



NeuroBo Pharmaceuticals Reports Year End 2019 Financial Results and Provides Corporate Strategic Update

March 30, 2020

BOSTON, March 30, 2020 /PRNewswire/ -- **NeuroBo Pharmaceuticals, Inc.** (Nasdaq: NRBO), a clinical-stage biotechnology company focused on developing and commercializing multimodal, disease-modifying therapies for neurodegenerative and cardiometabolic diseases, today announced financial results for the year ended December 31, 2019 and provided a corporate strategic update.

"The closing of the merger between Gemphire Therapeutics, Inc. and NeuroBo Pharmaceuticals, Inc. at year end 2019 was a pivotal moment for NeuroBo, as it provided increased visibility with a Nasdaq listing and afforded the company a platform to pursue its long-term goals," stated Richard J. Kang, Ph.D., President and Chief Executive Officer of the combined company. "With the current macroeconomic environment, however, including the global health emergency caused by the COVID-19 pandemic, we have recently taken a number of prudent strategic steps to ensure that the company is positioned to weather this unprecedented situation. Specifically, to conserve financial resources, we have decided to postpone the initiation of Phase 3 clinical trials for NB-01, which would be very challenging in the short- or medium-term. Consequently, in the first quarter of 2020, we ceased work on Phase 3 trials for NB-01 and gave notice of termination of all related contract arrangements with our contract research organizations. We are currently re-evaluating alternatives to bring the NB-01 asset to the market through a different regulatory pathway. Development of NB-01 as an orphan drug is among the alternatives we are considering, and we may conduct feasibility studies to identify a rare disease relevant to NB-01. Additionally, we are considering marketing the NB-01 product line as nutraceutical products.

"We remain optimistic about the considerable promise of our second program, NB-02, which, in preclinical studies, has shown potential as a neuroprotective agent, and we believe that the multimodal therapeutic advantages of NB-02 could potentially represent a paradigm shift in the treatment of Alzheimer's disease and other neurodegenerative diseases," continued Dr. Kang. "Although NB-02 is almost ready for the submission of an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA), we intend to postpone our first-in-human clinical trials until market conditions improve. In the interim, we remain very excited about this particular program and, based on the strength of the data generated to date, we are assessing whether to pursue further development of NB-02 as an orphan drug."

Dr. Kang also noted that the company expects a response from the FDA in the second quarter of this year regarding removal of the partial clinical hold for Gemcabene.

With the above-described pause in clinical activity, management noted that the \$13.9 million in cash on hand as of December 31, 2019, should be sufficient to fund operations at current levels through December 2020. "We look forward to reinstating the clinical activities of our robust platform of disease-modifying therapies for neurodegenerative and cardiometabolic diseases and we are actively pursuing various financing opportunities in the interim," concluded Dr. Kang.

Overview of Current Clinical Pipeline

- **NB-01** – addresses a range of mechanisms that contribute to neuropathic pain and nerve degeneration in diabetic and other peripheral neuropathies. These include a decrease in key inflammatory markers, restoration of nerve growth factor (NGF) to normal levels, and reduction of advanced glycation end products (AGEs). NB-01 also reduces levels of TNF- α and IL-6, both of which are markers of inflammation, which are implicated in diabetes-related complications. NB-01 also restores the neurotrophin NGF, which is involved in nerve growth, maintenance and repair.

NB-01 was developed primarily as a treatment for painful diabetic neuropathy (PDN), but NB-01 can also treat other neuropathic pain conditions, including chemotherapy-induced peripheral neuropathy and post-traumatic peripheral neuropathy. The global neuropathic pain market is currently estimated to be greater than \$5 billion and is projected to grow to more than \$10 billion by 2026. In the United States, there are currently only three FDA-approved treatments for PDN.

The company believes that NB-01 has the potential to offer pain alleviation with minimal side effects and to be potentially the first disease-modifying therapy impacting the underlying disease mechanisms. NB-01 has successfully completed two Phase 2 proof-of-concept clinical trials for PDN.

In addition to the pharmaceutical market to treat pain, there is a very large and growing market for nutraceuticals in this arena. Since NB-01 is derived from natural products, the company is considering marketing NB-01 as a nutraceutical (non-pharmaceutical) product.

- **NB-02** - has the potential to treat the symptoms of cognitive impairment and modify the progression of neurodegenerative diseases associated with the malfunction of a protein called tau, and with amyloid beta plaque deposition. NB-02 has shown considerable promise as a neuroprotective agent in preclinical studies, demonstrating a multimodal mechanism of

action including inhibition of tau phosphorylation, acetylcholinesterase (AChE) inhibition, inhibition of A β toxicity and amyloid plaque formation, and anti-inflammatory effects. The company intends to further leverage the benefits of tau modulation by NB-02 in conjunction with the other pathway effects to explore treatment of certain dementias such as the tauopathies.

The company believes that leveraging the therapeutic advantages of NB-02 will drive a paradigm shift in the treatment of Alzheimer's disease and other neurodegenerative diseases. The company also is assessing whether to pursue further development of NB-02 as an orphan drug.

- **Gemcabene** – is a novel, once-daily, oral therapy designed to target known lipid metabolic pathways to lower levels of LDL-C, hsCRP and triglycerides, that originally was licensed from Pfizer. It is in development for the treatment of dyslipidemia, a serious medical condition that increases the risk of life-threatening cardiovascular disease, focused on orphan indications such as homozygous familial hypercholesterolemia (HoFH), as well as severe hypertriglyceridemia (SHTG). Gemcabene has been tested as a monotherapy and in combination with statins and other drugs in more than 1,100 subjects across 25 Phase 1 and Phase 2 clinical trials and has demonstrated promising evidence of efficacy, safety and tolerability.

In August 2018, Gemphire announced that the FDA, following submission of its two-year rodent carcinogenicity study, had requested additional preclinical studies, including a 13-week PPAR α knockout mouse study. The *in vitro* PPAR transactivation studies and subchronic study of Gemcabene in PPAR α knock-out mice are completed, and the company is expecting to receive a response from the FDA in the second quarter of 2020 regarding removal of the partial clinical hold.

NeuroBo Financial and Operating Results Highlights

Although public company Gemphire was considered the legal acquirer in the merger and issued shares of its common stock to effect the merger, the formerly private NeuroBo was considered the accounting acquirer. In accordance with generally accepted accounting principles, the historical financial statements of private company NeuroBo are considered the financial statements of the combined company, with the merger accounted for as an acquisition of the Gemcabene family of related assets on December 30, 2019. The following highlights therefore represent the operations of NeuroBo as a private company except for the effects of the merger on December 30, 2019 and the combined operations of both companies for the post-merger balance of December 2019.

- **Research and Development (R&D) Expenses** were approximately \$5.3 million for the year ended December 31, 2019, as compared to approximately \$5.1 million for the year ended December 31, 2018. The increase of approximately \$0.3 million was largely due to payroll costs in connection with newly hired personnel and costs attributed to the newly constituted Scientific Advisory Board, offset in part by a reduction in clinical trial activity due to timing of underlying studies.
- **Acquired In-process Research and Development Expenses** were approximately \$12.2 million for the year ended December 31, 2019, as compared to approximately \$8.8 million for the year ended December 31, 2018. The increase of approximately \$3.3 million was attributable to research and development projects of Gemphire which were in-process at the merger date and expensed on the merger date.
- **General and Administrative Expenses** were approximately \$2.7 million for the year ended December 31, 2019, as compared to approximately \$1.6 million for the year ended December 31, 2018. The approximate increase of \$1.1 million was primarily due to an increase in personnel-related costs, legal expenses, and operational consulting fees, among others.
- **Net Loss** for year ended December 31, 2019 was approximately \$21.3 million, or \$4.08 per basic and diluted share, based on 5,224,178 weighted average common shares outstanding, compared to a net loss of approximately \$15.5 million, or \$3.65 per basic and diluted share, based on 4,251,330 weighted average common shares outstanding for the year ended December 31, 2018.
- **Cash and Cash Equivalents** as of December 31, 2019 of \$13.9 million should be sufficient to fund the company's operations at the planned level of scientific activity through December 2020.

About NeuroBo Pharmaceuticals

NeuroBo Pharmaceuticals, Inc. is focused on novel treatments for neurodegenerative diseases affecting millions of patients worldwide. The company's multimodal approach has the potential to address the multiple underlying mechanisms of neurodegenerative diseases, alleviate symptoms and slow disease progression. The company's lead drug candidate, NB-01, for the treatment of painful diabetic neuropathy (PDN), has been shown in a Phase 2 study to significantly reduce pain symptoms associated with PDN with a superior safety profile when compared to currently available treatments. NeuroBo's IND-ready second drug candidate, NB-02, is focused on the treatment of Alzheimer's disease and neurodegenerative diseases associated with the pathological dysfunction of tau proteins in the brain.

NeuroBo Pharmaceuticals was jointly founded by Dr. Roy Freeman, professor of neurology at Harvard Medical School and renowned expert in neuropathic pain, and JK BioPharma Solutions, a biotechnology consulting company, to commercialize natural product-based research into ethical medicines. For more information, visit: <https://www.neurobopharma.com/>.

Forward Looking Statements

Any statements in this press release that are not statements of historical fact constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements include, but are not limited to, statements regarding the development of NeuroBo's product candidates and the therapeutic potential, timing and nature of clinical trials and potential regulatory approval of NeuroBo's clinical programs and pipeline. Forward-looking statements are usually identified by the use of words, such as "believes," "anticipates," "expects," "intends," "plans," "may," "potential," "will," "could" and similar expressions. Actual results may differ materially from those indicated by forward-looking statements as a result of various important factors and risks. These factors, risks and uncertainties include, but are not limited to: the occurrence of health epidemics or contagious diseases, such as COVID-19, and potential effects on NeuroBo's business, clinical trial sites, supply chain and manufacturing facilities; NeuroBo's ability to continue as a going concern; the timing of completion of NeuroBo's planned clinical trials; the timing of the availability of data from NeuroBo's clinical trials; NeuroBo's plans to research, develop and commercialize its current and future product candidates, including the potential alternative pathways for NB-01; NeuroBo's ability to successfully collaborate with existing collaborators or enter into new collaborations and to fulfill its obligations under any such collaboration agreements; the clinical utility, potential benefits and market acceptance of NeuroBo's product candidates; the impact of government laws and regulations; NeuroBo's ability to protect its intellectual property position; and NeuroBo's need for additional financing to fulfill its stated goals; and other factors discussed in the "Risk Factors" section of NeuroBo's Annual Report on Form 10-K filed with the SEC on or about the date hereof. In addition, the forward-looking statements included in this press release represent NeuroBo's views as of the date hereof. NeuroBo anticipates that subsequent events and developments will cause its views to change. However, while NeuroBo may elect to update these forward-looking statements at some point in the future, NeuroBo specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing NeuroBo's views as of any date subsequent to the date hereof.

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Financials

NeuroBo Pharmaceuticals, Inc.
Consolidated Balance Sheets
(in thousands)

	At December 31,	
	2019	2018
Assets		
Current assets:		
Cash	\$ 13,908	\$ 2,845
Restricted Cash	15	-
Prepaid expenses	153	929
Other assets	<u>42</u>	<u>34</u>
Total current assets	14,118	3,808
Right-of-use assets and other	150	9
Property and equipment, net	<u>200</u>	<u>3</u>
Total assets	<u>\$ 14,468</u>	<u>\$ 3,820</u>
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities		
Accounts payable	\$ 638	\$ 170
Accrued liabilities	1,422	49
Lease liability, short-term	<u>22</u>	<u>-</u>
Total current liabilities	2,082	219
Convertible notes-related party	-	118
Lease and other long-term liabilities	<u>94</u>	<u>23</u>
Total liabilities	2,176	360
Commitments and contingencies		
Redeemable convertible preferred stock	-	16,746
Stockholders' equity (deficit)		
Preferred stock	-	-
Common stock	16	-
Additional paid-in capital	49,130	2,266
Accumulated other comprehensive income	12	2
Accumulated deficit	<u>(36,866)</u>	<u>(15,554)</u>
Total stockholders' equity (deficit)	<u>\$ 12,292</u>	<u>(13,286)</u>
Total liabilities, redeemable convertible preferred stock stockholders' equity (deficit)	<u>\$ 14,468</u>	<u>\$ 3,820</u>

Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	For the Year Ended	
	December 31,	
	<u>2019</u>	<u>2018</u>
Operating expenses:		
Research and development	\$ 5,324	\$ 5,066
Acquired in-process research and development	12,151	8,815
General and administrative	<u>2,701</u>	<u>1,605</u>
Total operating expenses	<u>20,176</u>	<u>15,486</u>
Loss from operations	(20,176)	(15,486)
Loss on extinguishment	(1,114)	-
Interest (expense) income, net	(22)	(40)
Other income (expense), net	<u>-</u>	<u>(3)</u>
Loss before income taxes	(21,312)	(15,529)
Provision for income taxes	<u>-</u>	<u>-</u>
Net loss	<u>(21,312)</u>	<u>(15,529)</u>
Other comprehensive loss, net of tax	<u>10</u>	<u>2</u>
Comprehensive loss	<u>\$ (21,302)</u>	<u>\$ (15,527)</u>
Loss per share		
Net loss per share, basic and diluted	<u>\$ (4.08)</u>	<u>\$ (3.65)</u>
Weighted average common shares outstanding		
Basic and diluted	<u>5,224,178</u>	<u>4,251,330</u>

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