**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): May 26, 2020**

**NeuroBo Pharmaceuticals, Inc.**
**(Exact name of registrant as specified in its charter)**

| Delaware | 001-37809 | 47-2389984 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| 200 Berkeley Street, 19th Floor<br>Boston, Massachusetts | 02116 |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

**Registrant's telephone number, including area code: (857) 702-9600**

**Not applicable**
**(Former name or former address, if changed since last report)**

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 (see General Instruction A.2. below):

☐ 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 8.01 Other Events.**

On May 26, 2020, NeuroBo Pharmaceuticals, Inc. (the "Company") issued a press release regarding written communication received from the U.S. Food and Drug Administration concerning the partial clinical trial hold on the Company's Gemcabene drug candidate. A copy of the press release is attached as Exhibit 99.1 hereto and incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits**

**(d) Exhibits**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release, dated May 26, 2020 |

**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: May 26, 2020

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

# NeuroBo Pharmaceuticals Announces Continuation of Partial Clinical Hold of Gemcabene

**BOSTON, May 26, 2020 -- 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 that it received written communication from the U.S. Food and Drug Administration (FDA) that the clinical development program for Gemcabene, a peroxisome proliferation-activated receptor (PPARα) agonist, under development as a once-daily, oral therapy for the treatment of dyslipidemia, remains on partial clinical hold. In January 2016, the Gemcabene Phase 2 clinical study was placed on partial clinical hold as the FDA requested 2-year rat and mouse carcinogenicity studies to be completed and submitted.

In May 2018, the company submitted the requested data to the FDA, which the Agency determined was insufficient to lift the partial clinical hold at that time. On April 20, 2020, the company filed an amendment to the FDA's partial clinical hold letter received in June 2018.

"While we are disappointed that the partial clinical hold was not lifted at this time, we plan to request additional clarification regarding the resolution options the FDA suggest in their response letter, in order to better evaluate a path forward for Gemcabene as a treatment for dyslipidemia," said Richard J. Kang, Ph.D., President and Chief Executive Officer of NeuroBo.

**About NeuroBo Pharmaceuticals**

NeuroBo Pharmaceuticals, Inc. is focused on novel treatments for neurodegenerative and cardiometabolic diseases affecting millions of patients worldwide. The company's multimodal approach has the potential to address multiple underlying mechanisms of neurodegenerative diseases, alleviate symptoms and slow disease progression. The company's 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. Due to the global COVID-19 crisis, a planned Phase 3 study is currently postponed. In the interim, NeuroBo is exploring a potential orphan drug indication and/or a nutraceutical pathway targeting chronic pain for NB-01. NeuroBo's 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. The company is also exploring an orphan drug pathway for NB-02. The company's third program, Gemcabene, is focused on developing and commercializing therapies for the treatment of dyslipidemia, a serious medical condition that increases the risk of life-threatening cardiovascular disease.

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. In December 2019, NeuroBo merged with Gemphire Therapeutics and through such merger, became listed on the Nasdaq Stock Market and added the Gemcabene family of related assets to its portfolio. 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 factors discussed in the "Risk Factors" section of NeuroBo's Annual Report on Form 10-K and in our other filings with the Securities and Exchange Commission. 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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