#### 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): April 16, 2024



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:

 
 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  $\Box$ 

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 April 16, 2024, NeuroBo Pharmaceuticals, Inc. (the "*Company*") posted an updated corporate presentation to its website at <u>https://www.neurobopharma.com/events-presentations/presentations/presentations</u>, 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 April 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: April 16, 2024

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

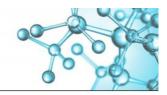


# NeuroBo Pharmaceuticals, Inc.



April 2024 NASDAQ: NRBO

### Forward-Looking Statements

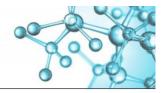


This presentation may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that do not relate solely to historical or current facts and can be identified by the use of words such as "believes", "expects", "aniticipates", "may", "will", "should", "seeks", "anitoms", "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 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 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 preceding and previous clinical trials; impact of costs related to the license agreement, known and unknown, including costs of any litigation or regulatory autiony autions relating the invesse our applicable laws or regulators; whether we are able to maintain compliance with Nasda listing requirements; and effects of changes to our stock pric

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 Soonghsil University, JD Washington University School of Law



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

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



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

- 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



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

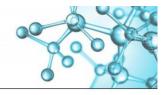


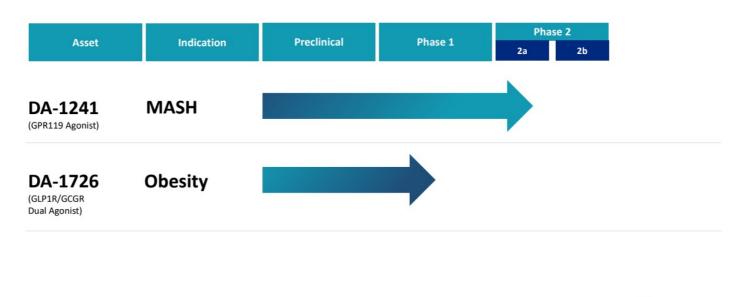


#### Targeting Obesity and MASH with a Pipeline of Next Generation Therapeutics

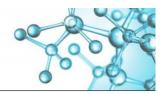
- Aiming to Increase Shareholder Value through Multiple, Near-Term, Value Creating Milestones
  - DA-1726
    - ✓ Open IND for Treatment of Obesity
    - $\checkmark$  First patient dosed and actively recruiting into a Phase 1 for obesity
  - DA-1241
    - ✓ Open IND for Treatment of MASH and Type 2 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)
- Backed by Strategic Partner and Major Shareholder, Dong-A ST
- Well Capitalized With \$22.4 million in Cash at the end of Q4 2023. Cash runway into Q4 2024
- Exploring Strategic Opportunities to out-license legacy assets



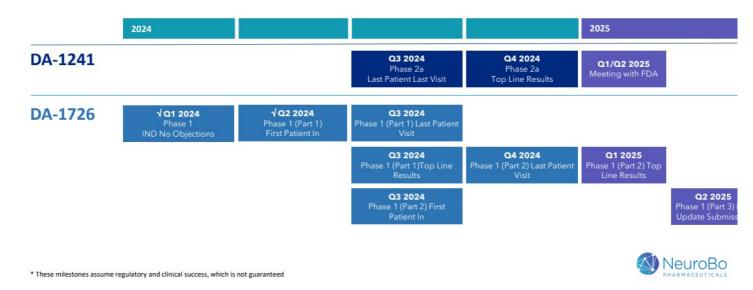


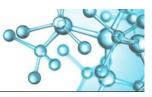




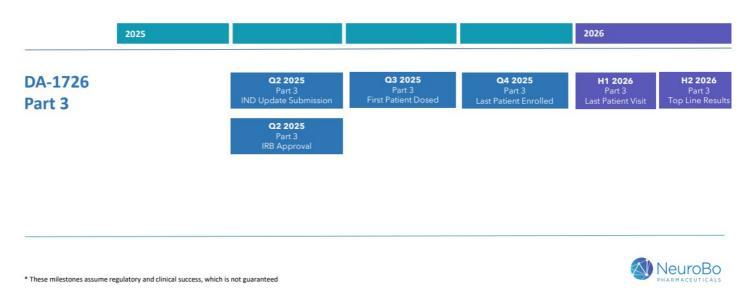


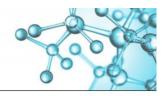
Investments in the **current DA-1241 Phase 2a** and **DA-1726 Phase 1** have the potential for significant returns in the event of clinical and regulatory success





Phase 1 Part 3 will assess total weight loss at 24 weeks, exploring maximum titratable dose and dietary changes.





#### **Study Objectives**

- Gain an understanding of drug titration and dosing
- Time to maximum-tolerated dose

- Titration up to the maximum-tolerated individualized dose

#### **Exploratory Efficacy Endpoints**

- Evaluate total weight loss at 24 weeks change in baseline at maximum-tolerated individualized dose to the end of treatment period
- Explore dietary changes including caloric intake and composition
- Explore type of weight loss lean muscle mass versus fat loss
- Evaluate sustained weight loss after discontinuation

Study Design	
Study Overview	<ul> <li>A multicenter, randomized, double-blind, placebo-controlled, Phase 1 clinical trial to evaluate the efficacy and safety of DA-1726 in obese, otherwise healthy subjects</li> </ul>
Additional Endpoints	<ul> <li>Biomarker changes (PK, PD)</li> <li>Longer term safety (i.e., AEs, Lab, ECG)</li> </ul>
Study Design	<ul> <li>3 Period design</li> <li>Titration Period – up to 12 weeks</li> <li>Treatment Period – at least 12 weeks at individualized maximum titratable dose</li> <li>Off-Drug Period – up to 8 weeks</li> </ul>
No. of Subjects and Location	<ul> <li>Approximately 50 subjects randomized in a 4:1 ratio of DA-1726 or Placebo at multiple centers in the United States</li> </ul>
Enrollment (estimated)	<ul> <li>FPFV Q3 2025</li> <li>LPLV 1H 2026</li> </ul>

Notes: FPFV (First Patient First Visit); LPLV (Last Patient Last Visit); PK (Pharmacokinetic); PD (Pharmacodynamic)





DA-1726

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

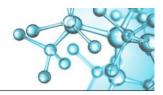


## DA-1726: Competitive Differentiation

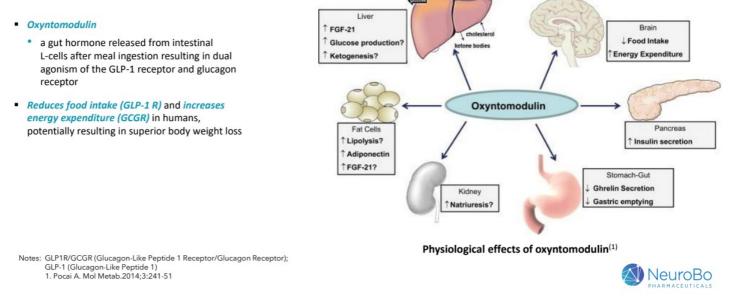
	Survodutide	Mazdutide	DA-1726	Semaglutide	Tirzepatide
Developer	Boehringer Ingelheim	Innovent Biologics Lilly	NeuroBo	Novo Nordisk	Lilly
Indication	Obesity	Obesity	Obesity	Obesity	Obesity
Status	Phase 2 completed	Phase 3 (China) Phase 1 (USA)	Phase 1	Marketed (Obesity/Wegovy <sup>®</sup> ) Marketed (T2D/Ozempic <sup>®</sup> )	Marketed (Obesity/Zepbound <sup>®</sup> ) Marketed (T2D/Mounjaro <sup>®</sup> )
Action	GLP-1R/GCGR dual agonist	GLP-1R/GCGR dual agonist	GLP-1R/GCGR (Glucagon receptor) dual agonist	GLP-1R agonist	GLP-1R/GIPR dual agonist
Dosage	once weekly, injection	once weekly, injection	Exploratory dosing in Phase 1	once weekly, injection	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> <li>Weight loss similar or better as compared to semaglutide</li> <li>Better tolerability due to balance approach as compared to semaglutide</li> </ul>	In recruiting participants for MASH P3	Higher efficacy





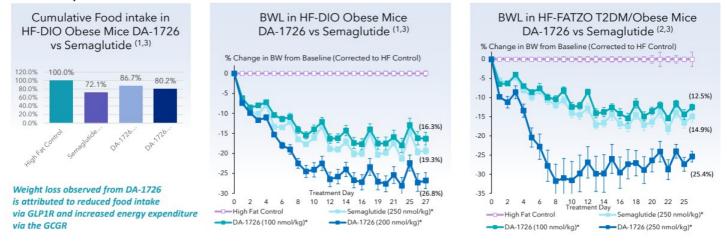


# DA-1726 is a **novel oxyntomodulin analogue** functioning as a GLP1R/GCGR dual agonist for **the treatment of obesity**



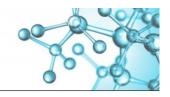


### DA-1726 outperformed Semaglutide (WEGOVY™), a GLP-1 agonist, in mouse models of obesity\*

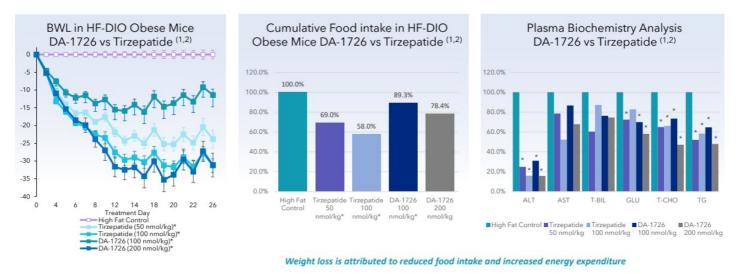


\*Statistically significant compared to control Notes: GLP1R/GCGR (Glucagon-Like Peptide 1 Receptor/ Glucagon Receptor); HF-DIO (High Fat-Diet Induced Obesity); GLP-1 (Glucagon-Like Peptide 1).
1. Dong-A Study Report 104561. All treatments given as twice weekly injections.
2. Dong-A Study Report 104455.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



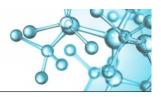


### DA-1726 shows similar weight loss while consuming more food compared to Tirzepatide (Mounjaro<sup>™</sup>)



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.





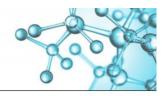
### Rationale for study

- Gain a robust understanding of safety, tolerability of various dose levels in humans.
- 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

Phase I		
Study overview	<ul> <li>2-part study</li> <li>Part 1—Single ascending dose study</li> <li>Part 2—Multiple ascending dose study</li> </ul>	
Population	Obese otherwise healthy	
No. of Subjects	Approximately 100 subjects for both studies	
Location	United States	

Notes: MAD (Multiple Ascending Dose); SAD (Single Ascending Dose); PK (Pharmacokinetic); PD (Pharmacodynamic); FPFV (First Patient First Visit); LPLV (Last Patient Last Visit).





#### **Study Objectives**

- Gain an understanding of drug titration and dosing
- Time to maximum-tolerated dose
- individualized dose to
- aximum-tolerated dose
- Titration up to the maximum-tolerated individualized dose

#### **Exploratory Efficacy Endpoints**

- Evaluate total weight loss at 24 weeks change in baseline at maximum-tolerated individualized dose to the end of treatment period
- Explore dietary changes including caloric intake and composition
- Explore type of weight loss lean muscle mass versus fat loss
- Evaluate sustained weight loss after discontinuation

Study Design	
Study Overview	<ul> <li>A multicenter, randomized, double-blind, placebo-controlled, Phase 1 clinical trial to evaluate the efficacy and safety of DA-1726 in obese, otherwise healthy subjects</li> </ul>
Additional Endpoints	<ul> <li>Biomarker changes (PK, PD)</li> <li>Longer term safety (i.e., AEs, Lab, ECG)</li> </ul>
Study Design	<ul> <li>3 Period design</li> <li>Titration Period – up to 12 weeks</li> <li>Treatment Period – at least 12 weeks at individualized maximum titratable dose</li> <li>Off-Drug Period – up to 8 weeks</li> </ul>
No. of Subjects and Location	<ul> <li>Approximately 50 subjects randomized in a 4:1 ratio of DA-1726 or Placebo at multiple centers in the United States</li> </ul>
Enrollment (estimated)	<ul> <li>FPFV Q3 2025</li> <li>LPLV 1H 2026</li> </ul>

Notes: FPFV (First Patient First Visit); LPLV (Last Patient Last Visit); PK (Pharmacokinetic); PD (Pharmacodynamic)



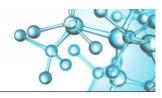


## DA-1241

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



### DA-1241: Competitive Differentiation



	Resmetirom	DA-1241
Developer	Madrigal	NeuroBo
Indication	MASH	MASH
Status	Phase 3 completed NDA Submitted	Phase 2
Action	THR (Thyroid hormone receptor) $\boldsymbol{\beta}$ agonist	GPR119 agonist
Dosage	Once daily, oral	Once daily, oral
Efficacy in Human	MASH resolution with more than a 2-point reduction in MASH Activity Score (100mg: 30%, 80mg: 26%, Placebo: 10%) <sup>(1)</sup>	Effective in treating or modifying the progression of MASH, NAFLD Activity Score and Biomarkers
Safety in Human	Mild/transient diarrhea, mild nausea <sup>(1)</sup>	Headache, somnolence, fatigue, hypoglycemia, and cold sweat (reported in Phase I studies)
Differentiation	If approved by the NDA, the first treatment for MASH	<ol> <li>Unique mechanism of action. Works on inflammation associated with MASH</li> <li>Can be used as a monotherapy or in combination with other therapies</li> <li>Synergistic effect(s) when co-administered with a DPP4 or GLP1R agonist</li> </ol>

 $\underline{1.\ https://ir.madrigalpharma.com/news-releases/news-release-details/madrigal-announces-positive-topline-results-pivotal-phase-3-product and the second second$ 



### DA-1241 Effect on Pathogenesis in MASH as a Monotherapy



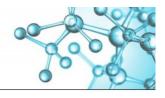
ACTA2 (a-S

COL1A1

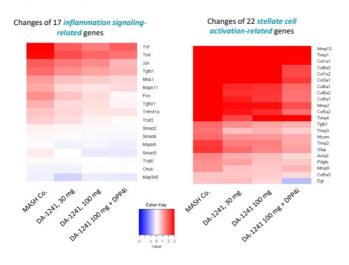
TIMP1

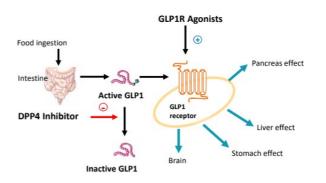
#### GPR119 activation: Steatosis Steatohepatitis Fibrosis Monocytes and macrophages Macrophage activation Monocyte recruitment Macrophage differentiation TNFa → Reduction in hepatic and systemic inflammation R119 Secon inflame injury dary Hepatic stellate cells GPR119 1 HHIP Stellate cell activation IL1B → Reduce hepatic fibrogenesis GPR1 GPR119 CCL2 Hepatocytes and intestinal L-cells TGFØ De novo lipogenesis Dietary fat absorption Quie GPR119 PDG → Reduce hepatic steatosis TGF\$ Galeci Ku DAMPs: danger-associated molecular patterns PAMPs: pathogen-associated molecular patterns ECM: extracellular matrix NeuroBo

# GPR119 in Glucose Control when Co-Administered with Other Therapies



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





#### Activation of GLP1 Receptor Effects

Pancreas

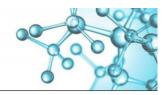
•

- Increase proliferation of beta cells
- Prevent the apoptosis of beta cells
  - Increase insulin biosynthesis
- Increase insulin secretion
- Increase insulin biosynthesis



- Stomach
   Decrease gastric emptying
- Brain
   Decrease appetite





#### Support use as a monotherapy

- DA-1241 modified the progression of MASH in Ob-MASH mice
- Exploring improved biomarkers (CCL2, TNFa, 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> <li>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</li> </ul>
Primary Endpoint	ALT change from baseline in alanine transaminase
Study Design	<ul> <li>2 Part study</li> <li>Part 1: DA-1241 50mg, DA-1241 100mg, Placebo</li> <li>Part 2: DA-1241 100mg + Sitagliptin 100mg, Placebo</li> </ul>
No. of Subjects	Approximately 90 subjects with presumed MASH
Location	Approximately 25 centers in the United States
Enrollment (planned)	<ul><li>FPI September 2023</li><li>LPLV August 2024</li></ul>

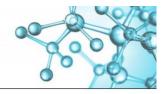
Notes: FPFV (First Patient First Visit); LPO (Last Patient Last Visit)





# Financials and Capitalization



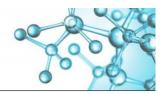


Cash Balance	As of December 31, 2023
Cash	\$22.4 million
Debt	none

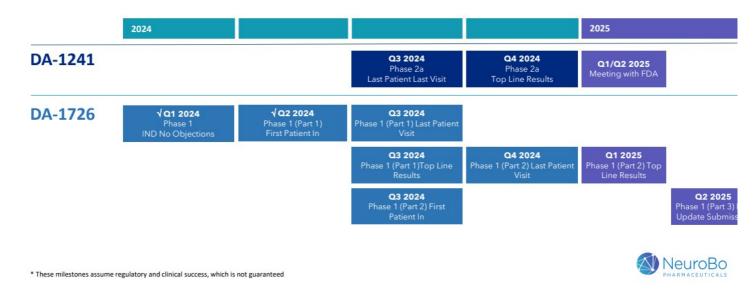
Common Stock Equivalents
4,906,032
203,914
4,700
469,820
5,584,466

1. No ratchets, price resets or anti-dilution provisions. Presumes \$0.00 exercise price for each Series B warrant exchangeable for one share of common stock.



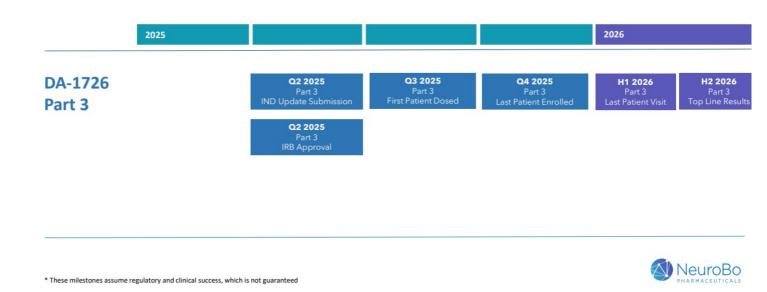


Investments in the **current DA-1241 Phase 2a** and **DA-1726 Phase 1** have the potential for significant returns in the event of clinical and regulatory success





Phase 1 Part 3 will assess total weight loss at 24 weeks, exploring maximum titratable dose and dietary changes.





# Investment Thesis





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

- Aiming to Increase Shareholder Value through Multiple, Near-Term, Value Creating Milestones
  - DA-1726
    - ✓ Open IND for Treatment of Obesity
    - $\checkmark$  First patient dosed and actively recruiting into a Phase 1 for obesity
  - DA-1241
    - ✓ Open IND for Treatment of MASH and Type 2 Diabetes
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- Backed by Strategic Partner and Major Shareholder, Dong-A ST
- Well Capitalized With \$22.4 million in Cash at the end of Q4 2023. Cash runway into Q4 2024
- Exploring Strategic Opportunities to out-license legacy assets





## Thank You!

Investor Contacts: Rx Communications Group Michael Miller +1 917.633.6086 mmiller@rxir.com

NeuroBo Pharmaceuticals Marshall Woodworth +1 919.749.8748 marshall.woodworth@neurobopharma.com

