Minerva Neurosciences Reports Fiscal 2020 Fourth Quarter and Year End Financial Results and Business Updates

March 8, 2021

Phase 3 open-label extension completed on schedule in patients with negative symptoms of schizophrenia and data will be available in H1 2021

Minerva's royalty interest in seltorexant acquired by 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

Cash, cash equivalents and restricted cash at December 31, 2020 of $25.5m and $60m upfront payment received from Royalty Pharma in January 2021 fund current development plans

WALTHAM, Mass., March 08, 2021 (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 and fiscal year ended December 31, 2020.

Program Updates

Roluperidone

Roluperidone, a proprietary orally dosed molecule acting on $5HT_{2A}$, $Sigma_2$, and α-adrenergic receptors, is Minerva's lead product candidate currently being evaluated in a Phase 3 study as a potential treatment for negative symptoms of schizophrenia.

Following completion of the 12-week double-blind phase of the Phase 3 study in H1 2020, a total of 333 patients (65%) entered the 9-month open-label extension in which those patients already being treated with roluperidone remained on treatment on the same dose received in the 12-week double-blind phase (32mg or 64mg) and those patients who received placebo in the 12-week double-blind phase were randomized to either 32mg or 64mg.

Patient evaluation in the open-label extension phase of the Phase 3 trial of roluperidone was achieved on schedule on February 15, 2021, with a total of 202 patients (61%) completing this phase. Data are expected to be available in the first half of 2021.

The Company expects the data from the open-label extension will demonstrate whether:

- improvement of negative symptoms is sustained or increased over the one-year duration;
- improvement of negative symptoms leads to improved functioning;
- roluperidone maintains or improves positive symptoms and/or agitation; and
- the safety and tolerability profile of roluperidone is maintained over the one-year administration period.

The Company intends to initiate a pivotal bioequivalence study in approximately 48 healthy volunteers comparing the formulations employed in the Phase 2b and Phase 3 trials as well as at least one new formulation designed in conjunction with its commercial supply partner, Catalent, Inc., to facilitate large scale manufacturing.

Following the completion of the bioequivalence study, the Company plans to request a pre-NDA meeting with the U.S. Food and Drug Administration (FDA) to discuss certain matters including data from the Phase 3 open-label extension, data from the pivotal bioequivalence study and potential NDA submission of roluperidone for the treatment of negative symptoms of schizophrenia.

"Following our Type C meeting with the U.S. Food and Drug Administration (FDA) in November, 2020, during which the FDA cautioned us that an NDA submission based on the then-current data from the Phase 2b and Phase 3 studies would be highly unlikely to be filed, we are moving forward with a number of important development activities with roluperidone in support of a potential NDA submission," said Dr. Remy Luthringer, Executive Chairman and Chief Executive Officer of Minerva. "The FDA has acknowledged the promising signals observed in our Phase 2b and Phase 3 trials and has encouraged us to continue the development of this important agent for the treatment of negative symptoms, a critical unmet need in the treatment of schizophrenia.

"We are very pleased that a large number of patients chose to enter and completed the open-label extension portion of the Phase 3 trial, data from which have the potential to demonstrate durability of effect and long-term safety of roluperidone," said Dr. Luthringer. "We are also initiating the bioequivalence study comparing the tablet formulations used in Phase 2b and in Phase 3 with the commercial formulation. Once we have data from both studies in hand, we look forward to furthering our dialogue with the FDA."

Seltorexant

On January 19, 2021, the Company announced that Royalty Pharma acquired the Company's royalty interest in seltorexant for an upfront payment of $60 million and up to $95 million in potential future 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 Pharmaceutica, N.V. (Janssen), a subsidiary of Johnson & Johnson.

Previously, the Company had exercised its right to opt out of its agreement with Janssen for the Phase 3 development and commercialization of seltorexant. Under this agreement, 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 Year Ended 2020 Financial Results

- **Net (Loss) Income:** Net loss was $7.3 million for the fourth quarter of 2020, or loss per share of $0.17 (basic and diluted), compared to net loss of $29.9 million for the fourth quarter of 2019, or loss per share of $0.77 (basic and diluted). Net income was $1.9 million for the year ended December 31, 2020, or income per share of $0.05 (basic and diluted), compared to a net loss of $72.2 million, or loss per share of $1.85 (basic and diluted) for the year ended December 31, 2019.

  Collaborative revenue was $41.2 million and $0.0 for the years ended December 31, 2020 and 2019, respectively. The increase in collaborative revenue was the result of the Company's exercising its right to opt out of the co-development agreement with Janssen during 2020. As a result of the opt out, the Company has no further performance obligations and recognized the $41.2 million which had previously been included on its balance sheet under deferred revenue.

- **R&D Expenses:** Research and development (R&D) expenses were $3.6 million and $28.5 million for the fourth quarters of 2020 and 2019, respectively. R&D expenses were $22.0 million and $58.1 million for the years ended December 31, 2020 and 2019, respectively.

  The decrease in R&D expense for the fourth quarter ended December 31, 2020 was primarily due to a $19.0 million charge taken in December 2019 for the impairment of the in-process research and development related to MIN-117 following the results of the Phase 2b trial in MDD which failed to meet its primary and key secondary endpoints. The decrease in R&D expense for the year ended December 31, 2020 was due also to approximately $11.0 million from the completion of the Phase 2b clinical trial of MIN-117 in December 2019 and the completion of the core study portion of the Phase 3 clinical trial of roluperidone in May 2020. Non-cash stock compensation expense included in R&D expenses was $3.0 million and $2.6 million for the years ended December 31, 2020 and 2019, respectively.

- **G&A Expenses:** General and administrative (G&A) expenses were $3.7 million and $3.8 million for the fourth quarters of 2020 and 2019, respectively. G&A expenses were $17.3 million and $17.7 million for the years ended December 31, 2020 and 2019, respectively.

  The decreases in G&A expenses for the fourth quarter and year ended December 31, 2020 were primarily due to lower pre-commercial expenses in 2020, offset by higher insurance costs. Non-cash stock compensation expense included in G&A expenses was $6.7 million and $6.5 million for the years ended December 31, 2020 and 2019, respectively.

- **Cash Position:** Cash, cash equivalents and restricted cash as of December 31, 2020 were approximately $25.5 million, compared to $46.0 million as of December 31, 2019. 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.

Conference Call Information:

Minerva Neurosciences will host a conference call and live audio webcast today at 8:30 a.m. Eastern Time to discuss these results and recent business activities. To participate, please dial (877) 312-5845 (domestic) or (765) 507-2618 (international) and refer to conference ID 5663077.

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, 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. 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 successful clinical trials, regulatory review, commercialization, and future sales of and potential 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, 2020, filed with the Securities and Exchange Commission on March 8, 2021. 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)

	December 31, 2020	December 31, 2019
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 25,357	$ 21,413
Marketable securities	-	24,442
Restricted cash	100	100
Prepaid expenses and other current assets	1,983	1,182
Total current assets	27,440	47,137
Equipment, net	-	16
Other noncurrent assets	15	15
Operating lease right-of-use assets	102	262
In-process research and development	15,200	15,200
Goodwill	14,869	14,869
Total Assets	$ 57,626	$ 77,499
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 996	$ 2,317
Accrued expenses and other current liabilities	2,053	4,139
Operating leases	111	173
Total current liabilities	3,160	6,629
Long-Term Liabilities:		
Deferred taxes	1,803	1,803
Deferred revenue	-	41,176
Noncurrent operating leases	-	111
Total liabilities	4,963	49,719
Stockholders' Equity:		
Common stock	4	4
Additional paid-in capital	337,454	314,512
Accumulated deficit	(284,795)	(286,736)
Total stockholders' equity	52,663	27,780
Total Liabilities and Stockholders' Equity	$ 57,626	$ 77,499

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)	
	2020	2019	2020	2019
Collaborative revenue	$ -	$ -	$ 41,176	$ -
Operating expenses:				
Research and development	3,551	28,524	22,040	58,123
General and administrative	3,748	3,843	17,289	17,741
Total operating expenses	7,299	32,367	39,329	75,864
(Loss) gain from operations	(7,299)	(32,367)	1,847	(75,864)

Foreign exchange losses	(27)	(11)	(67)	(29)
Investment income	1	206	161	1,456
(Loss) income before income taxes	(7,325)	(32,172)	1,941	(74,437)
Benefit for income taxes	-	(2,254)	-	(2,254)
Net (loss) income	(7,325)	(29,918)	1,941	(72,183)
Net (loss) income per share, basic	$ (0.17)	$ (0.77)	$ 0.05	$ (1.85)
Weighted average shares outstanding, basic	42,684	39,037	40,824	39,014
Net (loss) income per share, diluted	$ (0.17)	$ (0.77)	$ 0.05	$ (1.85)
Weighted average shares outstanding, diluted	42,684	39,037	40,917	39,014

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