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): September 30, 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)	(Zip Code)

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

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:

☐ 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 7.01. Regulation FD Disclosure.

On September 30, 2024, NeuroBo Pharmaceuticals, Inc. (the "Company") issued a press release announcing positive top-line safety, tolerability, and dose-linear pharmacokinetics (PK) data from the single ascending dose (SAD) Part 1 of its Phase 1 clinical trial of DA-1726, a novel, dual oxyntomodulin (OXM) analog agonist that functions as a glucagon-like peptide-1 receptor (GLP1R) and glucagon receptor (GCGR), for the treatment of obesity. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K (the "Report") 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 Report, and the inclusion of such website addresses in this Report by incorporation by reference of the press release is as inactive textual references only.

Exhibit 99.1 hereto contains forward-looking statements within the meaning of the federal securities laws. These forward-looking statements are based on current expectations and are not guarantees of future performance. Further, the forward-looking statements are subject to the limitations listed in Exhibit 99.1 and in the other reports of the Company filed with the Securities and Exchange Commission, including that actual events or results may differ materially from those in the forward-looking statements.

The information in this Report, including Exhibit 99.1 hereto, is furnished pursuant to Item 7.01 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing. The Company's submission of this Report shall not be deemed an admission as to the materiality of any information required to be disclosed solely to satisfy the requirements of Regulation FD.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release dated September 30, 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: September 30, 2024

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

NeuroBo Pharmaceuticals Announces Positive Top-Line Data From the SAD Part 1 of Its Phase 1 Clinical Trial Evaluating DA-1726 for the Treatment of Obesity

Data Revealed Favorable Safety, Tolerability and Dose-Linear Pharmacokinetics (PK)

Top-Line Data Readout from the MAD Part 2 Expected in the First Quarter of 2025

Planned Phase 1 Part 3 Will Evaluate Early Proof of Concept

CAMBRIDGE, Mass., September 30, 2024 – NeuroBo Pharmaceuticals, Inc. (Nasdaq: NRBO), a clinical-stage biotechnology company focused on transforming cardiometabolic diseases, today announced positive top-line safety, tolerability, and dose-linear pharmacokinetics (PK) data from the single ascending dose (SAD) Part 1 of its Phase 1 clinical trial of DA-1726, a novel, dual oxyntomodulin (OXM) analog agonist that functions as a glucagon-like peptide-1 receptor (GLP1R) and glucagon receptor (GCGR), for the treatment of obesity.

In the SAD Part 1 of the Phase 1 clinical trial, a total of 45 obese, otherwise healthy participants were randomized in a double-blind, 6:3 ratio of DA-1726 or placebo. Single ascending doses were found to be safe and well tolerated, with no serious adverse events. Only 5 subjects in the DA-1726 treatment group reported adverse events (AEs) compared with 3 subjects in the placebo group. A dose-linear PK profile was observed across the investigated dose range. Additional cohorts are being added to the SAD Part 1 to explore the maximum tolerated dose.

“The safety, tolerability and dose-linear PK data generated from the Part 1 SAD trial are highly encouraging and allowed for the accelerated initiation of our multiple ascending dose (MAD) study,” stated Hyung Heon Kim, President and Chief Executive Officer of NeuroBo. “In light of the strong safety profile from the SAD Part 1 of the study, we are in the process of adding one or more cohorts to further explore the maximum tolerated dose, which will allow us to realize the full potential of DA-1726. Based on the preclinical data generated to date, as well as DA-1726’s balanced activation of GLP1R and glucagon receptors, which increases energy expenditure, we continue to believe that DA-1726 may become a best-in-class obesity drug with a better tolerability profile than currently marketed GLP-1 agonists, and those now in late-stage clinical trials. We eagerly anticipate reporting top-line data from the MAD Part 2 in the first quarter of 2025, which will give us an early read on clinical efficacy. Additionally, we continue to plan Part 3 of the trial that will explore early proof of concept.”

The MAD Part 2 of the Phase 1 trial is a randomized, placebo-controlled, double-blind study to investigate the safety, tolerability, PK, and PD of multiple ascending doses of DA-1726 in obese, otherwise healthy subjects. Part 2 is expected to enroll approximately 36 participants, who will be randomized at the same 6:3 ratio into 4 planned cohorts, each to receive 4 weekly administrations of DA-1726 or placebo. The first patient in the MAD study was dosed ahead of schedule, in late June, as previously reported.

The primary endpoint of the Phase 1 trial is to 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.

For more information on this clinical trial, please visit: www.clinicaltrials.gov NCT06252220.

About DA-1726

DA-1726 is a novel oxyntomodulin (OXM) analogue functioning as a GLP1R/GCGR dual agonist for the treatment of obesity and Metabolic Dysfunction-Associated Steatohepatitis (MASH) that is to be administered once weekly subcutaneously. DA-1726 acts 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 pre-clinical mice models, resulted in improved weight loss compared to semaglutide (Wegovy®) and cotadutide (another OXM analogue). Additionally, in pre-clinical mouse models, DA-1726 elicited similar weight reduction, while consuming more food, compared tirzepatide (Zepbound®) and survodutide (a drug with the same MOA), while also preserving lean body mass and demonstrating improved lipid-lowering effects compared to survodutide.

About NeuroBo Pharmaceuticals

NeuroBo Pharmaceuticals, Inc. is a clinical-stage biotechnology company focused on transforming cardiometabolic diseases. The company is currently developing DA-1726 for the treatment of obesity, and is developing DA-1241 for the treatment of Metabolic Dysfunction-Associated Steatohepatitis (MASH). DA-1726 is a novel oxyntomodulin (OXM) analogue that functions 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. 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 pre-clinical 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.

For more information, please visit www.neurobopharma.com.

Forward Looking Statements

Certain statements in this press 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", “potential”, "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 press release, including, without limitation, those risks associated with NeuroBo's ability to execute on its commercial strategy; the timeline for regulatory submissions; the 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 NeuroBo's contract manufacturers, clinical study partners and others involved in the development of NeuroBo's current and future product candidates; potential negative interactions between NeuroBo's 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; NeuroBo's 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; the effects of changes in applicable laws or regulations; the 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 NeuroBo's filings with the Securities and Exchange Commission, including NeuroBo's most recent Annual Report on Form 10-K. 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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