Minerva Neurosciences Reports Fourth Quarter 2021 Financial Results and Business Updates

March 1, 2022

WALTHAM, Mass., March 01, 2022 (GLOBE NEWSWIRE) -- Minerva Neurosciences, Inc. (NASDAQ: NERV) a clinical-stage biopharmaceutical company focused on the development of innovative therapies to treat central nervous system disorders, today reported key business updates and financial results for the fourth quarter ended December 31, 2021. The Company is not hosting a call this quarter as it prepares for a meeting with the FDA and anticipates providing an update after the meeting, as appropriate.

Corporate Updates

“During 2021, we advanced our roluperidone program towards the potential filing of a New Drug Application (NDA) by completing several important development activities, including our 40-week Phase 3 Open Label Extension (OLE) and our pivotal bioequivalence study. In addition, we strengthened our financial position by selling our royalty rights to seltorexant, currently in development by Janssen Pharmaceutica, N.V. (Janssen) for treatment of major depressive disorders with insomnia symptoms, to Royalty Pharma for an upfront payment of $60 million and up to $95 million in additional payments contingent on certain clinical, regulatory and commercialization milestones,” said Dr. Remy Luthringer, Executive Chairman and Chief Executive Officer of Minerva.

Roluperidone

On November 3, 2021, the Company announced that the U. S. Food and Drug Administration (FDA) denied the Company’s request for a pre-NDA meeting for roluperidone and responded that a Type C guidance meeting would be more appropriate to discuss the evidence for use of roluperidone as monotherapy for the treatment of negative symptoms of schizophrenia. Following the scheduled Type C meeting and, subject to the timing and feedback from the FDA, Minerva continues to prepare for a potential NDA submission for roluperidone in the first half of 2022.

On September 30, 2021, the Company announced results from a pivotal bioequivalence study comparing the roluperidone formulations used in its Phase 2b and Phase 3 clinical trials and the planned commercial formulation. The planned commercial formulation was tested under both fasted and fed conditions. The study met key pharmacokinetic objectives and the data demonstrate bioequivalence in terms of exposure across the various formulations.

On May 11, 2021, the Company announced results of the Open-Label Extension of the Phase 3 trial of roluperidone for the treatment of negative symptoms of schizophrenia following the completion of the 40-week OLE period. The results showed continuous improvement in negative symptoms as measured by the Positive and Negative Syndrome Scale and Marder Negative Symptom Factor Score observed over one year (12-week double-blind plus the 40-week open-label periods) in patients receiving both 64 mg and 32 mg doses. In addition, data showed continuous improvement in Personal and Social Performance total score over one year, suggesting improvement in everyday life functioning. Roluperidone showed a favorable safety profile with few serious adverse events and no evidence of somnolence, extrapyramidal side effects or weight gain, as well as a very limited number of relapses observed over one year.

Seltorexant

On January 19, 2021, the Company announced that Royalty Pharma acquired its royalty interest in seltorexant for an upfront payment of $60 million and up to $95 million in additional payments contingent on certain clinical, regulatory and commercialization milestones. Seltorexant is currently in Phase 3 development for the treatment of major depressive disorder with insomnia symptoms by Janssen, a subsidiary of Johnson & Johnson.

During 2020, the Company exercised its right to opt out of its agreement with Janssen for the Phase 3 development and commercialization of seltorexant. Under this agreement, following the opt out, the Company was entitled to collect a royalty on worldwide sales of seltorexant in all indications in the mid-single digits with no further future financial obligations to Janssen.

Fourth Quarter and 2021 Financial Results

Net (Loss) Income

Net loss was $21.3 million for the fourth quarter of 2021, or loss per share of $0.50 (basic and diluted), compared to net loss of $7.3 million for the fourth quarter of 2020, or loss per share of $0.17 (basic and diluted). Net loss was $49.9 million for the year ended December 31, 2021, or loss per share of $1.17 (basic and diluted), compared to net income of $1.9 million, or income per share of $0.05 (basic and diluted) for the year ended December 31, 2020.

Collaborative revenue was $0.0 and $41.2 million for the years ended December 31, 2021 and 2020, respectively. During 2020 the Company exercised its right to opt out of the co-development agreement with Janssen. As a result of the opt out, the Company had no further performance obligations under the development agreement and recognized $41.2 million in revenue, which had previously been included on its balance sheet under deferred revenue.

Research and Development (R&D) Expenses

R&D expenses were $18.7 million and $3.6 million for the fourth quarters of 2021 and 2020, respectively. R&D expenses were $32.0 million and $22.0 million for the years ended December 31, 2021 and 2020, respectively. The increase in R&D expenses for both the fourth quarter and year ended December 31, 2021 versus the prior year periods was primarily due to a $15.2 million non-cash impairment charge for an intangible asset related to MIN-301. During 2021 we focused our resources on advancing our lead drug candidate roluperidone and, as a result, deferred the development of MIN-301. We had previously recognized an intangible asset for MIN-301 for In-Process Research and Development in conjunction with the acquisition

of MIN-301 in 2014. The increase in R&D expense for the year ended December 31, 2021 was also partially offset by lower non-cash stock compensation expense and a decrease in clinical costs due to the completion of the roluperidone OLE in May 2021. Non-cash stock compensation expense included in R&D expense was $2.4 million and $3.0 million for the years ended December 31, 2021 and 2020, respectively.

General and Administrative (G&A) Expenses

G&A expenses were $2.6 million and $3.7 million for the fourth quarters of 2021 and 2020, respectively. G&A expenses were $13.3 million and $17.3 million for the years ended December 31, 2021 and 2020, respectively. The decrease in G&A expenses for both the fourth quarter and year ended December 31, 2021 versus the prior year periods was primarily due to lower staffing related costs and non-cash stock compensation expense, partially offset by higher insurance and legal costs. Non-cash stock compensation expense included in G&A expenses was $2.8 million and $6.7 million for the years ended December 31, 2021 and 2020, respectively.

Liquidity

Cash, cash equivalents and restricted cash as of December 31, 2021 were approximately $60.9 million, as compared to $25.5 million at December 31, 2020. In January 2021 the Company received a $60 million cash payment from Royalty Pharma, in connection with Royalty Pharma's acquisition of the Company's royalty interest in seltorexant.

Non-GAAP Operating Loss

Excluding non-cash revenue and expenses, net loss for the three months ended December 31, 2021 and 2020 was $5.0 million and $5.3 million, respectively, or a basic and diluted loss per share of $0.12 and $0.12, respectively. Net loss for the twelve months ended December 31, 2021 and 2020 was $25.0 million and $29.6 million, respectively. For the twelve months ended December 31, 2021 and 2020, basic non-GAAP loss per share was $0.59 and $0.73 respectively, diluted non-GAAP loss per share was $0.59 and $0.72, respectively. The decrease in non-GAAP net loss for both the three and twelve-month periods ended December 31, 2021 versus the prior year periods was due primarily to lower clinical trial expenses as well as lower staffing related expenses, partially offset by higher legal and insurance costs. Non-GAAP results are summarized below, in the table included after the financial statements.

About Minerva Neurosciences

Minerva Neurosciences, Inc. (Nasdaq: NERV) is a clinical-stage biopharmaceutical company focused on developing product candidates to treat central nervous system (CNS) diseases. Our goal is to transform the lives of patients with improved therapeutic options. Minerva's portfolio of compounds includes roluperidone (MIN-101), in clinical development for negative symptoms of schizophrenia, and MIN-301, for Parkinson's disease. For more information, please visit our website.

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, but are not limited to, statements herein with respect to the timing and scope of clinical trials and regulatory review and results and outcomes of such clinical trials and regulatory review with roluperidone (MIN-101); the clinical and therapeutic potential of this compound; the likelihood of successful clinical trials, regulatory review, 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 or seltorexant 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-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission on March 1, 2022. 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.

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CONDENSED CONSOLIDATED BALANCE SHEET DATA
(Unaudited)

	December 31, 2021	December 31, 2020
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 60,755	$ 25,357
Restricted cash	100	100
Prepaid expenses and other current assets	1,346	1,983
Total current assets	62,201	27,440
Capitalized software, net	52	-
Other noncurrent assets	-	15
Operating lease right-of-use assets	-	102
In-process research and development	-	15,200
Goodwill	14,869	14,869
Total Assets	$ 77,122	$ 57,626
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,853	$ 996
Accrued expenses and other current liabilities	966	2,053
Operating leases	-	111
Total current liabilities	2,819	3,160
Long-Term Liabilities:		
Deferred taxes	-	1,803
Liability related to the sale of future royalties	66,327	-
Total liabilities	69,146	4,963
Stockholders' Equity:		
Common stock	4	4
Additional paid-in capital	342,673	337,454
Accumulated deficit	(334,701)	(284,795)
Total stockholders' equity	7,976	52,663
Total Liabilities and Stockholders' Equity	$ 77,122	$ 57,626

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended December 31, (in thousands, except per share amounts)		Twelve Months Ended December 31 (in thousands, except per share amounts)	
	2021	2020	2021	2020
Collaborative revenue	$ -	$ -	$ -	$ 41,176
Operating expenses:				
Research and development	18,746	3,551	32,039	22,040
General and administrative	2,631	3,748	13,327	17,289
Total operating expenses	21,377	7,299	45,366	39,329
(Loss) gain from operations	(21,377)	(7,299)	(45,366)	1,847
Foreign exchange losses	(4)	(27)	(33)	(67)
Investment income	4	1	17	161
Non-cash interest expense for the sale of future royalties	(1,733)	-	(6,327)	-
(Loss) income before income taxes	(23,110)	(7,325)	(51,709)	1,941
Benefit for income taxes	1,803	-	1,803	-
Net (loss) income	(21,307)	(7,325)	(49,906)	1,941
Net (loss) income per share, basic	$ (0.50)	$ (0.17)	$ (1.17)	$ 0.05
Weighted average shares outstanding, basic	42,722	42,684	42,722	40,824
Net (loss) income per share, diluted	$ (0.50)	$ (0.17)	$ (1.17)	$ 0.05

Weighted average shares outstanding, diluted	42,722	42,684	42,722	40,917

Reconciliation of Net (loss) income per GAAP to Non-GAAP net loss

(Unaudited)

	Three Months Ended December 31, (in millions, except per share amounts)		Twelve Months Ended December 31 (in millions, except per share amounts)	
	2021	**2020**	**2021**	**2020**
Net (loss) income per GAAP	$ (21.3)	$ (7.3)	$ (49.9)	$ 1.9
Collaborative revenue	-	-	-	(41.2)
Impairment of intangible asset	15.2	-	15.2	-
Non-cash interest expense for the sale of future royalties	1.7	-	6.3	-
Stock compensation expense	1.2	2.0	5.2	9.7
Subtotal non-cash items	18.1	2.0	26.7	(31.5)
Benefit for income taxes	(1.8)	-	(1.8)	-
Non-GAAP net loss	$ (5.0)	(5.3)	$ (25.0)	$ (29.6)
Non-GAAP loss per share, basic	$ (0.12)	$ (0.12)	$ (0.59)	$ (0.73)
Weighted average shares outstanding, basic	42.7	42.7	42.7	40.8
Non-GAAP loss per share, diluted	$ (0.12)	$ (0.12)	$ (0.59)	$ (0.72)
Weighted average shares outstanding, diluted	42.7	42.7	42.7	40.9