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 2, 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 May 2 2023, NeuroBo Pharmaceuticals, Inc. issued a press release announcing that the U.S. Food and Drug Administration had cleared an Investigational New Drug application for a Phase 2a clinical trial of DA-1241 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 May 2, 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: May 2, 2023

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

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

Initiation of Phase 2a Clinical Trial Expected to Occur in Q3 2023

BOSTON, May 2, 2023 – NeuroBo Pharmaceuticals, Inc. (Nasdaq: NRBO), a clinical-stage biotechnology company on a quest to transform cardiometabolic diseases, today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for DA-1241, a novel G-Protein-Coupled Receptor 119 (GPR119) agonist. The company plans to initiate a two-part, Phase 2a clinical trial of DA-1241, for the treatment of nonalcoholic steatohepatitis (NASH), in the third quarter of 2023.

“Clearance of the IND for DA-1241 brings us one step closer to our goal of bringing this very promising cardiometabolic asset into clinical trials in patients with NASH, for which there is currently no approved treatment,” stated Joe Hooker, Interim President and Chief Executive Officer of NeuroBo. “In Phase 1a/1b clinical studies, DA-1241 was well tolerated in both healthy volunteers and in patients with type 2 diabetes mellitus (T2DM). Importantly, preclinical studies demonstrated that DA-1241 attenuated NASH progression by reducing pro-inflammatory cytokines and chemokines, stellate cell activation, and collagen deposition in the liver, thereby improving inflammation, hepatic steatosis, and fibrosis. In those studies, DA-1241 also improved both lipid metabolism and glucose control. For these reasons, we believe that the mechanism of action of DA-1241 will translate into a safe and effective treatment for NASH. We are eager to initiate the two-part, Phase 2a clinical trial of DA-1241, which we expect will occur in the third quarter of this year. The two-part design provides optionality for an interim analysis in the first half of 2024 and we anticipate full data in the second half of 2024.

"Looking ahead, we expect additional, near-term value creating milestones, including advancement of DA-1726, our second asset, through the IND process, with the goal of initiating a Phase 1a safety study in the first half of 2024 and an expected data readout in the second half of 2024. DA-1726 is a novel oxyntomodulin (OXM) analogue that acts as a glucagon-like peptide-1 receptor (GLP1R) and glucagon receptor (GCGR) dual agonist. The drug candidate is in development for the treatment of obesity and has demonstrated superior body weight loss in preclinical studies compared with other selective GLP1R agonists.

"It is truly an exciting time at NeuroBo, following the recent in-licensing of DA-1241 and DA-1726, with a new focus on cardiometabolic diseases and the enormous NASH, obesity, and T2DM markets.”

The two-part, Phase 2a trial of DA-1241 is designed to be a 16-week, multicenter, randomized, double-blind, placebo-controlled, parallel clinical study to evaluate the efficacy and safety of DA-1241 in subjects with presumed NASH and confirmed pre-diabetes or T2DM. Part 1 will explore the efficacy of DA-1241 versus placebo, and is expected to enroll 49 subjects, with a planned maximum of 55 subjects to account for early discontinuations. Subjects will be randomized in a 1:2:1 ratio into 3 treatment groups: DA-1241 50 mg, DA-1241 100 mg, or placebo. Part 2 will explore the efficacy of DA-1241 in combination with sitagliptin, versus placebo, and will begin after completion of a confirmatory preclinical safety study of DA-1241 in combination with sitagliptin. It is expected to enroll 37 subjects, with a planned maximum of 43 subjects to account for early discontinuations, and subjects will be randomized in 2:1 ratio into 2 treatment groups: DA-1241

100 mg/sitagliptin 100 mg or placebo. Randomization of Part 1 and Part 2 will be stratified by T2DM status at baseline.

For both Part 1 and Part 2, the primary endpoint is the change from baseline in alanine transaminase (ALT) levels at Week 16. 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), serious adverse events (SAEs) and AEs leading to discontinuation and laboratory abnormalities.

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 T2DM. In preclinical studies, DA-1241 demonstrated that GPR-119 agonism promotes release of the key gut peptides GLP-1, GIP, and PYY, which have a beneficial effect on liver inflammation, lipid metabolism, weight loss, and glucose metabolism. The therapeutic potential of DA-1241 has been demonstrated in multiple pre-clinical animal models of NASH and T2DM whereby DA-1241 reduced hepatic steatosis, hepatic inflammation, and liver fibrosis, while also improving glucose control. Furthermore, in Phase 1a and 1b trials, DA-1241 was well tolerated in both healthy volunteers and those with T2DM.

About NeuroBo Pharmaceuticals

NeuroBo Pharmaceuticals, Inc. is a clinical-stage biotechnology company on a quest to transform cardiometabolic diseases. The company is currently developing DA-1241 for the treatment of Non-Alcoholic Steatohepatitis (NASH) and Type 2 Diabetes Mellitus (T2DM), and is developing DA-1726 for the treatment of obesity. 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. In preclinical studies, DA-1241 demonstrated positive effect on liver inflammation, lipid metabolism, weight loss, and glucose metabolism, reducing hepatic steatosis, hepatic inflammation, and liver fibrosis, while also improving glucose control. DA-1726 is a novel oxyntomodulin (OXM) analogue that acts as a glucagon-like peptide-1 receptor (GLP1R) and glucagon receptor (GCGR) dual agonist. OXM is a naturally-occurring gut hormone that activates GLP1R and GCGR, thereby decreasing food intake while increasing energy expenditure, thus potentially resulting in superior body weight loss compared to selective GLP1R 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 initiate and complete clinical

trials on a timely basis; 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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