
**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): March 23, 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 1.01 Entry into a Material Definitive Agreement.

As previously disclosed, on December 30, 2019, in connection with the business combination (the “2019 Merger”) between NeuroBo Pharmaceuticals, Inc. (“NeuroBo”) and Gemphire Therapeutics, Inc. (“Gemphire”), Gemphire entered into the Contingent Value Rights Agreement (the “CVR Agreement”) with Grand Rapids Holders’ Representative, LLC, as representative of Gemphire’s stockholders prior to the Merger (the “Holders’ Representative”), and Computershare Inc. and Computershare Trust Company, N.A. as the rights agents (collectively, the “Rights Agent”). Under the CVR Agreement, which NeuroBo assumed in connection with the 2019 Merger, the holders of Gemphire shares at the time of the 2019 Merger (collectively, the “CVR Holders”) were entitled to receive 80% of the proceeds from the grant, sale, or transfer of rights to Gemcabene.

On March 23, 2021, NeuroBo, the Holders’ Representative, and the Rights Agent entered into the First Amendment to Contingent Value Rights Agreement (the “CVR Amendment”) to amend the CVR Agreement. Pursuant to the CVR Amendment, (i) the CVR Holders will continue to have the right to receive 80% of the proceeds from the grant, sale, or transfer of rights to Gemcabene as a treatment for cardiovascular conditions and (ii) the CVR Holders will now also receive 10% of the proceeds from the grant, sale, or transfer of rights to Gemcabene as a treatment for any indication outside of treating cardiometabolic diseases, including COVID-19.

The foregoing description of the CVR Agreement does not purport to be complete and is qualified in its entirety by reference to the CVR Agreement, which is incorporated herein by reference to Exhibit 10.1 to NeuroBo’s Current Report on Form 8-K, filed on December 31, 2019. The foregoing description of the CVR Amendment does not purport to be complete and is qualified in its entirety by reference to the CVR Amendment, which is filed as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 8.01 Other Events.

On March 24, 2021, NeuroBo issued a press release announcing the approval of the CVR Amendment from holders of a majority of the contingent value rights outstanding under the CVR Agreement and the execution of the CVR Amendment. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
10.1	<u>First Amendment to Contingent Value Rights Agreement, dated as of December 30, 2019, by and among NeuroBo, the Holders’ Representative, and the Rights Agent, dated as of March 23, 2021.</u>
99.1	<u>Press release, dated March 24, 2021.</u>

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 thereunto duly authorized.

NEUROBO PHARMACEUTICALS, INC.

Date: March 24, 2021

By: /s/ Richard Kang

Richard Kang

President and Chief Executive Officer

FIRST AMENDMENT TO CONTINGENT VALUE RIGHTS AGREEMENT**March 23, 2021**

This Amendment (this “**Amendment**”) is made and entered into as of the date first written above, and amends that certain Contingent Value Rights Agreement (the “**Agreement**”), dated as of December 30, 2019, by and among Gemphire Therapeutics Inc. a Delaware corporation (“**Gemphire**”), Grand Rapids Holders’ Representative, LLC, as representative of Holders (“**Holders’ Representative**”), and Computershare Inc. and Computershare Trust Company, N.A., jointly, as rights agent (“**Rights Agent**”). Capitalized terms used herein without definition shall have the meanings ascribed to such terms in the Agreement.

RECITALS

WHEREAS, the Merger Agreement between Gemphire, Sub, and NeuroBo Pharmaceuticals, Inc. (the “**Company**”) closed.

WHEREAS, a submission to the FDA of the toxicity study designed to release of the partial clinical hold on Gemcabene has been rejected by FDA resulting in a continued partial clinical hold.

WHEREAS, the Covenant End Date has passed and the Company has exercised its right to discontinue any and all further efforts to develop, divest or otherwise monetize the Gemcabene Technology.

WHEREAS, the Holders’ Representative desires for the Company to develop or otherwise monetize the Gemcabene Technology for use other than to target known lipid metabolic pathways to lower levels of LDL-C, hsCRP and triglycerides.

WHEREAS, the Company and Holders’ Representative desire to amend the Agreement to incentivize the Company to invest in the development of Gemcabene Technology for use in certain indications as the Company may so develop as better described below.

WHEREAS, Section 5.2 of the Agreement provides that, with the consent of the Acting Holders, the Holders’ Representative, Company (when authorized by a Board Resolution), and the Rights Agent may amend the Agreement.

AGREEMENT

The parties agree as follows:

1. Amendments.

(a) Section 1.22 of the Agreement is hereby amended and restated in its entirety as follows:

“**Gemcabene Technology**” means any and all Intellectual Property Rights that are (a) owned or licensed by Parent or its Affiliates as of the Effective Date or during the term of this Agreement, but prior to the closing of any Acquisition and (b) related to or constituting forms of Gemcabene or any salt, hydrate, solvate, anhydrous form, or polymorph thereof, including the monocalcium salt Gemcabene calcium, which is also identified as CI-1027, PF-01430506, and/or PD-072953, methods of using Gemcabene, and methods of manufacturing Gemcabene, including the targeting of known lipid metabolic pathways to lower levels of LDL-C, hsCRP and triglycerides. Notwithstanding the foregoing, Gemcabene Technology shall not include any Intellectual Property Rights owned or controlled by an Acquiror prior to the closing of an Acquisition or developed or acquired by such Acquiror subsequent to such closing

independently of any activities of Parent and its Affiliates (excluding such Acquiror) related to Gemcabene Technology and without reliance on or use of any Gemcabene Technology (provided that the Acquiror establishes reasonable internal safeguards designed to ensure that such conditions of independence are satisfied) nor Gemcabene Technology developed by the Company for any uses except chronically treating cardiometabolic diseases (including HoFH, HeFH, SHTG, and FCS) as an agent alone or in combination with another agent (“**Company Technology**”). Such Intellectual Property Rights as of the date of this Agreement are as set forth on Exhibit A.”

(b) Section 1.24 of the Agreement is hereby amended and restated in its entirety as follows:

“**Gross Consideration**” means, after the retention of an aggregate amount equal to \$500,000 by Parent or its Affiliates from the proceeds of a Gemcabene Deal or the Beijing SL Transaction, an amount equal to 80% of the following amounts: (a) all cash consideration paid by a Third Party to Parent or its Affiliates during the CVR Term in connection with any Gemcabene Deal or the Beijing SL Transaction (including royalty payments, but not including, in the case of the Beijing SL Transaction, the \$2,500,000 upfront payment), plus (b) with respect to any non-cash consideration received by Parent or its Affiliates from a Third Party during the CVR Term in connection with any Gemcabene Deal or the Beijing SL Transaction, all amounts received by Parent and its Affiliates for such non-cash consideration at the time such non-cash consideration is monetized by the Parent or its Affiliates (which amounts will be subject to payment to the Rights Agent when such non-cash consideration is monetized and such amounts are received by Parent or any of its Affiliates). If a Gemcabene Deal or Beijing SL Transaction also involves assets that are not related to Gemcabene Technology but are related to other proprietary technology, products or assets of Parent or its Affiliates, then the total consideration will be allocated between all such technology, products and assets, and only that consideration allocated to the Gemcabene Technology will be included in Gross Consideration. Notwithstanding the foregoing, with respect to the Company Technology, the Gross Consideration shall mean an amount equal to 10% of the following amounts: (a) all cash consideration paid by a Third Party to Parent or its Affiliates during the CVR Term in connection with any Company Technology minus Permitted Deductions, plus (b) with respect to any non-cash consideration received by Parent or its Affiliates from a Third Party during the CVR Term in connection with Company Technology, all amounts received by Parent and its Affiliates for such non-cash consideration at the time such non-cash consideration is monetized by the Parent or its Affiliates (which amounts will be subject to payment to the Rights Agent when such non-cash consideration is monetized and such amounts are received by Parent or any of its Affiliates).”

(c) Section 1.32 of the Agreement is hereby amended and restated in its entirety as follows:

“**Permitted Deductions**” means the sum of: (i) any and all fees, milestone payments and royalties paid by Parent and its Affiliates to Pfizer pursuant to the Pfizer License Agreement with respect to the Gemcabene Technology that is subject to a Gemcabene Deal, plus (ii) all fees, milestones, royalties and other payments paid by Parent and its Affiliates to any other Third Party licensor in consideration for a license to such Third Party’s patents that would be infringed, absent such license, by the practice of such Gemcabene Technology, plus (iii) all patent prosecution and maintenance costs, and drug product storage costs, incurred by Parent and its Affiliates with respect to the Gemcabene Technology, plus (iv) all out-of-pocket transaction costs incurred by Parent and its Affiliates to Third Parties for the negotiation, entry into and closing of a Gemcabene Deal, or any transaction described under (i) – (iii) in this paragraph, including any broker fees, finder’s fees, advisory fees, accountant or attorney’s fees, plus (v) all fees and costs (including any amounts paid for indemnification) payable by Parent to the Rights Agent pursuant to this Agreement, plus (vi) all fees and costs incurred by Parent and its Affiliates after the Closing in connection with the Beijing SL Transaction, including but not limited to those relating to insurance costs, plus (vii) all

fees and costs incurred by Parent and its Affiliates to settle any claims relating to tail provisions under investment banking engagement letters entered into by Gemphire prior to the Closing, in each case to the extent such costs have been incurred during the CVR Term and are not reimbursed or paid to Parent or its Affiliate by a Third Party (including a Governmental Entity), plus (vii) with respect to Company Technology only, all cost associated with developing the Company Technology.”

2. Reference to and Effect on the Agreement. On or after the date hereof, each reference in the Agreement to “this Agreement,” “hereunder,” “herein” or words of like import shall mean and be a reference to the Agreement as amended hereby.

3. No Other Amendments. Except as set forth herein, the Agreement shall remain in full force and effect in accordance with its terms.

4. Recitals. The recitals contained herein shall be taken as the statements of the Company, and the Rights Agent assumes no responsibility for the correctness or completeness of the same.

5. Counterparts. This Amendment may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal E-SIGN Act of 2000, e.g., www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

6. Governing Law. This Amendment shall be governed by and construed in accordance with the laws of the State of Delaware without reference to any principle or rule (whether of the State of Delaware or any other jurisdiction) that would cause the application of laws of any jurisdiction other than those of the State of Delaware.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties have executed this Amendment to Contingent Value Rights Agreement to be executed on its behalf by its duly authorized officers as of the day and year first above written.

NEUROBO PHARMACEUTICALS, INC.

By: /s/ Richard J. Kang

Name: Richard J. Kang

Title: President & CEO

COMPUTERSHARE INC.

COMPUTERSHARE TRUST COMPANY, N.A.

By: /s/ Collin Ekeogu

Name: Collin Ekeogu

Title: Manager, Corporate Actions

GRAND RAPIDS HOLDERS' REPRESENTATIVE, LLC

By: /s/ Steve Gullans

Name: Steve Gullans

Title: Manager



NeuroBo Pharmaceuticals Receives Approval for Amendment of Contingent Value Rights for Gemcabene

Gemcabene to be Studied as a Stand-alone Treatment for COVID-19 and in Combination with Lead Asset, ANA001

BOSTON, March 24, 2021 -- NeuroBo Pharmaceuticals, Inc. (Nasdaq: NRBO), a clinical-stage biotechnology company, today announced that it has received approval of an amendment to its Contingent Value Rights (CVR) agreement from a majority of the holders of a majority of the outstanding CVRs, incentivizing the evaluation of Gemcabene as a treatment for COVID-19.

The CVRs were distributed to the holders of Gemphire Therapeutics, Inc. common stock on December 30, 2019, immediately prior to its merger with NeuroBo Pharmaceuticals, Inc. The CVR amendment will allow NeuroBo to pursue Gemcabene as a therapy for COVID-19, with its own resources. In exchange, CVR holders will receive 10% of certain gross proceeds received by the company for any indication outside of treating cardiometabolic diseases. CVR holders will retain the original CVR for 80% of any proceeds of Gemcabene for cardiovascular conditions.

"The amendment to the CVR agreement represents another important milestone for NeuroBo and underscores investors' enthusiasm to explore additional therapeutic indications for Gemcabene that may strengthen our pipeline of assets to treat viral diseases including COVID-19," stated Richard J. Kang, Ph.D., President and Chief Executive Officer of NeuroBo. "We intend to evaluate Gemcabene both as a stand-alone treatment for COVID-19, and in a treatment combination with ANA001, our proprietary oral niclosamide formulation, which is currently in a 60-patient phase 2/3 trial as a treatment for moderate to severe COVID-19. We expect data from the Phase 2 segment of the ANA001 study in the third quarter of 2021 and are currently pursuing an abbreviated 505(b)(2) regulatory pathway.

Dr. Kang continued, "Even with the development of COVID-19 vaccines, current and future variants of the virus will likely necessitate a toolbox of effective therapies to treat various patient populations suffering from COVID-19. We look forward to achieving multiple value-creating milestones in the coming year, including the data monitoring committee results, the pharmacokinetic (PK) data for the phase 2 trial of ANA001, the top-line data readout from the phase 2 trial of ANA001 to treat COVID-19 and preclinical *in vitro* data for Gemcabene against COVID-19 variants alone and in treatment combination with ANA001. We are excited to continue the development of these potentially life-saving therapies to address the ongoing need for safe and effective COVID-19 treatments on a global scale."

About Gemcabene

Gemcabene, a peroxisome proliferation-activated receptor (PPAR α) agonist, is a novel, once daily, oral therapy, for patients who are unable to achieve normal levels of LDL C or triglycerides with currently approved therapies, primarily statin therapy. Gemcabene's mechanism of action is designed to enhance the clearance of very low-density lipoproteins (VLDLs) in the plasma and inhibit the production of fatty acids and cholesterol in the liver.

Gemcabene was being evaluated in a Phase 2 randomized, double-blind, placebo-controlled study to assess its efficacy safety and tolerability in patients with severe hypertriglyceridemia. In January 2016, the Gemcabene Phase 2 clinical study was placed on partial clinical hold as the U.S. Food and Drug Administration requested 2-year rat and mouse carcinogenicity studies to be completed and submitted. The study currently remains on partial clinical hold for the treatment of dyslipidemia. Gemcabene is currently being assessed as an acute treatment for COVID-19.

About Niclosamide and ANA001

ANA001 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. In preclinical research by an independent academic group published in Antimicrobial Agents and Chemotherapy, niclosamide inhibited viral replication in vitro and was more potent than remdesivir in the same assay.

Specifically, studies have shown that niclosamide prevents replication of SARS-CoV-2 at very low concentrations and that the compound appears to exhibit three distinct mechanisms of action: 1) acting as a potent antiviral to a broad homology of other viruses including influenza; 2) reducing inflammation without suppressing the immune system; and 3) providing bronchodilation, which is a useful pulmonary mechanism for at-risk patients with underlying cardiovascular and/or pulmonary conditions.

As a result, the company believes ANA001 has the potential to reduce the viral load and inflammation associated with cytokine dysregulation, acute respiratory distress syndrome (ARDS), and coagulation abnormalities and thus improve time to clinical improvement as defined as hospital discharge recorded using the WHO Ordinal Scale for Clinical Improvement.

The company believes ANA001 has distinct competitive advantages in this market, including (1) offering an effective treatment for moderate to severe COVID-19 (patients not requiring ventilators); (2) having 3+ year marketing exclusivity in the U.S. upon U.S. Food and Drug Administration (FDA) approval; (3) providing ease of administration via a capsule formulation and potential to dramatically lower overall treatment cost; and (4) possessing a proven safety profile (generic niclosamide has been used safely for 50 years as a treatment for tapeworm infections).

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 global COVID-19 crisis, a planned Phase 3 study 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 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 SAR-CoV-2.

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 timeline for niclosamide for the treatment of COVID-19, the market size for COVID-19-related therapeutics and the competitive advantages of ANA001, the potential benefits of ANA001 as a treatment for patients with moderate to severe COVID-19 (patients not requiring ventilators), the potential distribution of proceeds to CVR holders, and the timing or receipt of regulatory approvals. 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 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; the clinical utility, potential benefits and market acceptance of NeuroBo's product candidates, including ANA001 and Gemcabene; 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 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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