
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): April 15, 2021

NeuroBo Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37809
(Commission
File Number)

47-2389984
(IRS Employer
Identification No.)

200 Berkeley Street, Office 19th Floor
Boston, Massachusetts 02116
(Address of principal executive offices, including Zip Code)

Registrant's Telephone Number, Including Area Code: (857) 702-9600

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	NRBO	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On April 15, 2021, NeuroBo Pharmaceuticals, Inc. issued a press release announcing its 2020 financial results. A copy of the press release is furnished herewith as Exhibit 99.1.

The information included herein and in Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (“Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press release dated April 15, 2021.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

NEUROBO PHARMACEUTICALS, INC.

Date: April 15, 2021

By: /s/ Richard Kang
Richard Kang
President and Chief Executive Officer



NeuroBo Pharmaceuticals Reports Full Year 2020 Financial Results and Provides Corporate Strategic Update

Acquisition of ANA Therapeutics provides late-stage COVID-19 clinical development program with numerous key inflection points in 2021

BOSTON, April 15, 2020 -- NeuroBo Pharmaceuticals, Inc. (Nasdaq: NRBO), a clinical-stage biotechnology company focused on developing and commercializing multimodal disease-modifying therapies for viral, neuropathic and neurodegenerative diseases, today announced financial results for the year ended December 31, 2020 and provided a corporate strategic update.

“In December 2020, we significantly expanded our clinical pipeline with the acquisition of ANA Therapeutics and the addition of lead drug candidate, ANA001, a proprietary oral niclosamide formulation, currently in a 60-patient Phase 2/3 trial as a treatment for moderate to severe COVID-19,” stated Richard J. Kang, Ph.D., President and Chief Executive Officer of NeuroBo. “The recent approval of the Contingent Value Rights (CVR) Agreement amendment from a majority of the company’s CVR holders incentivizes our evaluation of Gemcabene as a treatment for COVID-19 and expands our pipeline in this indication of continued urgent need. We have a series of potentially value creating milestones over the next twelve months related to our development programs to treat COVID-19. Regarding our Phase 2 trial for ANA001, we expect to report the data monitoring committee safety results, pharmacokinetic (PK) data and the top-line data readout. We also look forward to releasing preclinical *in vitro* data for Gemcabene against COVID-19 variants alone and in combination with ANA001.”

Dr. Kang continued, “Due to the COVID-19 pandemic, we paused our plans to conduct Phase 3 trials for NB-01 in the first quarter of 2020. We continue to evaluate potential options for bringing the NB-01 asset to the market through a different regulatory pathway, including as an orphan drug for a rare disease indication. In April 2020, we were issued a key U.S. composition patent covering NB-02 which, given its demonstrated multimodal therapeutic advantages, may represent an important new alternative for the prevention and treatment of Alzheimer’s and other neurodegenerative disorders. Although NB-02 was nearing an Investigational New Drug submission with the U.S. Food and Drug Administration, we intend to postpone the first human clinical trials until global macroeconomic conditions improve, with a view toward commencing clinical trial activity in the second half of 2021, subject to improvement of the constraints imposed by the COVID 19-pandemic.”

“Importantly, we significantly bolstered our balance sheet with the \$10.0 million private placement of our common shares completed in January 2021, which we believe provides the resources to fund our operations into the fourth quarter of this year,” concluded Dr. Kang.

Full Year 2020 Financial and Operating Results Highlights

Upon the merger between Gemphire Therapeutics, Inc. and NeuroBo Pharmaceuticals, Inc. (“NeuroBo”) at year-end 2019, 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 before January 1, 2020, 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 combined operations of both companies for the year ended December 31, 2020 and the operations of NeuroBo as a private company for the comparable year ended December 31, 2019.

In December 2020, NeuroBo successfully completed the acquisition of ANA Therapeutics, Inc. (“ANA”) and its lead product candidate, ANA001, a proprietary oral niclosamide formulation in Phase 2/3 clinical development as a treatment for patients with moderate COVID-19.

- **Research and Development (R&D) Expenses** were approximately \$4.5 million for the year ended December 31, 2020, as compared to approximately \$5.3 million for the year ended December 31, 2019. The \$0.8 million decrease was primarily related to the overall reduction of clinical trial activity, as Contract Research Organization (CRO) fees, supply and personnel related costs decreased by approximately \$2.5 million, offset in part by approximately \$1.3 million in CRO termination costs associated with the March 2020 determination to postpone Phase 3 clinical trials of NB-01 in the amount of approximately \$1.3 million, and \$0.4 million for the development of Gemcabene, which was acquired in NeuroBo’s 2019 business combination with Gemphire Therapeutics, Inc.
 - **Acquired In-process Research and Development Expenses (IPR&D)** for the year ended December 31, 2020 amounted to \$17.3 million and was attributable to research and development projects of niclosamide which were in-process at the date NeuroBo acquired ANA. Acquired in-process research and development expenses for the year ended December 31, 2019 amounted to \$12.2 million and was attributable to research and development projects of Gemphire, which were in-process upon Gemphire’s merger with NeuroBo. Current accounting standards require that the fair value of IPR&D with no alternative future use be charged to expense on the acquisition date.
 - **General and Administrative Expenses** were \$7.8 million for the year ended December 31, 2020, compared to \$2.7 million for the year ended December 31, 2019. The increase of \$5.1 million was primarily due to the costs associated with operating as a public company when compared to the comparable prior year. The cost increases in 2020 included legal costs of \$1.6 million, \$1.5 million in director and officer and other insurance premiums, \$0.8 million in accounting and auditing fees, \$0.6 million in board of director and other public company costs and \$0.6 million in stock-based compensation.
 - **Net Loss** for the year ended December 31, 2020 was \$29.7 million, or \$1.83 per basic and diluted share, based on 16,217,339 weighted average common shares outstanding, compared with a net loss of \$21.3 million, or \$4.08 per basic and diluted share, based on 5,224,178 weighted average common shares outstanding for the year ended December 31, 2019.
 - **Cash and Cash Equivalents** were \$10.1 million as of December 31, 2020, compared with \$13.9 million as of December 31, 2019. Operating at its level of scientific activity during the year ended December 31, 2020, NeuroBo expects that its cash position will be adequate to fund operations into the fourth quarter of 2021.
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About NeuroBo Pharmaceuticals

NeuroBo Pharmaceuticals, Inc., a clinical-stage biotechnology company focused on developing and commercializing multi-modal disease-modifying therapies for viral, neuropathic, and neurodegenerative diseases, has a current portfolio of four drug candidates. The company's recently acquired ANA001 candidate is a proprietary oral niclosamide formulation in development as a treatment for patients with moderate to severe COVID-19 (patients not requiring ventilators). Niclosamide is a potential oral antiviral and anti-inflammatory agent with a long history of use and a well-understood safety profile in humans. ANA001 is currently being studied in a 60-subject Phase 2/3 clinical trial conducted at up to 20 clinical sites in the U.S. Niclosamide has demonstrated both antiviral and immunomodulatory activity with possible downstream effects on coagulation abnormalities observed in COVID-19. The company's NB-01 candidate has been shown in a Phase 2 study to significantly reduce pain symptoms associated with painful diabetic neuropathy (PDN), with a superior safety profile when compared to currently available treatments. Due to the global COVID-19 crisis, a planned Phase 3 study of NB-01 was postponed. In the interim, NeuroBo is exploring a potential orphan drug indication targeting chronic pain for NB-01. NeuroBo's NB-02 drug candidate is focused on the treatment of Alzheimer's disease and neurodegenerative diseases associated with the pathological dysfunction of tau proteins in the brain. The company's fourth program, Gemcabene, was previously being developed for the treatment of dyslipidemia, a serious medical condition that increases the risk of life-threatening cardiovascular disease. Gemcabene is currently being assessed as an acute treatment for COVID-19.

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 failure to obtain all of the benefits or recognize all of the synergies anticipated from the ANA acquisition; the integration of ANA potentially diverting management resources from operational matters and other strategic opportunities; the effect of future milestone payments and royalties specified in the ANA acquisition agreement on the results of operations and financial position of NeuroBo; 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, including with respect to ANA001 and Gemcabene; the timing of the availability of data from NeuroBo's clinical trials, including with respect to ANA001 and Gemcabene; 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, including ANA001 and Gemcabene; 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 Securities and Exchange Commission 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.

Contacts:

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- Tables to Follow -

NeuroBo Pharmaceuticals, Inc.
Consolidated Balance Sheets
(in thousands, except share amounts and par value)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash	\$ 10,089	\$ 13,908
Restricted cash	—	15
Prepaid expenses	546	153
Other assets	48	42
Total current assets	10,683	14,118
Right-of-use assets and other	130	150
Property and equipment, net	155	200
Total assets	<u>\$ 10,968</u>	<u>\$ 14,468</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,575	\$ 638
Accrued liabilities	1,096	1,422
Lease liability, short-term	24	22
Total current liabilities	3,695	2,082
Lease liability, long-term	70	94
Total liabilities	3,765	2,176
Commitments and contingencies (Notes 4, 5, 6 and 14)		
Stockholders' equity		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized as of December 31, 2020 and 2019, respectively; no shares issued or outstanding as of December 31, 2020 and 2019.	—	—
Common stock, \$0.001 par value per share, 100,000,000 shares authorized as of December 31, 2020 and 2019; 19,671,182 and 15,592,718 shares issued and outstanding as of December 31, 2020 and 2019, respectively.	20	16
Additional paid-in capital	73,713	49,130
Accumulated other comprehensive income	14	12
Accumulated deficit	(66,544)	(36,866)
Total stockholders' equity	7,203	12,292
Total liabilities and stockholders' equity	<u>\$ 10,968</u>	<u>\$ 14,468</u>

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

	For the Year Ended	
	December 31,	
	2020	2019
Operating expenses:		
Research and development	\$ 4,531	\$ 5,324
Acquired in-process research and development	17,339	12,151
General and administrative	7,846	2,701
Total operating expenses	<u>29,716</u>	<u>20,176</u>
Loss from operations	(29,716)	(20,176)
Loss on note extinguishment	—	(1,114)
Interest income (expense), net	39	(22)
Other expense, net	(1)	—
Loss before income taxes	(29,678)	(21,312)
Provision for income taxes	—	—
Net loss	<u>(29,678)</u>	<u>(21,312)</u>
Other comprehensive income, net of tax	2	10
Comprehensive loss	<u>\$ (29,676)</u>	<u>\$ (21,302)</u>
Loss per share:		
Net loss per share, basic and diluted	<u>\$ (1.83)</u>	<u>\$ (4.08)</u>
Weighted average common shares outstanding:		
Basic and diluted	<u>16,217,339</u>	<u>5,224,178</u>