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): February 1, 2024

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.)

545 Concord Avenue, Suite 210
Cambridge, Massachusetts 02138
(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 February 1 2024, NeuroBo Pharmaceuticals, Inc. (the ***"Company"***) issued a press release announcing that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for DA-1726, a novel, dual oxyntomodulin (OXM) analog agonist that functions as a glucagon-like peptide-1 receptor (GLP1R) and glucagon receptor (GCGR). The company plans to initiate a Phase 1 clinical trial, for the treatment of obesity, in the first half of this year. 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 February 1, 2024
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: February 1, 2024

By: /s/ Hyung Heon Kim
Hyung Heon Kim
President and Chief Executive Officer

Exhibit 99.1

NeuroBo Pharmaceuticals Announces FDA Clearance of IND for a Phase 1 Clinical Trial of DA-1726 for the Treatment of Obesity

Preclinical Studies Show DA-1726 Elicits Superior Weight Loss Compared to Semaglutide (Wegovy™) and Similar Weight Loss Compared to Tirzepatide (Mounjaro™), While Consuming More Food

Initiation of Phase 1 Clinical Trial Expected to Occur in the First Half of 2024

CAMBRIDGE, Mass., February 1, 2024 – NeuroBo Pharmaceuticals, Inc. (Nasdaq: NRBO), a clinical-stage biotechnology company focused on transforming cardiometabolic diseases, today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for DA-1726, a novel, dual oxyntomodulin (OXM) analog agonist that functions as a glucagon-like peptide-1 receptor (GLP1R) and glucagon receptor (GCGR). The company plans to initiate a Phase 1 clinical trial, for the treatment of obesity, in the first half of this year.

"Clearance of the IND for DA-1726 allows us to proceed with the Phase 1 program for this novel GLP-1 and glucagon dual receptor, a potential new treatment to address the significant obesity market," stated Hyung Heon Kim, President and Chief Executive Officer of NeuroBo. "As previously reported, preclinical evidence has shown that DA-1726 results in persistent weight loss in diet-induced obese mice and rats by reducing food intake while increasing energy expenditure. Additionally, in mouse models, DA-1726 showed superior weight loss compared to semaglutide (Wegovy™), and its administration resulted in similar weight reduction while consuming more food compared to tirzepatide (Mounjaro™). Based on these results, it is our belief that DA-1726 may have a better tolerability profile than currently available GLP-1 agonists due to its balanced activation of GLP1R and glucagon receptors. We look forward to dosing the first patient with DA-1726 during the first half of this year with an expected data readout in the first half of 2025."

The Phase 1 trial is designed to be a randomized, placebo-controlled, double-blind, sequential parallel group study to investigate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of single and multiple ascending doses of DA-1726 in obese, otherwise healthy subjects. Part 1 will be a single ascending dose (SAD) study, expected to enroll approximately 45 participants, randomized into one of 5 planned cohorts. Each cohort will be randomized in a 6:3 ratio of DA-1726 or placebo. Part 2 will be a multiple ascending dose (MAD) study, expected to enroll approximately 36 participants, who will be randomized into 4 planned cohorts, each to receive 4 weekly administrations of DA-1726 or placebo.

The primary endpoint will assess the safety and tolerability of DA-1726 by monitoring adverse events (AEs), serious adverse events (SAEs), treatment emergent adverse events (TEAEs) and AEs leading to treatment discontinuation. Secondary endpoints include the PK of DA-1726, assessed via serum concentrations over time and metabolite profiling at the highest doses of DA-1726. Exploratory endpoints will include the effect of DA-1726 on metabolic parameters, cardiac parameters, fasting lipid levels, body weight, waist circumference and body mass index (BMI), among others.

About DA-1726
DA-1726 is a novel oxyntomodulin (OXM) analogue functioning as a GLP1R/GCGR dual agonist for the treatment of obesity and NASH that is to be administered once weekly subcutaneously. DA-1726 as a dual agonist of GLP-1 receptors (GLP1R) and glucagon receptors (GCGR), leading to weight loss through reduced appetite and increased energy expenditure. DA-1726 has a well understood mechanism and, in preclinical mice models, resulted in improved weight loss compared to semaglutide and cotadutide (another OXM analogue).

About NeuroBo Pharmaceuticals
NeuroBo Pharmaceuticals, Inc. is a clinical-stage biotechnology company focused on transforming cardiometabolic diseases. The company is currently developing DA-1241 for the treatment of Metabolic Dysfunction-Associated Steatohepatitis (MASH) 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 that promotes the release of key gut peptides GLP-1, GIP, and PYY. In preclinical studies, DA-1241 demonstrated a 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, dual oxyntomodulin (OXM) analog that functions as a glucagon-like peptide-1 receptor (GLP1R) and glucagon receptor (GCGR) for the treatment of obesity. 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. Words such as “believes”, “expects”, “anticipates”, “may”, “will”, “should”, “seeks”, “approximately”, “intends”, “projects,” “plans”, “estimates” or the negative of these words or other comparable terminology (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. 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 NeuroBo’s ability to execute on its commercial strategy; the timeline for regulatory submissions; ability to obtain regulatory approval through the development steps of NeuroBo’s 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 cooperation of our contract manufacturers, clinical study partners and others involved in the development of NeuroBo’s current and future product candidates; potential negative interactions between our product candidates and any other products with which they are combined for treatment; NeuroBo’s ability to initiate and complete clinical trials on a timely basis; our ability to recruit subjects for its clinical trials; whether NeuroBo receives results from NeuroBo’s clinical trials that are consistent with the results of pre-clinical and previous clinical trials; impact of costs related to the license agreement, known and unknown, including costs of any litigation or regulatory actions relating to the license agreement; effects of 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, except as required by law.

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