August 3, 2017

Minerva Neurosciences Reports Second Quarter 2017 Financial Results and Business Updates

FDA feedback on clinical trial design and completion of bridging study with new formulation enable initiation of Phase 3 trial with MIN-101 to treat negative symptoms of schizophrenia in second half of 2017

Amended agreement with Janssen supports dual focus of clinical development with MIN-202 in insomnia and major depressive disorder

Extended financial runway allows for timely advancement of clinical development with multiple product candidates

WALTHAM, Mass., Aug. 03, 2017 (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, 2017.

"A highly productive second quarter of 2017 included progress on a number of fronts related to clinical trial preparation, business development and financing activities," said Dr. Remy Luthringer, president and chief executive officer of Minerva. "This progress will support the timely initiation of five late-stage clinical efficacy trials with three product candidates by the end of 2017."

MIN-101:

· Following an "end-of-Phase 2 meeting" with the U.S. Food and Drug Administration (FDA), the Company is finalizing the design of a pivotal Phase 3 trial of MIN-101 to treat negative symptoms in patients with a diagnosis of schizophrenia. Key elements in this design include:

- A three-month randomized, double blind placebo controlled core stage followed by a nine-month extension phase;
- Monotherapy administration of MIN-101;
- Testing of the same daily doses, 32 milligrams (mg) and 64 mg, as those used in the successfully completed Phase 2b study;
- Primary outcome of improvement in negative symptoms;
- Recruitment of approximately 500 patients from approximately 60 clinical sites, one third of whom will come from the U.S.;
- Recruitment of patients who have been symptomatically stable in terms of positive and negative symptoms for six months, with moderate to severe negative symptoms.

· The Company has recently completed a bridging study to identify a new, improved formulation of MIN-101 to be used in the Phase 3 trial. The improved formulation is designed to provide bioequivalent exposures with the Phase 2b formulation while enhancing the safety profile of the compound.

· The Phase 3 trial is planned to be initiated on schedule in the second half of 2017, and we expect to release top-line results from the three-month double blind phase of the trial in the first half of 2019.

MIN-202 (JNJ-42847922):

· The Company announced on May 31, 2017 that it entered into an amended agreement with Janssen, conditional upon final approval by the European Commission, whereby Minerva will gain strategic control of the development of MIN-202 to treat insomnia. Janssen will forego its right to royalties on MIN-202 insomnia sales in Minerva territories. Minerva will retain all of its current rights to MIN-202 in all indications.

· Key financial terms of the amended agreement include payments to Minerva by Janssen of $30 million on final approval by the European Commission, $20 million at the start of a Phase 3 insomnia trial and $20 million when 50% of the patients are enrolled in this trial. Janssen will waive all remaining costs payable by Minerva (approximately $13 million) to completion of Phase 2 development of this compound. Minerva will assume all responsibility for Phase 3 development costs in insomnia and contribute 40% of Phase 3 development costs in other indications, including major depressive disorder (MDD).

· All Minerva stock currently owned by Johnson & Johnson Innovation - JJDC, Inc., totaling approximately 3.9 million shares and representing approximately 10% of total Minerva shares outstanding at June 30, 2017 will be repurchased by Minerva at par value of $.0001 per share or approximately $389 in total.

· Three Phase 2b trials with MIN-202 are planned for initiation before the end of 2017, including two trials in patients suffering from MDD and one in insomnia disorder without neuropsychiatric comorbid symptoms.

MIN-117:

· A Phase 2b clinical trial with MIN-117 in MDD is planned for initiation in late 2017 and expected to include patients who have both mood and anxiety disorders.

· The Company currently plans to define a primary endpoint of MDD and a secondary endpoint of anxiety in this trial, building upon previous Phase 2a clinical results that showed effects in both depressive symptomatology and anxiety, as well pharmacodynamic effects showing the preservation of sleep continuity and architecture with no detrimental effects on rapid eye movement sleep distribution and duration.

MIN-301:

· Minerva is planning to advance its pre-clinical stage compound, MIN-301, into the initial stage of clinical development as a treatment for Parkinson's disease.

· MIN-301 is a recombinant protein with the extra-cellular domain of neuregulin-1 beta primarily activating the ErbB4 receptor. Pre-clinically, MIN-301 has been shown to cross the blood-brain barrier and to have neuro-protective and neuro-restorative effects.

· The next planned 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).

FINANCING:

· The Company completed a public offering of 5,750,000 shares of common stock, including 750,000 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares, on July 5, 2017 that resulted in net proceeds of approximately $41.5 million. These resources will support the continued clinical development of MIN-101, MIN-202 and MIN-117, as well as the initial clinical development of MIN-301 for Parkinson's disease.

Second Quarter 2017 Financial Results

· **Cash Position:** Cash, cash equivalents and marketable securities as of June 30, 2017 were approximately $77.6 million, compared to $83.0 million as of December 31, 2016.

· **R&D Expenses:** Research and development (R&D) expenses were $7.1 million in the second quarter of 2017, compared to $2.7 million in the second quarter of 2016, an increase in total expense of $4.4 million. R&D expense in the three months ended June 30, 2017 and 2016 included non-cash stock-based compensation expenses of $0.5 million and $0.2 million, respectively. This increase in R&D expenses primarily reflects higher development expenses under the MIN-202 program for Phase 2 clinical trial preparation, increased expenses for the MIN-101 program and an increase in non-cash stock-based compensation expenses. These amounts were partially offset by reduced costs related to our Phase 2a clinical trial of MIN-117 due to its completion in May 2016.

For the six months ended June 30, 2017, R&D expenses were $14.8 million, compared to $8.1 million for the six months ended June 30, 2016, an increase in total expense of $6.7 million. R&D expense in the six months ended June 30, 2017 and 2016 included non-cash stock-based compensation expenses of $1.0 million and $0.5 million, respectively. This increase in R&D expenses primarily reflects higher development expenses under the MIN-202 program for Phase 2 clinical trial preparation, increased expenses for the MIN-101 program and an increase in non-cash stock-based compensation expenses. These amounts were partially offset by reduced costs related to our Phase 2a clinical trial of MIN-117 due to its completion in May 2016.

· **G&A Expenses:** General and administrative (G&A) expenses were $2.6 million in the second quarter of 2017, compared to $2.3 million in the second quarter of 2016, an increase of approximately $0.3 million. G&A expense in the three months ended June 30, 2017 and 2016 included non-cash stock-based compensation expenses of $0.7 million and $0.6 million, respectively. This increase was primarily due to an increase in professional fees during the three months ended June 30,

2016.

For the six months ended June 30, 2017, G&A expenses were $5.5 million, compared to $4.6 million for the same period in 2016, an increase of approximately $0.9 million. G&A expense in the six months ended June 30, 2017 and 2016 included non-cash stock-based compensation expenses of $1.5 million and $1.2 million, respectively. This increase was primarily due to an increase in professional fees during the six months ended June 30, 2017.

· **Net Loss:** Net loss was $9.8 million for the second quarter of 2017, or a loss per share of $0.27 (basic and diluted), as compared to a net loss of $5.2 million, or a loss per share of $0.18 (basic and diluted) for the second quarter of 2016. Net loss was $20.4 million for the first six months of 2017, or a loss per share of $0.57 (basic and diluted), as compared to a net loss of $13.2 million, or a loss per share of $0.47 (basic and diluted) for the first six months of 2016.

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 53086270.

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, in clinical development for schizophrenia; MIN-202 (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 improved formulation of MIN-101 to be used in the planned Phase 3 trial of MIN-101; the approval by the European Commission of the amendment to our co-development agreement with Janssen and the related stock repurchase agreement; our ability to negotiate and execute the definitive agreements described above; the timing and results of future clinical milestones with MIN-202 in insomnia and major depressive disorder, including the timing and scope of future clinical trials and results of clinical trials with this compound; the timing and outcomes of future interactions with U.S. and foreign regulatory bodies; our agreements with Janssen related to MIN-202; our ability to successfully develop and commercialize MIN-101, MIN-202, MIN-117 and MIN-301; 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, the inherent uncertainty in approval by the European Commission of the amendment to our co-development agreement with Janssen and the related stock repurchase agreement; whether MIN-101, MIN-202, MIN-117 and MIN-301 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 the results of future clinical trials of MIN-101, MIN-202, MIN-117 and MIN-301, if any, will be consistent with the results of past clinical trials; whether MIN-101, MIN-202, MIN-117 and MIN-301 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, 2017, filed with the Securities and Exchange Commission on August 3, 2017. 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, 2017	December 31, 2016
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 50,191	$ 82,981
Marketable securities	27,381	-
Restricted cash	80	80
Prepaid expenses and other current assets	423	803
Total current assets	78,075	83,864
Equipment, net	3	10
In-process research and development	34,200	34,200
Goodwill	14,869	14,869
Deferred public offering costs	233	-
Total Assets	$ 127,380	$ 132,943
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Notes payable - current portion	$ 5,067	$ 4,854
Accounts payable	1,432	1,467
Accrued expenses and other current liabilities	1,443	816
Accrued collaborative expenses	6,646	2,548
Total current liabilities	14,588	9,685
Long-Term Liabilities:		
Notes payable - noncurrent	1,326	3,841
Deferred taxes	13,434	13,434
Total liabilities	29,348	26,960
Stockholders' Equity:		
Common stock	4	4
Additional paid-in capital	251,311	238,837
Accumulated deficit	(153,283)	(132,858)
Total stockholders' equity	98,032	105,983
Total Liabilities and Stockholders' Equity	$ 127,380	$ 132,943

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)	
	2017	2016	2017	2016
Revenues	$ -	$ -	$ -	$ -
Operating expenses:				

Research and development	7,144	2,714	14,758	8,089
General and administrative	2,601	2,250	5,472	4,632
Total operating expenses	9,745	4,964	20,230	12,721
Foreign exchange losses	(20)	(16)	(37)	(25)
Investment income	156	35	214	67
Interest expense	(170)	(268)	(372)	(539)
Net loss	$ (9,779)	$ (5,213)	$ (20,425)	$ (13,218)
Loss per share:				
Basic and diluted	$ (0.27)	$ (0.18)	$ (0.57)	$ (0.47)
Weighted average shares:				
Basic and diluted	36,720	29,122	36,048	28,163

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