between the MIN-101 and placebo groups. No metabolic adverse effects and no weight gain were observed. Two patients out of 162 who received MIN-101 were discontinued based on QTcF prolongation (both on the higher dose).
- A number of patients who completed the 12-week double-blind core phase of this study have entered an ongoing 24-week, open-label extension phase during which all patients are receiving one of the two doses of MIN-101. The extension phase is expected to conclude in the third quarter of 2016. Thereafter, the Company plans to meet with regulatory authorities regarding the design of pivotal clinical trials.

MIN-117:

- The primary endpoint of improvement in depressive symptomatology was achieved in a four-arm, parallel-group, randomized double-blind, placebo- and positive-control Phase IIa trial which tested two daily doses of MIN-117, 0.5 mg and 2.5 mg, in 84 patients with moderate to severe MDD.
- Improvements in depressive symptomatology and in anxiety were initially observed at two weeks following initiation of treatment. Prospectively defined remission in symptoms was achieved by 24 percent of patients treated with the 2.5 mg dose.
- Pharmacodynamic measurements showed that MIN-117 preserved sleep continuity and architecture and had no detrimental effects on rapid eye movement sleep distribution and duration.
- Both doses demonstrated a favorable tolerability profile, and the incidence and types of side effects did not differ significantly between MIN-117 and placebo. No unexpected adverse events were reported, and treatment with MIN-117 was not associated with cognitive impairment, sexual dysfunction, suicidal ideation or weight gain.
- As established prospectively, this trial was designed for signal detection and effect size estimation and was not powered to demonstrate statistically significant differences between MIN-117 and placebo.

MIN-202:

- Earlier this year, Minerva released positive data from a Phase IIa trial with MIN-202 in insomnia disorder and a Phase Ib trial in MDD.
- In the Phase IIa trial, patients treated with MIN-202 were observed to have statistically significant improvements in multiple key sleep parameters, compared to patients treated with placebo. These included sleep efficiency as measured by objective polysomnography, the primary endpoint of the trial.
- In the Phase Ib trial in MDD, treatment with MIN-202 was observed to result in consistent improvements in the symptoms of depression in MDD patients. These improvements support the potential of MIN-202 to have a direct effect on mood independent from its effect on sleep.
- Minerva and Janssen are planning the next steps in the clinical development program for MIN-202, including potential Phase IIb clinical trials in both insomnia disorder and MDD.

MIN-301:

- Building upon data from a non-human primate study with an analog of MIN-301, Minerva is continuing to conduct pre-clinical development and manufacturing scale-up activities with MIN-301 as a treatment for Parkinson's disease.
- We expect that the next steps in the MIN-301 program, after completion of the regular toxicology studies and final production of the GMP batch, will include filing an Investigational New Drug application (IND) and/or Investigational Medicinal Product Dossier (IMPD), with a Phase 1 study to commence upon acceptance by the U.S. Food and Drug Administration (FDA).

Second Quarter 2016 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities as of June 30, 2016 were approximately $97.1 million, compared to $32.2 million as of December 31, 2015. Minerva expects that its cash, cash equivalents and marketable securities on hand at June 30, 2016 will be sufficient to fund its operations into 2018.

- **R&D Expenses:** Research and development (R&D) expenses were $2.7 million in the second quarter of 2016, compared to $4.5 million in the second quarter of 2015. For the six months ended June 30, 2016, R&D expenses were $8.1 million, compared to $8.4 million for the six months ended June 30, 2015.

  R&D expense in the three months ended June 30, 2016 and 2015 included non-cash stock-based compensation expenses of $0.2 million in both periods. Excluding stock-based compensation, total R&D expense related to drug development programs for the three months ended June 30, 2016 and 2015 was $2.5 million and $4.3 million, respectively, a decrease of $1.8 million. This decrease in R&D expense primarily reflects lower development expenses on MIN-202 as we fulfilled our funding obligation under the co-development agreement for the current development phase, the completion of the 12-week double-blind core phase of our Phase IIb clinical trial of MIN-101 and completion of our Phase IIa clinical trial of MIN-117. These amounts were partially offset by increased personnel costs.

  R&D expense in the six months ended June 30, 2016 and 2015 included non-cash stock-based compensation expenses of $0.5 million and $0.2 million, respectively. Excluding stock-based compensation, total R&D expense related to drug development programs for the six months ended June 30, 2016 and 2015 was $7.6 million and $8.2 million, respectively, a decrease of $0.6 million. This decrease in R&D expense primarily reflects lower development expenses on MIN-202 as we fulfilled our funding obligation under the co-development agreement for the current development phase. These amounts were partially offset by increased expenses related to our Phase IIa clinical trial of MIN-117, our Phase IIb clinical trial of MIN-101, and increased personnel costs.

- **G&A Expenses:** General and administrative (G&A) expenses were $2.3 million in the second quarter of 2016, compared to $1.8 million in the second quarter of 2015. For the six months ended June 30, 2016, G&A expenses were $4.6 million, compared to $3.8 million for the same period in 2015.

  G&A expense in the three months ended June 30, 2016 and 2015 included non-cash stock-based compensation expenses of $0.6 million and $0.4 million, respectively. Excluding stock-based compensation, G&A expense for the three months ended June 30, 2016 and 2015 was $1.7 million and $1.4 million, respectively.

  G&A expense in the six months ended June 30, 2016 and 2015 included non-cash stock-based compensation expenses of $1.2 million and $0.6 million, respectively. Excluding stock-based compensation, G&A expense for the six months ended June 30, 2016 and 2015 was $3.4 million and $3.2 million, respectively.

  The increases in G&A expenses for the three and six months ended June 30, 2016 were primarily due to an increase in personnel costs and professional fees.

- **Net Loss:** Net loss was $5.2 million for the second quarter of 2016, or a loss per share of $0.18 (basic and diluted), as compared to a net loss of $6.6 million, or a loss per share of $0.27 (basic and diluted) for the second quarter of 2015. Net loss was $13.2 million for the first six months of 2016, or a loss per share of $0.47 (basic and diluted), as compared to a net loss of $12.7 million, or a loss per share of $0.58 (basic and diluted) for the first six months of 2015.

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 48847859.

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 products to treat CNS diseases. Minerva's proprietary compounds include: MIN-101, which recently completed a Phase IIb clinical trial for schizophrenia; MIN-117, which recently completed a Phase IIa clinical trial development for MDD; MIN-202 (JNJ-42847922), which recently completed Phase IIa and Phase Ib clinical trials for insomnia and MDD, respectively; 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 results of future clinical and pre-clinical milestones with MIN-101, MIN-202, MIN-117 and MIN-301; the timing of future clinical trials and results of clinical trials with these compounds; the clinical and therapeutic potential of these compounds; 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 any of our therapeutic products 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; our ability to achieve the results contemplated by our co-development agreements; 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, 2016, filed with the Securities and Exchange Commission on August 4, 2016. 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, 2016	December 31, 2015
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 88,670	$ 14,284
Marketable securities	8,387	17,921
Restricted cash	80	80
Prepaid expenses and other current assets	278	1,196
Total current assets	97,415	33,481

Equipment, net	18	26
In-process research and development	34,200	34,200
Goodwill	14,869	14,869
Total Assets	$ 146,502	$ 82,576
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Notes payable - current portion	$ 3,879	$ 1,435
Accounts payable	877	1,360
Accrued expenses and other current liabilities	1,483	2,525
Total current liabilities	6,239	5,320
Long-Term Liabilities:		
Notes payable - noncurrent	6,225	8,503
Deferred taxes	13,434	13,434
Total liabilities	25,898	27,257
Stockholders' Equity:		
Common stock	3	2
Additional paid-in capital	235,632	157,130
Accumulated deficit	(115,031)	(101,813)
Total stockholders' equity	120,604	55,319
Total Liabilities and Stockholders' Equity	$ 146,502	$ 82,576

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)	
	2016	**2015**	**2016**	**2015**
Revenues	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	2,714	4,485	8,089	8,446
General and administrative	2,250	1,847	4,632	3,765
Total operating expenses	4,964	6,332	12,721	12,211
Foreign exchange (losses)/gains	(16)	(29)	(25)	(13)
Investment income	35	27	67	27
Interest expense	(268)	(276)	(539)	(506)
Net loss	$ (5,213)	$ (6,610)	$ (13,218)	$ (12,703)
Loss per share:				
Basic and diluted	$ (0.18)	$ (0.27)	$ (0.47)	$ (0.58)
Weighted average shares:				
Basic and diluted	29,122	24,721	28,163	22,084

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