

**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): December 7, 2023

NEUROBO PHARMACEUTICALS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37809
(Commission
File Number)

47-2389984
(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 7.01 Regulation FD Disclosure.

On December 7, 2023, NeuroBo Pharmaceuticals, Inc. (the “*Company*”) posted an updated corporate presentation to its website at <https://www.neurobopharma.com/events-presentations/presentations>, which the Company may use from time to time in communications or conferences. A copy of the corporate presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K (this “*Report*”).

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 a 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.

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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Corporate Presentation, dated December 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.

Date: December 7, 2023

NEUROBo PHARMACEUTICALS, INC.

By: /s/ Hyung Heon Kim

Hyung Heon Kim

President and Chief Executive Officer

NeuroBo Pharmaceuticals, Inc.

NASDAQ: NRBO

December 2023

This presentation may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that do not relate solely to historical or current facts and can be identified by the use of 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). 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. These forward-looking statements include statements regarding the market size and potential growth opportunities of our current and future product candidates, capital requirements and use of proceeds, clinical development activities, the timeline for, and results of, clinical trials, regulatory submissions, and potential regulatory approval and commercialization of its current and future product candidates. 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 its commercial strategy; the timeline for regulatory submissions; ability to obtain regulatory approval through the development steps 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 cooperation of our contract manufacturers, clinical study partners and others involved in the development of our current and future product candidates; potential negative interactions between our product candidates and any other products with which they are combined for treatment; our ability to initiate and complete clinical trials on a timely basis; our ability to recruit subjects for our clinical trials; whether we receive results from our 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; whether we are able to regain compliance with Nasdaq listing requirements; and effects of changes to our stock price on the terms of the license agreement and any future fundraising. These forward-looking statements are based on information currently available to us and our current plans or expectations and are subject to a number of known and unknown uncertainties, risks and other important factors that may cause our actual results, performance or achievements expressed or implied by the forward-looking statements. These and other important factors are described in detail in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2022 and our other filings with the Securities and Exchange Commission.

While we may elect to update such forward-looking statements at some point in the future, except as required by law, we disclaim any obligation to do so, even if subsequent events cause our views to change. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to this presentation.

This presentation also may contain estimates and other statistical data made by independent parties and by us relating to market size and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

Management Team



Hyung Heon Kim, Chief Executive Officer

- 20+ years of experience in M&A, financing and corporate governance
- 10+ years of licensing, M&A and compliance with Dong-A Group
- Former General Counsel/SVP at Dong-A ST and Dong-A Socio Group
- BA Soongsil University, JD Washington University School of Law



Stephen Harrison, M.D., Consulting Chief Medical Officer

- NASH/NAFLD clinical trials expert, ~300 peer reviewed publications
- Visiting Professor, Hepatology, Oxford University
- M.D. University of Mississippi
- Col (ret.) USA, MC



Mi-Kyung Kim, Ph.D, RPh, Chief Scientific Officer

- 25+ years in drug discovery research at Dong-A ST
- Specialized in diabetes, obesity, NASH, immune-mediated diseases
- Ph.D, RPh, College of Pharmacy, Ewha Womans University



Marshall H. Woodworth, Acting Chief Financial Officer

- 35+ years of financial experience
- 20+ years working with life science investors and analysts
- CFO of Nevakar Inc., Braeburn Pharmaceuticals Inc., Aerocrine AB and Furlex Pharmaceuticals Inc.
- BS University of Maryland, MBA Indiana University



Robert Homolka, SVP Clinical Operations

- 35+ years in pharmaceutical and biotech development
- Sr. director of clinical operations in Adiso Therapeutics
- Director of clinical operations at Shire/Takeda pharmaceuticals
- Director of experimental trial management at AstraZeneca



Sung-Jin Kim, Pharmacist, Director of Corporate Strategy

- 18+ years on pharmaceutical industry at Dong-A ST
- Team lead of corporate planning
- Study manager of clinical trials specialized in diabetes
- Manager of business development

Targeting **MASH and Obesity** with a Pipeline of **Next Generation Therapeutics**

- Aiming to Increase Shareholder Value through *Multiple, Near-Term, Value Creating Milestones*
 - **DA-1241**
 - ✓ Open IND for Treatment of MASH and Type 2 Diabetes
 - ✓ Actively recruiting into a Phase 2a for DA-1241 in subjects with presumed MASH
 - ✓ Completed SAD and MAD studies (in healthy volunteers and subjects with T2D)
 - **DA-1726**
 - Submission of IND for Obesity in late December 2023
- Backed by Strategic Partner and Major Shareholder, Dong-A ST
- Well Capitalized With **\$25.8 million** in Cash at the end of Q3 2023. Cash runway into Q4 2024
- Exploring *Strategic Opportunities* to Out-License legacy assets



Multiple Near-Term Milestones: Targeting to Increase Shareholder Value

Investments in the **current DA-1241 Phase 2a** and **planned DA-1726 Phase 1** have the potential for significant returns in the event of clinical and regulatory success



* These milestones assume regulatory and clinical success, which is not guaranteed

DA-1241

Orally Available, Potential First-in-Class GPR119 Agonist
for the Treatment of **MASH**

	Resmetirom	DA-1241
Developer	Madrigal	NeuroBo
Indication	MASH	MASH
Status	Phase 3 completed NDA Submitted	Phase 2
Action	THR (Thyroid hormone receptor) β agonist	GPR119 agonist
Dosage	Once daily, oral	Once daily, oral
Efficacy in Human	¹ MASH resolution with more than a 2-point reduction in MASH Activity Score (100mg: 30%, 80mg: 26%, Placebo: 10%)	Effective in treating or modifying the progression of MASH, NAFLD Activity Score and Biomarkers
Safety in Human	1. Mild/transient diarrhea, mild nausea	Headache, somnolence, fatigue, hypoglycemia, and cold sweat (reported in Phase I studies).
Differentiation	If approved by the NDA, the first treatment for MASH	<ol style="list-style-type: none"> 1. Unique mechanism of action. Works on inflammation associated with MASH 2. Can be used as a monotherapy or in combination with other therapies 3. Synergistic effect(s) when co-administered with a DPP4 or GLP1 inhibitor

¹ <https://ir.madrigalpharma.com/news-releases/news-release-details/madrigal-announces-positive-topline-results-pivotal-phase-3>

GPR119 activation:

Monocytes and macrophages

- Macrophage activation
- Monocyte recruitment
- Macrophage differentiation

→ *Reduction in hepatic and systemic inflammation*

Hepatic stellate cells

- Stellate cell activation

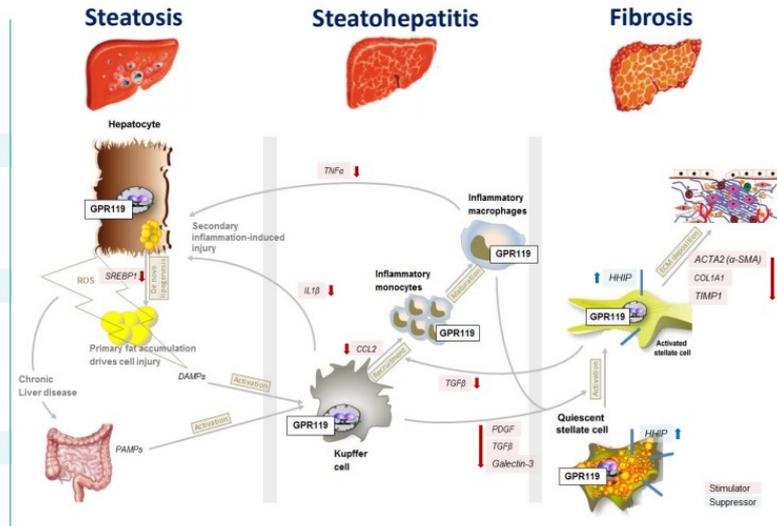
→ *Reduce hepatic fibrogenesis*

Hepatocytes and intestinal L-cells

- De novo lipogenesis
- Dietary fat absorption

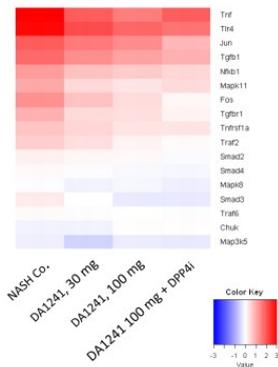
→ *Reduce hepatic steatosis*

DAMPs : danger-associated molecular patterns
 PAMPs: pathogen-associated molecular patterns
 ECM: extracellular matrix

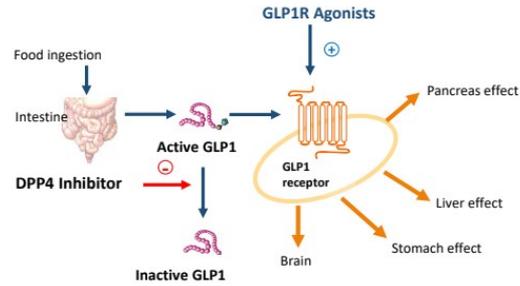
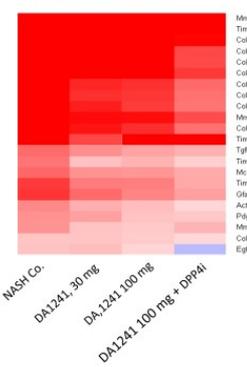


- Effectively decreased hepatic inflammation
- Reduced systemic inflammation and fibrosis biomarkers
- Reduced hepatic lipid and collagen deposition in the liver of MASH mice

Changes of 17 inflammation signaling-related genes



Changes of 22 stellate cell activation-related genes



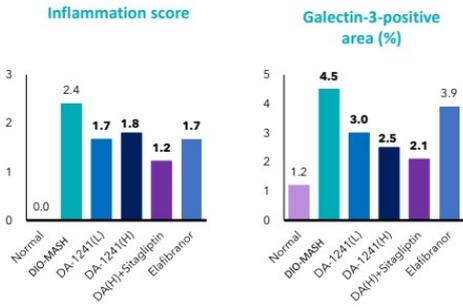
Activation of GLP1 Receptor Effects

- Pancreas
 - Increase proliferation of beta cells
 - Prevent the apoptosis of beta cells
 - Increase insulin biosynthesis
 - Increase insulin secretion
 - Increase insulin biosynthesis
- Liver
 - Decrease glucose production
- Stomach
 - Decrease gastric emptying
- Brain
 - Decrease appetite

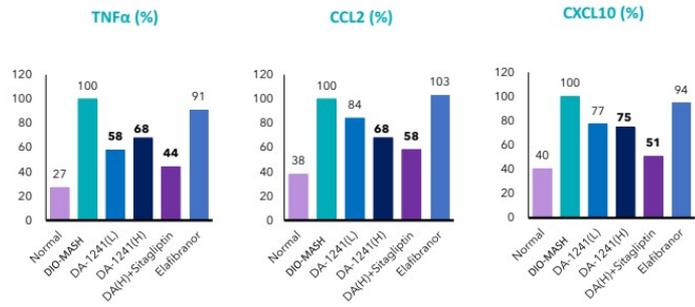
DA-1241: Differentiated Anti-Inflammatory Effect in MASH Mice⁽¹⁻³⁾

- DA-1241 was shown to improve BOTH hepatic and systemic inflammation effectively
- Co-administered with a DPP4 potentiated the anti-inflammatory effect

Change in **Hepatic Immune Cell Infiltration** after 8-week treatment in DIO-MASH mice ^(1,3)

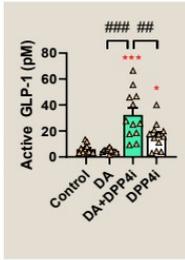


Change in **Plasma Inflammatory Cytokine & Chemokines** after 8-week treatment in DIO-MASH mice ^(2,3)

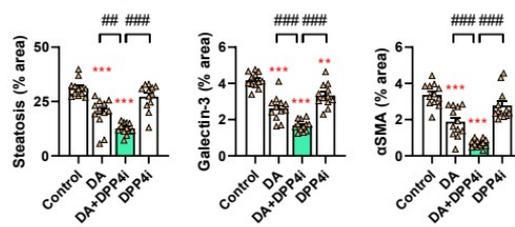


Notes: GPR119 (G Protein-Coupled Receptor 119); MASH (Non-Alcoholic Steatohepatitis); GLP-1 (Glucagon-Like Peptide 1); DA-1241 (L), 30 mg/kg/day; DA-1241 (H), 100 mg/kg/day; Elafibranor (PPARα/δ agonist with anti-inflammatory effects; discontinued in Phase 3 for MASH); Sitagliptin (JANUVIA™, approved DPP4 inhibitor for T2DM)
 1.Dong-A Study Report 103420
 2.Dong-A Study Report 104458.
 3.Park H et al. 80th Scientific Session of American Diabetes Association, 2020, Poster presentation 216-LB

Combo: Synergistic Effects with a DPP4 Inhibitor in DIO-MSH Mice

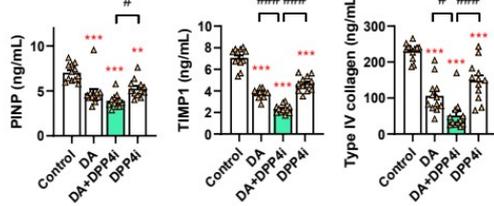


Liver Histology

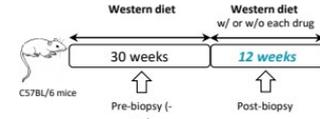
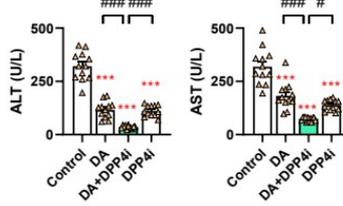


- Increased plasma active GLP-1 in DIO-MASH mice
- Augmented improvement in steatosis, inflammation, and fibrosis compared to monotherapy
- Inhibited stellate cell activation (α SMA⁺ area) further in the liver
- Improved Fibrosis-related biomarkers (PINP and TIMP-1) in plasma accordingly

Plasma Fibrosis Markers



Liver Damage Markers



Support use as a monotherapy

- DA-1241 modified the *progression of MASH* in Ob-MASH mice
- Exploring improved *biomarkers (CCL2, TNFα, and TIMP1), liver fat content, and stiffness* as measured by Fibroscan and MRI

Exploring Co-Administration with a DPP4 inhibitor

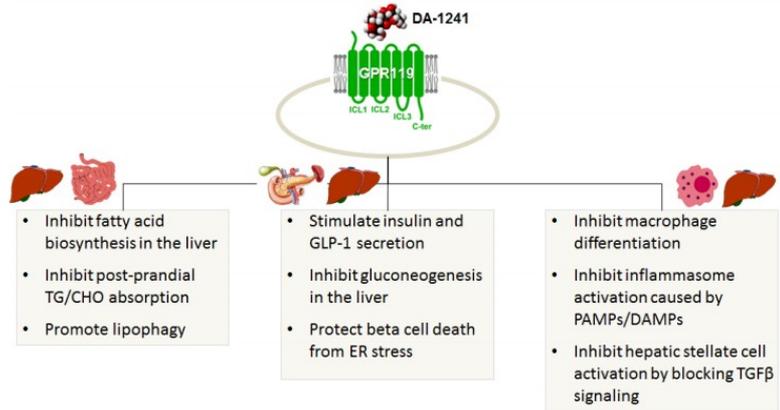
- *Identify ability to effectively decreased hepatic inflammation*
- *Explore ability to reduce systemic inflammation* and fibrosis biomarkers
- *Reduced hepatic lipid and collagen deposition* in Ob-MASH mice

Study Design

Study Overview:	<ul style="list-style-type: none"> ▪ A multicenter, randomized, double-blind, placebo-controlled, parallel, Phase 2a clinical trial to evaluate the efficacy and safety of DA-1241 in subjects with presumed non-alcoholic steatohepatitis
Primary Endpoint:	<ul style="list-style-type: none"> ▪ ALT change from baseline in alanine transaminase
Study Design	<ul style="list-style-type: none"> ▪ 2 Part study <ul style="list-style-type: none"> • Part 1: DA-1241 50mg, DA-1241 100mg, Placebo • Part 2: DA-1241 100mg + Sitagliptin 100mg, Placebo
No. of Subjects:	<ul style="list-style-type: none"> ▪ Approximately 90 subjects with presumed MASH
Location:	<ul style="list-style-type: none"> ▪ Approximately 25 centers in the United States
Enrollment (planned):	<ul style="list-style-type: none"> ▪ FPI August 2023 ▪ LPLV June 2024

DA-1241 Potential Advantages in MASH

- **GPR119** therapeutic target is to inhibit steatosis, inflammation and fibrosis and the treatment or progression of MASH
- **DA-1241** is an **advanced GPR119 agonist** with proven enhanced efficacy in animal models
- Its effect is enhanced when combined with a **DPP4 inhibitor**



DA-1726

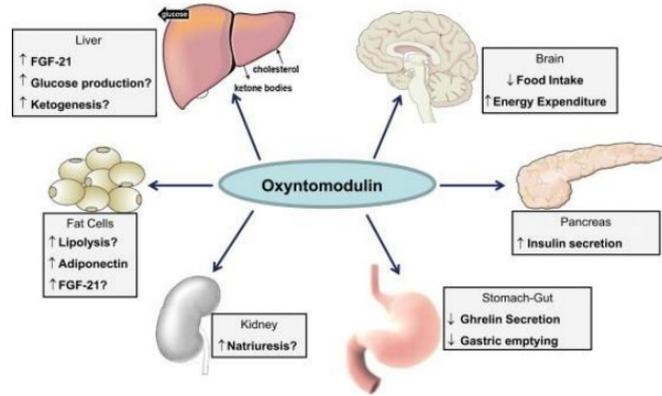
A Novel **GLP1R/GCGR** Dual Agonist
for the Treatment of **Obesity**

	Survodutide	Mazdutide	DA-1726	Semaglutide (Wegovy®)	Tirzepatide (Mounjaro®)
Developer	Boehringer Ingelheim	Innovent Biologics Lilly	NeuroBo	Novo Nordisk	Lilly
Indication	Obesity	Obesity	Obesity	Obesity	Obesity
Status	Phase 2 completed	Phase 3 (China) Phase 1 (USA)	Phase 1 IND in 2H 2023	Marketed	Phase 3 (Obesity) Marketed (T2D)
Action	Glucagon/GLP-1 receptor dual agonist	Glucagon/GLP-1 receptor dual agonist	Dual Agonist: GLP-1R (Glucagon-Like Peptide 1 receptor), GCGR (Glucagon receptor) dual agonist	GLP-1R(Glucagon-like peptide-1 receptor) agonist	GLP-1R(Glucagon-like peptide-1 receptor) & GIPR(Glucose-dependent insulinotropic polypeptide receptor) dual agonist
Dosage	Survodutide 4.8mg, once weekly, injection	Mazdutide 9mg, once weekly, injection	Exploratory dosing in Phase 1	Semaglutide 2.4mg, once weekly, injection	Tirzepatide 15mg, once weekly, injection
Efficacy in Human	Body weight loss, 16.7% @ 46-week	Body weight loss, 15.4% @ 24-week (Interim analysis)	Exploratory efficacy in Phase 1	Body weight loss, 12.4% @ 68-week	Body weight loss, 20.1% @ 72-week
Safety in Human	Nausea, vomiting, diarrhea, constipation, Treatment discontinuations due to AEs: 28.6%	Nausea, diarrhea, vomiting, abdominal distension	Exploratory safety in Phase 1	Nausea, diarrhea, vomiting, constipation, abdominal pain	Nausea, diarrhea, decreased appetite, vomiting, constipation
Differentiation	First-in-class for obesity, Not reached plateau at week 46	No discontinued treatment due to adverse events in interim analysis	<ul style="list-style-type: none"> • Weight loss similar or better as compared to semaglutide • Better tolerability due to balance approach as compared to semaglutide 	In clinical preparation for 7.2 mg dose in obesity and T2D patients; In recruiting participants for MASH P3	Higher efficacy

DA-1726 is a **novel oxyntomodulin analogue** functioning as a GLP1R/GCGR dual agonist for **the treatment of obesity**

▪ **Oxyntomodulin**

- a gut hormone released from intestinal L-cells after meal ingestion resulting in dual agonism of the GLP-1 receptor and glucagon receptor
- **Reduces food intake (GLP-1 R)** and **increases energy expenditure (GCGR)** in humans, potentially resulting in superior body weight lowering



Physiological effects of oxyntomodulin ⁽¹⁾

Notes: GLP1R/GCGR (Glucagon-Like Peptide 1 Receptor/ Glucagon Receptor); NASH (Non-Alcoholic Steatohepatitis); T2DM (Type 2 Diabetes Mellitus); OXM (Oxyntomodulin); GLP-1 (Glucagon-Like Peptide 1).
1. Pocai A. Mol Metab. 2014;3:241-51.

DA-1726: Therapeutic Potential in Obesity (1-3) — Semaglutide Comparison

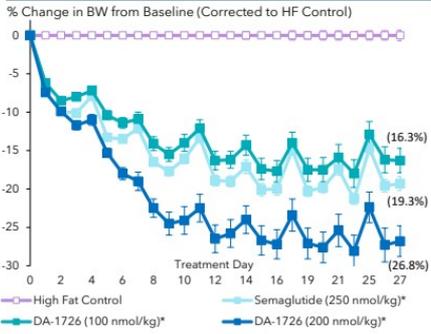
DA-1726 outperformed Semaglutide (WEGOVY™), a GLP-1 agonist, in mouse models of obesity*

Cumulative Food Intake in HF-DIO Obese Mice DA-1726 vs Semaglutide (1,3)

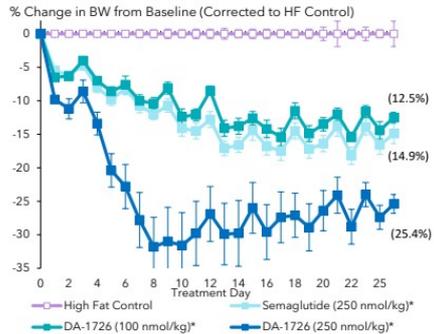


Weight loss observed from DA-1726 is attributed to reduced food intake via GLP1R and increased energy expenditure via the GCGR

BWL in HF-DIO Obese Mice DA-1726 vs Semaglutide (1,3)



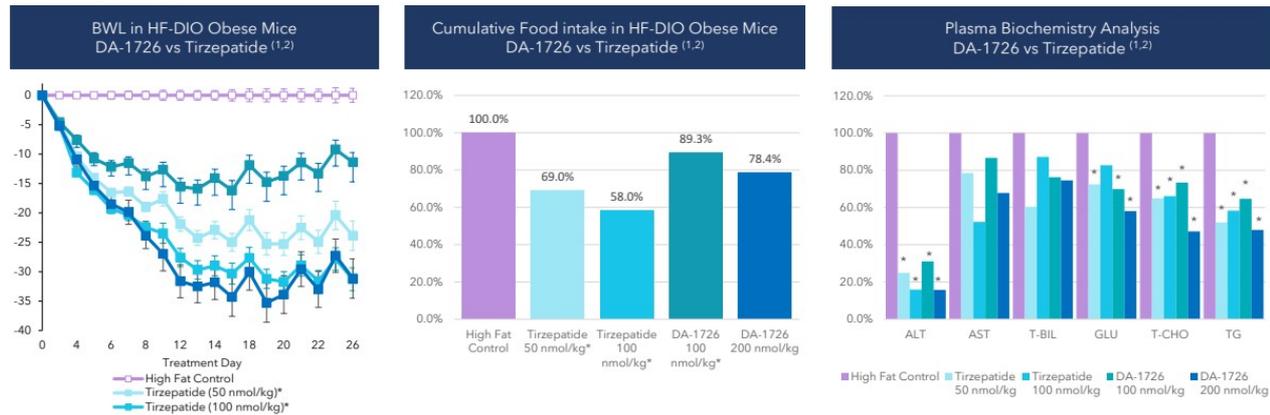
BWL in HF-FATZO T2DM/Obese Mice DA-1726 vs Semaglutide (2,3)



*Statistically significant compared to control
 Notes: GLP1R/GCGR (Glucagon-Like Peptide 1 Receptor/ Glucagon Receptor); HF-DIO (High Fat-Diet Induced Obesity); GLP-1 (Glucagon-Like Peptide 1).
 1. Dong-A Study Report 104561. All treatments given as twice weekly injections.
 2. Dong-A Study Report 104455. All treatments given every 3 days as injections.
 3. Kim TH et al. 82nd Meeting of the American Diabetes Association. 2022; Abstract 1403-P.

DA-1726: Therapeutic Potential in Obesity (1,2) - Tirzepatide Comparison

DA-1726 shows similar weight loss while consuming more food compared to Tirzepatide (Mounjaro™)



Notes: HF-DIO (High Fat-Diet Induced Obesity); BWL (Body Weight Loss)
 1. Dong-A Study Report 105497. All treatments given as twice weekly injections.
 2. Jung I-H et al. 83rd Meeting of the American Diabetes Association. 2023; Abstract 1668-P.

Weight loss is attributed to reduced food intake and increased energy expenditure

Rationale for study

- *Superior weight loss* compared with the pair-fed group, indicating much of the weight loss was attributed to reduced food intake via activation of GLP-1
- *Superior to both the pair-fed and control groups* in energy expenditure (secondary to glucagon activation)
- *Potentially superior weight loss compared to approved obesity products*
- *Sustained weight loss due to more normal food consumption*

Phase I

Study overview:	<ul style="list-style-type: none">• 2-part study<ul style="list-style-type: none">○ Part 1—Single ascending dose study○ Part 2—Multiple ascending dose study
Population:	<ul style="list-style-type: none">• Obese otherwise healthy
No. of Subjects:	<ul style="list-style-type: none">• Approximately 100 subjects for both studies
Location:	<ul style="list-style-type: none">• United States

Financials and Capitalization

Financial Overview	As of September 30, 2023
Cash	\$25.8 million
Debt	none

Capitalization as of September 30, 2023	Common Stock Equivalents
Common Stock	38,429,185
Warrants (WAEP \$13.00) ⁽¹⁾	2,458,576
Options (WAEP \$59.21)	40,272
Common Stock Shares Available for Issuance under Equity Incentive Plans	3,789,032
Fully Diluted	44,717,065

Investment Thesis

Targeting MASH and Obesity with a Pipeline of Next Generation Therapeutics

- Aiming to Increase Shareholder Value through *Multiple, Near-Term, Value Creating Milestones*
 - **DA-1241**
 - ✓ Open IND for Treatment of MASH and Type 2 Diabetes
 - ✓ Actively recruiting into a Phase 2a for DA-1241 in subjects with presumed MASH
 - ✓ Completed SAD and MAD studies (in healthy volunteers and subjects with T2D)
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- Backed by Strategic Partner and Major Shareholder, Dong-A ST
- Well Capitalized With **\$25.8 million** in Cash at the end of Q3 2023. Cash runway into Q4 2024
- Exploring *Strategic Opportunities* to Out-License legacy assets

THANK YOU!

INVESTOR CONTACTS:

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