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 3, 2023

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
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 8.01 Other Events.

On April 3 2023, NeuroBo Pharmaceuticals, Inc. issued a press release announcing the submission of an Investigational New Drug application to the U.S. Food and Drug Administration. The IND application supports a Phase 2a clinical trial of DA-1241, a novel G-Protein-Coupled Receptor 119 agonist, in development for the treatment of nonalcoholic steatohepatitis. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Information contained on or accessible through any website reference in the press release is not part of, or incorporated by reference in, this Current Report on Form 8-K, and the inclusion of such website addresses in this Current Report on Form 8-K by incorporation by reference of the press release is as inactive textual references only.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release dated April 3, 2023
104	Cover Page Interactive Data File (embedded within Inline XBRL document).

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 3, 2023

By: /s/ Joseph Hooker
Joseph Hooker
Interim President and Chief Executive Officer

NeuroBo Pharmaceuticals Announces Submission of IND Application to the FDA for a Phase 2a Clinical Trial of DA-1241 for the Treatment of NASH

BOSTON, April 3, 2023 – NeuroBo Pharmaceuticals, Inc. (Nasdaq: NRBO), a clinical-stage biotechnology company primarily focused on cardiometabolic diseases, today announced that it has submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA). The IND application supports a Phase 2a clinical trial of DA-1241, a novel G-Protein-Coupled Receptor 119 (GPR119) agonist, in development for the treatment of nonalcoholic steatohepatitis (NASH).

"Filing of the IND for DA-1241 marks the first significant milestone for NeuroBo since acquiring the rights to this very promising cardiometabolic asset which is targeted to address the underserved NASH market," stated Joe Hooker, Interim President and Chief Executive Officer of NeuroBo. "I would like to thank our entire team, who worked tirelessly to move this asset into the IND process, ahead of schedule, bringing us one step closer in the development of this potential therapy, for which there are currently no approved treatments.

"Based on preclinical evidence generated, to date, administration of DA-1241 has shown reduced hepatic steatosis, inflammation, and fibrosis, as well as improved lipid metabolism and glucose control regardless of body weight reduction. Additionally, in Phase 1a/1b clinical studies, DA-1241 was well tolerated in both healthy volunteers and in patients with type 2 diabetes (T2D). It is our belief, based on this evidence, that the mechanism of DA-1241 will translate into a safe and effective treatment for NASH. We look forward to initiating the clinical development for DA-1241 and, if regulatory review of our IND is completed, key upcoming milestones for this program include enrollment of our first patient, expected in the third quarter of this year, with data targeted for the second half of 2024. We also intend to advance our second cardiometabolic asset, DA-1726, through the IND process this year, with the goal of initiating a Phase 1a safety study in the first half of next year, for which data would also be expected in the second half of the year. We are excited about the new direction of the company as well as the potential of these assets and look forward to executing on these new pipeline programs."

The Phase 2a trial of DA-1241 is expected to be a 16-week, multicenter, randomized, double-blind, placebo-controlled, parallel arm study to evaluate the efficacy and safety of DA-1241 in subjects with presumed NASH. The trial is expected to enroll a total of 87 subjects, with a planned maximum of 98 subjects to account for early discontinuations, who will be randomized into 4 treatment groups and will be dosed with: DA-1241 50 mg, DA-1241 100 mg, DA-1241 100 mg/Sitagliptin 100 mg, or Placebo in a 1:2:2:2 ratio. Randomization will be stratified by Type 2 Diabetes Mellitus (T2DM) status at baseline. The primary endpoint is the change from baseline in alanine transaminase (ALT) levels at Week 16/Day 112. Secondary efficacy endpoints include the proportion of subjects with normalization of ALT, relative percent change in liver fat fraction from baseline, absolute change in liver fat from baseline, and proportion of subjects with a 30% or more reduction in liver fat from baseline, among others. Safety will be evaluated by monitoring adverse events (AEs) including determination of serious adverse events (SAEs) and AEs leading to discontinuation and laboratory abnormalities as characterized by type,

frequency, timing, severity (mild, moderate, severe), seriousness and relationship to DA-1241, vital signs measurements, clinical laboratory tests and electrocardiogram (ECG) assessments.

About DA-1241

DA-1241 is a novel G-Protein-Coupled Receptor 119 (GPR119) agonist with development optionality as a standalone and/or combination therapy for both NASH and T2D. Agonism of GPR119 in the gut promotes the release of key gut peptides GLP-1, GIP, and PYY. These peptides play a further role in glucose metabolism, lipid metabolism and weight loss. DA-1241 has beneficial effects on glucose, lipid profile and liver inflammation, supported by potential efficacy demonstrated during in vivo preclinical studies. The therapeutic potential of DA-1241 has been demonstrated in multiple pre-clinical animal models of NASH and T2D where DA-1241 reduced hepatic steatosis, inflammation, fibrosis, and improved glucose control. Furthermore, in Phase 1a and 1b human trials DA-1241 was well tolerated in both healthy volunteers and those with T2D.

About NeuroBo Pharmaceuticals

NeuroBo Pharmaceuticals, Inc., is a clinical-stage biotechnology company focused primarily on therapies for cardiometabolic diseases. Its primary therapeutics programs include DA-1241 and DA-1726. DA-1241 is a novel G-Protein-Coupled Receptor 119 (GPR119) agonist, which promotes the release of key gut peptides GLP-1, GIP and PYY, which, in turn, play an important role in glucose metabolism, lipid metabolism and weight loss. DA-1726 is a novel oxyntomodulin (OXM) analogue functioning as a glucagon-like peptide-1 receptor (GLP1R) and glucagon receptor (GCGR) dual agonist. OXM is a naturally-occurring, 37-amino acid peptide hormone that is released from the gut after ingestion of a meal, activating both the GLP-1 and glucagon receptors, prompting reduced food intake as well as an increase in energy expenditure, potentially resulting in superior body weight loss compared to selective GLP-1 receptor agonists. For more information, please visit www.neurobopharma.com.

Forward Looking Statements

Certain statements in this release may be considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including without limitation, statements about the closing of the offering of securities. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Many factors could cause actual future events to differ materially from the forward-looking statements in this release, including, without limitation, those risks associated with our ability to execute on our commercial strategy, the timeline for regulatory submissions, regulatory steps and potential regulatory approval of our current and future product candidates, the ability to realize the benefits of the license agreement with Dong-A ST Co. Ltd., including the impact on future financial and operating results of NeuroBo; the ability to integrate the new product candidates into NeuroBo′s business in a timely and cost-efficient manner; the cooperation of our contract manufacturers, clinical study partners and others involved in the development of our current and future product candidates; our ability to recruit subjects for our clinical trials; costs related to the license agreement, known and unknown, including costs of any litigation or regulatory actions relating to the license agreement; changes in applicable laws or regulations; effects of changes to NeuroBo′s stock price on the terms of the license agreement and any future fundraising; and other risks and uncertainties described in our filings with the SEC. Forward-looking statements speak only as of the date

when made. NeuroBo does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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