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): June 27, 2023

NEUROBO PHARMACEUTICALS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-37809**	**47-2389984**
(State or other jurisdiction	**(Commission**	**(IRS Employer**
of incorporation)	**File Number)**	**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 June 27, 2023, NeuroBo Pharmaceuticals, Inc. issued a press release announcing that DA-1726, a novel oxyntomodulin (OXM) analogue functioning as a glucagon-like peptide-1 receptor (GLP1R) and glucagon receptor (GCGR) dual agonist, had been shown to elicit superior weight loss efficacy compared to Semaglutide (SEMA) and Tirzepatide (TIR) in preclinical testing and providing other data presented in one ePoster theater discussion and two general poster presentations at the American Diabetes Association's 83rd Scientific Sessions, held June 23-26, 2023. 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 June 27, 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: June 27, 2023

By: /s/ Joseph Hooker

Joseph Hooker
Interim President and Chief Executive Officer

Exhibit 99.1

NeuroBo Pharmaceuticals' Novel GLP1R and GCGR Dual Agonist, DA-1726, Shown to Elicit Superior Weight Loss Efficacy Compared to Semaglutide and Tirzepatide in Preclinical Models

Preclinical Data Also Show DA-1726 Effectively Reduces Body Weight and Glycemic Control

Data Presented in One ePoster Theater Discussion and Two General Poster Presentations at the American Diabetes Association 83rd Scientific Sessions

BOSTON, June 27, 2023 – NeuroBo Pharmaceuticals, Inc. (Nasdaq: NRBO), a clinical-stage biotechnology company on a quest to transform cardiometabolic diseases, today announced that DA-1726, a novel oxyntomodulin (OXM) analogue functioning as a glucagon-like peptide-1 receptor (GLP1R) and glucagon receptor (GCGR) dual agonist, had been shown to elicit superior weight loss efficacy compared to Semaglutide (SEMA) and Tirzepatide (TIR) in preclinical testing. This, and other data, was presented in one ePoster theater discussion and two general poster presentations at the American Diabetes Association's 83rd Scientific Sessions, held June 23-26, 2023.

"DA-1726, a long acting OXM analog that binds and activates both GLP-1 and glucagon receptors using a well understood mechanism, has shown weight loss efficacy, despite similar or higher food intake, in a dose-dependent manner, that is better than SEMA in diet-induced obese (DIO) rats (32.6% for DA-1726 at a high dose compared to 24.0% for SEMA, $p < 0.05$)," stated Yuna Chae, DA-1726 Project Manager, Dong-A ST Research Center. "Additionally, the high-dose DA-1726 increased the expression of the thermogenic-related gene (Ucp1) in white adipose tissues, supporting increased energy expenditure, and the gene expression in white adipose tissue was increased. This suggests that major genetic changes related to energy expenditure are directly related to weight loss. As a result, we believe that DA-1726 will have similar, superior weight loss effects in humans utilizing its novel mechanism of action."

"In preclinical mice models, DA-1726 also showed the ability to improve plasma glucose insulin and Homeostatic Model Assessment for Insulin Resistance (HOMA-IR) as compared to Cotadutide (COTA), another OXM analog. Importantly, DA-1726 showed superior plasma triglyceride (TG) reduction and a similar reduction of total cholesterol (T-CHO) compared to COTA. In a comparative preclinical mouse study with GLP1R/glucose-dependent insulinotropic polypeptide receptor (GIPR) dual agonist, Tirzepatide (TIR), DA-1726 showed similar efficacy on weight loss, despite consuming more food. However, DA-1726 was more efficacious in improving plasma metabolic parameters such as glucose, TG, and T-CHO compared to TIR, indicating differential metabolic effects caused by GCGR agonism. Taken together, these data suggest that DA-1726 is a well-balanced GLP-1 receptor and glucagon receptor dual agonist and we anticipate that DA-1726 will have effective weight loss and glycemic control in humans," concluded Ms. Chae.

"DA-1726 is a long-acting, novel peptide drug candidate in preclinical development with therapeutic promise for obesity and NASH, in preparation for a phase 1 clinical trial for obesity," stated Joe Hooker, Interim President and Chief Executive Officer of NeuroBo. "Presenting two general posters and one ePoster theater discussion at this important scientific meeting provided us the ability to highlight positive preclinical data for DA-1726 as a potential treatment for obesity, and data showing superior effectiveness as compared to competitor peptide therapeutics including SEMA. During the second half of this year, our

goal is to advance DA-1726 through the IND process. Assuming acceptance by the U.S. Food and Drug Administration, we plan to initiate a phase 1a safety study during the first half of 2024 and anticipate a data readout in the second half of 2024."

Abstract Title: *A Novel GLP1R/GCGR Dual Agonist, DA-1726 Elicits Weight Loss Superior to Semaglutide in Diet-Induced Obese Rats*
Poster: 1676
Authors: Tae-Hyoung Kim, Il-Hun Jung, Kyumin Kim, Hyung Heon Kim, Mi-Kyung Kim, Yuna Chae
Presenter: Yuna Chae, Dong-A ST Research Center
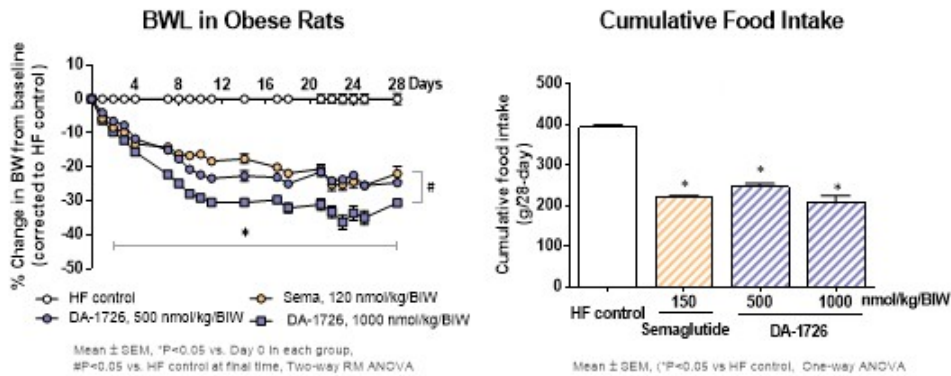**Session:** General Poster Session
Date and Time: Monday, June 26, 2023, 11:30 AM - 12:30 PM PDT
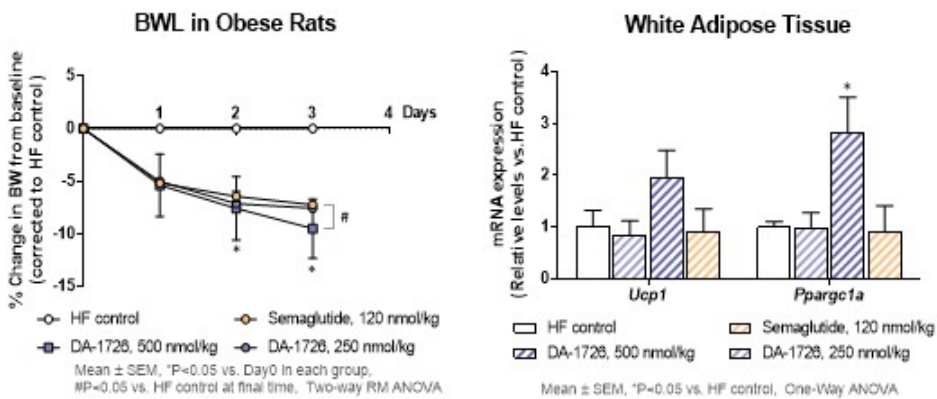**Location:** Poster Halls B-C

DA-1726 showed superior weight loss efficacy compared to Semaglutide (SEMA) in diet-induced obese (DIO) mice. In this study, a dose-response of DA-1726 was evaluated to determine the maximum efficacy in DIO rats which are known for translatability to human studies. The half-life of DA-1726 was longer in rats compared to mice, however the in vitro activity of DA-1726 against rat glucagon receptor was less potent than in mice, and plasma protein binding was approximately 10-fold higher in rats. Therefore, the effective dose for rats was set higher than for mice. DA-1726 was injected twice a week for approximately 4 weeks, and a dose-dependent and significant weight loss effect was observed. The minimum effective dose in DIO rats was found to be 250 nmol/kg. Then, the maximum body weight loss effects of DA-1726 (500 and 1000 nmole/kg) and SEMA were compared in the DIO rat model. DA-1726 showed an excellent weight loss effect compared to SEMA (32.6% for DA-1726 at a high dose vs. 24.0% for SEMA, $p < 0.05$). The low-dose DA-1726 group showed a similar effect compared to SEMA in spite of consuming more food. The high-dose DA-1726 group showed similar food intake as SEMA, however it led to a higher weight loss effect. After repeated dosing, the high-dose DA-1726 increased the expression of energy metabolism-related genes (Ucp1, Ppargc1a) in white adipose tissues (WAT), supporting increased energy expenditure. In order to confirm whether this increased gene change was a direct effect leading to weight loss or an indirect effect caused by weight loss, changes in gene expression were assessed after single dosing. DA-1726 (250 and 500 nmol/kg) induced small but significant weight loss 3 days after a single injection (-7.6% and -9.5% vs. control). However, the genes expression (Ucp1, Ppargc1a) in WAT was increased only in the 500 nmol/kg-treated group suggesting a direct effect. Therefore, DA-1726 is expected to elicit significant weight loss effects in humans with a new mechanism of action.

DA-1726 showed equal or greater efficacy with higher food intake compared to Semaglutide in reducing body weight

BWL in Obese Rats

Mean ± SEM, *P<0.05 vs. Day 0 in each group,
#P<0.05 vs. HF control at final time, Two-way RM ANOVA

HF control — Sema, 120 nmol/kg/BIW — DA-1726, 500 nmol/kg/BIW — DA-1726, 1000 nmol/kg/BIW

Cumulative Food Intake

Mean ± SEM, (*P<0.05 vs HF control, One-way ANOVA

DA-1726 showed significant increase in white adipose tissue gene expression suggesting energy expenditure's direct impact on weight loss

BWL in Obese Rats

HF control — Semaglutide, 120 nmol/kg — DA-1726, 500 nmol/kg — DA-1726, 250 nmol/kg

Mean ± SEM, *P<0.05 vs. Day0 in each group,
#P<0.05 vs. HF control at final time, Two-way RM ANOVA

White Adipose Tissue

HF control — DA-1726, 500 nmol/kg — Semaglutide, 120 nmol/kg — DA-1726, 250 nmol/kg

Mean ± SEM, *P<0.05 vs. HF control, One-Way ANOVA

Abstract Title: *Differentiated Metabolic Effects of DA-1726, a Balanced GLP1R/GCGR Dual Agonist*
Authors: Il-Hun Jung, Tae-Hyoung Kim, Su Jin Lee, Hyung Heon Kim, Mi-Kyung Kim, Yuna Chae
Poster: 1668
Session: ePoster Theater
Date and Time: Sunday, June 25, 2023, 12:10 PM – 12:20 PM PDT
Location: Exhibit Hall (ePoster Theater A)
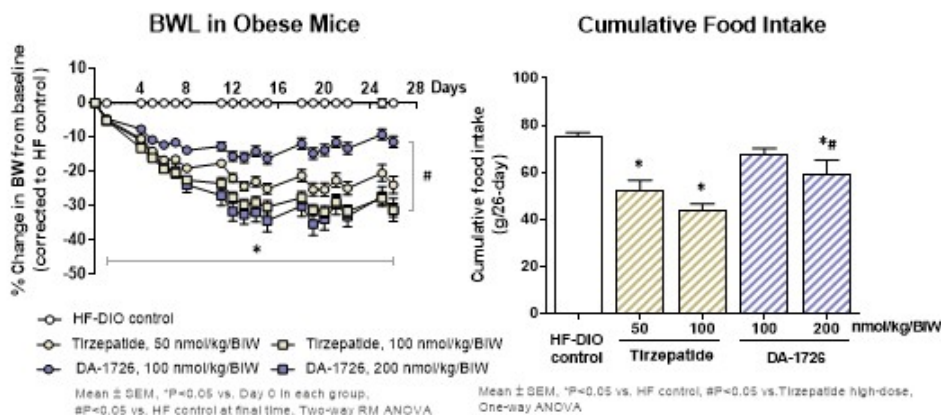**Session:** General Poster Session
Date and Time: Monday, June 26, 2023, 11:30 AM - 12:30 PM PDT
Location: Poster Halls A-B

The pharmacological effect of DA-1726 was evaluated compared to other competitor peptides. DA-1726 showed superior efficacy compared to another GLP1R/GCGR dual agonist, Cotadutide (COTA), in reducing body weight (14.4% for DA-1726 and 6.4% for COTA vs. diet-induced obese (DIO) mice control at 30 nmol/kg, p<0.05) and improving plasma glucose, insulin, and Homeostatic Model Assessment for Insulin Resistance (HOMA-IR) (-91% for DA-1726 vs. -52% for COTA) in DIO mice. In addition, DA-1726 showed superior plasma triglyceride (TG) reduction and similar reduction of total cholesterol (T-CHO) compared to COTA. The data suggests that the balanced dual agonist DA-1726 was superior to a GLP1R-biased dual

agonist in metabolic effects. Additionally, enhanced glucagon action of GLP1R/GCGR dual agonists may increase the risk of hyperglycemia when GLP1R agonism is reduced. DA-1726 was injected for 3 weeks and a glucose tolerance test was performed at 72 hours after the last dosing. DA-1726 did not impair glucose tolerance even at minimal plasma concentrations during repeated dosing up to 100 nmol/kg. In the case of repeated dosing of 100 nmol/kg, the plasma drug concentration at 72 hours after the final injection is similar to the concentration that induces about 50% activation of receptors under 4% human albumin condition. In a comparative study with a GLP1R/glucose-dependent insulinotropic polypeptide receptor (GIPR) dual agonist, Tirzepatide (TIR), DA-1726 showed a similar maximum efficacy on weight loss (31.2% for DA-1726 and 31.3% for TIR vs. DIO control, $p < 0.05$). However, DA-1726 was more efficacious in improving plasma metabolic parameters such as glucose, TG, and T-CHO compared to TIR, indicating differential metabolic effects caused by GCGR agonism. Taken together, this data suggests that DA-1726 is a well-balanced GLP1R/GCGR dual agonist that effectively reduces body weight and glycemic control.

DA-1726 showed similar efficacy with higher food intake compared to Tirzepatide in reducing body weight

Copies of the presentation materials are available on the NeuroBo Pharmaceuticals website at https://www.neurobopharma.com/presentations.

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; the ability to achieve results in human clinical trials that are similar to those received in preclinical animal trials; NeuroBo's ability to achieve similar results in future preclinical trials; regulatory steps and potential regulatory approval 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 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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