
**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): August 14, 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**

(Address of principal executive offices)

02138
(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 2.02. Results of Operations and Financial Condition.

On August 14, 2024, NeuroBo Pharmaceuticals, Inc. (the “*Company*”) issued a press release announcing its financial results for the second quarter ended June 30, 2024 and providing a corporate strategic update. A copy of this press release is furnished herewith as Exhibit 99.1 to this Current Report and is 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, and the inclusion of such website addresses in this Current 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release dated August 14, 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: August 14, 2024

By: /s/ Hyung Heon Kim

Hyung Heon Kim

President and Chief Executive Officer



NeuroBo Pharmaceuticals Reports Second Quarter 2024 Financial Results and Provides Corporate Update

Successfully Completed a Financing of up to \$70 Million, With \$20 Million Upfront and an Additional \$50 Million of Aggregate Gross Proceeds Upon the Exercise in Full of Clinical Milestone-Based Warrants

\$27.9 Million in Cash at End of Second Quarter is Expected to Fund the Company Through Multiple Value-Creating Milestones, Into the Second Quarter of 2025. Assuming Positive Results From the DA-1726 Phase 1 MAD Study, the Company Anticipates That the Series A Warrants From the June Financing Could be Exercised in the First Half of 2025, Resulting in Gross Proceeds of \$20 Million

In Pre-Clinical Models, DA-1726 Demonstrated Superiority in Weight Loss, Retention of Lean Body Mass and Lipid-Lowering Effects, Plus Superior Glucose Lowering Effects Compared to Survodutide; Lipid-Lowering Effect Also Shown to be Superior Compared to Tirzepatide

Fully Enrolled the SAD Part 1 of the Phase 1 Trial of DA-1726, With Top-Line Data Readout Expected in the Third Quarter of 2024, and From the MAD Part 2 in the First Quarter of 2025

Planned Phase 1 Part 3 Trial of DA-1726 in Obesity Will Assess Total Weight Loss at 24 Weeks, Exploring Maximum Titratable Dose and Dietary Changes; Interim Data Readout Expected Mid-2026 with Top-Line Data in the Second Half of 2026

Entered into a Joint Research Agreement, Together With Dong-A ST and ImmunoForge to Develop a Long-Acting Once-Monthly Formulation of DA-1726

Part 2 of the Phase 2a Trial of DA-1241 for the Treatment of MASH Underway With Top-Line Data Expected in the Fourth Quarter of 2024

CAMBRIDGE, Mass., August 14, 2024 – NeuroBo Pharmaceuticals, Inc. (Nasdaq: NRBO), a clinical-stage biotechnology company focused on transforming cardiometabolic diseases, today announced financial results for the second quarter ended June 30, 2024 and provided a corporate update.

“During the second quarter and subsequently, we made remarkable progress advancing the clinical development of our two, next generation cardiometabolic assets and are now well capitalized to execute on our upcoming DA-1726 milestones following our recent, successful financing of up to \$70 million in aggregate gross proceeds, with \$20 million upfront and \$50 million of clinical milestone-based warrants,” stated Hyung Heon Kim, President and Chief Executive Officer of NeuroBo. “We expect this financing will enable us to fully fund an early proof-of-concept multicenter, randomized, double-blind, placebo-controlled Part 3 of the 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. Part 3, which will begin upon completion of Part 2, will explore changes in baseline,

at 24 weeks, for total weight loss, weight loss through fat or lean muscle mass reduction, dietary changes, maximum-tolerated individualized dose and other exploratory endpoints. Additionally, dosing of the first patient in Part 2 of this trial, late in the second quarter, ahead of schedule, is a further reflection of our strong commitment to swiftly advancing the clinical development of DA-1726, which holds promise as a highly differentiated therapy for the treatment of obesity. It is also worth noting that, just last week, we signed a joint research agreement, together with our collaboration partner, Dong-A ST and ImmunoForge, as a first step toward potentially developing a long-acting formulation of DA-1726 which would both enhance patient compliance and ease of administration.

"During the American Diabetes Association (ADA) 84th Scientific Sessions in June, we shared pre-clinical data that highlighted the unique characteristics of DA-1726 compared to other obesity drugs in the same class. The data suggests that DA-1726's unique GLP-1 and glucagon receptor activity ratio may be responsible for its differentiated profile. In obese mouse models, DA-1726 demonstrated significant reductions in cholesterol levels and superior weight loss, compared to survodutide, a drug with the same mechanism of action, while also exhibiting superior glucose lowering and retention of relative lean body mass preservation. Previous pre-clinical research also indicated that DA-1726 led to weight reduction while consuming more food than tirzepatide. Additional data presented at the ADA, from a hypercholesterolemia rat model, confirmed that DA-1726 is also more effective than tirzepatide in lowering cholesterol levels potentially due to its glucagon action and GLP-1 effect, while also preventing weight gain. These pre-clinical findings suggest that DA-1726 could emerge as a best-in-class obesity drug with improved tolerability compared to current GLP-1 agonists and those in late-stage clinical trials, given its balanced activation of GLP1R and glucagon receptors, while increasing energy expenditure. Yesterday, we announced the full enrollment of the single ascending dose (SAD) Part 1, for which we anticipate reporting top-line data in the third quarter of this year and top-line data from the MAD Part 2 in the first quarter of 2025. Upon clearance of an updated Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA), we expect to dose the first patient in Part 3 during the third quarter of 2025, providing an interim data readout in or around mid-2026 and issuing top-line results in the second half of 2026."

Mr. Kim concluded, "Additionally, early in the quarter, we fully enrolled Part 1 of the Phase 2a clinical trial for DA-1241, a novel G-Protein-Coupled Receptor 119 (GPR119) agonist for treating MASH, exploring the efficacy of DA-1241 in combination with sitagliptin, a DPP-4 inhibitor, which we believe will show synergistic effects compared to DA-1241, alone. New pre-clinical evidence on DA-1241 in combination with semaglutide (Wegovy®), was presented at the EASL Congress 2024, in June. Based on both pre-clinical and clinical evidence generated to date, we continue to believe that DA-1241 has the potential to be a safe and effective treatment for MASH and anticipate reporting top-line results in the fourth quarter of this year."

First Quarter 2024 and Subsequent Highlights

- August 2024: Completed enrollment in the SAD Part 1 of the Phase 1 clinical trial evaluating DA-1726 for the treatment of obesity. A total of 45 participants were enrolled and randomized into one of 5 cohorts, with each cohort having been randomized in a 6:3 ratio of DA-1726 to placebo.
 - August 2024: Signed a joint research agreement, along with Dong-A ST and ImmunoForge, to develop a long-acting, once-monthly, formulation of DA-1726 utilizing ImmunoForge's long-lasting half-life extension Elastin-Like Polypeptide (ELP) platform technology.
 - July 2024: Signed an exclusive out-license agreement, providing MThera Pharma Co., Ltd. (MThera) with the rights to develop and commercialize NB-01, one of four legacy assets, for the
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treatment of painful diabetic neuropathy, allowing MThera to conduct research and clinical trials, including, but not limited to, a potential Phase 3 clinical trial in the United States and South Korea, for the future commercialization of NB-01.

- July 2024: Engaged veteran biotech and pharmaceutical professional, Chris Fang, MD, as Advisor/Consulting Chief Medical Officer, effective July, 2, 2024.
- June 2024: Completed enrollment of Part 2 of the Phase 2a trial evaluating the efficacy and safety of DA-1241 in MASH. Approximately 37 patients with presumed MASH were randomized with a 2:1 ratio into 2 treatment groups: DA-1241 100 mg/sitagliptin 100 mg or placebo.
- June 2024: Dosed the first patient in the MAD Part 2 of its two-part 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.
- June 2024: Closed a concurrent placement and registered direct offering priced at-the-market under Nasdaq rules, with \$20 million up front with up to an additional \$50 million of aggregate gross proceeds upon the exercise in full of clinical milestone-based warrants.
- June 2024: Presented pre-clinical data at the American Diabetes Association (ADA) 84th Scientific Sessions, suggesting that DA-1726 demonstrated superiority in weight loss, retention of lean body mass, and lipid-lowering effects compared to survodutide.
- June 2024: Presented new pre-clinical data, at the EASL Congress, that suggests DA-1241, in combination with semaglutide (Wegovy®), a GLP1R agonist, improves liver fibrosis and demonstrates additive hepatoprotective effects in pre-clinical metabolic dysfunction-associated steatohepatitis (MASH) models compared to either treatment alone.
- April 2024: Dosed the first patient in the SAD Part 1 of its Phase 1 clinical trial of DA-1726 for the treatment of obesity.
- April 2024: Completed enrollment of Part 1 of its two-part Phase 2a trial evaluating the efficacy and safety of DA-1241 in MASH. Approximately 49 patients with presumed MASH were randomized with a 1:2:1 ratio into 3 treatment groups: DA-1241 50 mg, DA-1241 100 mg, or placebo.

Anticipated Clinical Milestones

- **DA-1726 in Obesity:** Top-line data from the single ascending dose (SAD) Part 1 is expected in the third quarter of 2024. The last patient visit in the multiple ascending dose (MAD) study Part 2 is expected in the fourth quarter of 2024 and the top-line data is expected in the first quarter of 2025. Upon clearance of an updated IND application with the FDA, the first patient in Part 3 is expected to be enrolled during the third quarter of 2025, with an interim data readout in or around mid-2026 and top-line results are expected in the second half of 2026.
- **DA-1241 in MASH:** Top-line results from the two-part Phase 2a clinical trial of DA-1241 in MASH are expected to be available in the fourth quarter of 2024.

Second Quarter Financial and Operating Results

- **Research and Development (R&D) Expenses** were approximately \$8.1 million for the three months ended June 30, 2024, as compared to approximately \$2.4 million for the three months ended June 30, 2023. The increase of approximately \$5.7 million was primarily related to increased R&D activities for DA-1241 and DA-1726 for the three months ended June 30, 2024 following commencement of the Phase 2a clinical trial for DA-1241 and Phase 1 trial for DA-1726,
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compared to the three months ended June 30, 2023 when R&D activities were starting to ramp up following the acquisition of DA-1241 and DA-1726 in the fourth quarter of 2022. Specifically, the \$5.7 million increase in R&D expenses was primarily attributable to (i) \$5.4 million in higher expenditures for investigational drug manufacturing costs, non-clinical and preclinical services, clinical trials and consulting and (ii) \$0.3 million in higher employee compensation and benefits.

R&D expenses were approximately \$13.0 million for the six months ended June 30, 2024, as compared to approximately \$3.0 million for the six months ended June 30, 2023. The approximately \$10.0 million increase was primarily related to increased R&D activities for DA-1241 and DA-1726. Specifically, the \$10.0 million increase in R&D expenses was primarily attributable to (i) \$9.3 million in higher expenditures for investigational drug manufacturing costs, non-clinical and preclinical services, clinical trials and consulting and (ii) \$0.7 million in higher employee compensation and benefits.

- **General and Administrative (G&A) Expenses** were approximately \$2.0 million for the three months ended June 30, 2024, compared to approximately \$1.4 million for the three months ended June 30, 2023. The increase of approximately \$0.6 million was primarily attributable to \$0.4 million in higher employee compensation and benefits and \$0.1 million in higher non-cash stock-based compensation.

G&A expenses were approximately \$4.0 million for the six months ended June 30, 2024, as compared to approximately \$3.3 million for the six months ended June 30, 2023. The approximately \$0.7 million increase was primarily attributable to \$0.4 million in higher employee compensation and benefits and \$0.2 million in higher non-cash stock-based compensation.

- **Other Income** was approximately \$31 thousand for the three months ended June 30, 2024, as compared to approximately \$3.1 million for the three months ended June 30, 2023. The approximately \$3.0 million decrease was primarily attributable to a loss of \$0.1 million related to the change in fair value of warrant liabilities for the three months ended June 30, 2024, compared to a gain of \$3.1 million for the three months ended June 30, 2023, partially offset by \$0.2 million of interest income earned on the cash balance for the three months ended June 30, 2024, of which there was none for the three months ended June 30, 2023.

Other income was approximately \$0.2 million for the six months ended June 30, 2024, as compared to approximately \$3.0 million for the six months ended June 30, 2023. The approximately \$2.8 million decrease was primarily attributable to the recording of a loss of \$0.2 million related to the change in fair value of warrant liabilities for the six months ended June 30, 2024 compared to a gain of \$3.0 million for three months ended June 30, 2023, partially offset by \$0.4 million of interest income earned on the cash balance for the six months ended June 30, 2024, of which there was none for the six months ended June 30, 2023.

- **Net Loss** for the three months ended June 30, 2024, was approximately \$10.1 million, or \$1.85 per basic and diluted share, based on 5,428,906 weighted average shares of common stock, basic and diluted, compared with a net loss of approximately \$0.7 million, or \$0.15 per basic and diluted share, based on 5,059,003 weighted average shares of common stock, basic and diluted, for the three months ended June 30, 2023.
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Net loss for the six months ended June 30, 2024, was approximately \$16.8 million, or \$3.19 per basic and diluted share, based on 5,259,939 weighted average shares of common stock, basic and diluted, compared with a net loss of approximately \$3.3 million, or \$0.66 per basic and diluted share, based on 5,059,003 weighted average shares of common stock, basic and diluted, for the six months ended June 30, 2023.

- Cash was approximately \$27.9 million as of June 30, 2024, compared to approximately \$22.4 million as of December 31, 2023. The company expects its cash position will be adequate to fund operations into the second quarter of 2025. The Company anticipates that the Series A Warrants from the June financing could be exercised in the first half of 2025, resulting in gross proceeds of \$20 million.

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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- Tables to Follow -

NeuroBo Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except per share amounts)

	As of	
	June 30, 2024	December 31, 2023
	(Unaudited)	
Assets		
Current assets:		
Cash	\$ 27,934	\$ 22,435
Prepaid expenses and other current assets	583	77
Total current assets	28,517	22,512
Property and equipment, net	44	46
Right-of-use asset	169	202
Other assets	21	21
Total assets	\$ 28,751	\$ 22,781
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,632	\$ 821
Clinical trial accrued liabilities	2,066	3,033
Accrued expenses and other current liabilities	463	592
Warrant liabilities	861	658
Related party payable	3,617	789
Lease liability, short-term	72	67
Total current liabilities	9,711	5,960
Lease liability, long-term	98	136
Total liabilities	9,809	6,096
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$0.001 par value per share; 10,000 shares authorized as of June 30, 2024 and December 31, 2023; no shares issued or outstanding as of June 30, 2024 and December 31, 2023	—	—
Common stock, \$0.001 par value per share, 100,000 shares authorized as of June 30, 2024 and December 31, 2023; 8,221 and 4,906 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	8	5
Additional paid-in capital	143,966	124,945
Accumulated deficit	(125,032)	(108,265)
Total stockholders' equity	18,942	16,685
Total liabilities and stockholders' equity	\$ 28,751	\$ 22,781

NeuroBo Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(Unaudited - In thousands, except share and per share amounts)

	Three Months Ended June		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ 8,074	\$ 2,364	\$ 12,978	\$ 3,001
General and administrative	2,010	1,442	3,987	3,325
Total operating expenses	10,084	3,806	16,965	6,326
Loss from operations	(10,084)	(3,806)	(16,965)	(6,326)
Other income (expense):				
Change in fair value of warrant liabilities	(133)	3,072	(203)	2,988
Interest income	164	—	401	—
Total other income	31	3,072	198	2,988
Loss before income taxes	(10,053)	(734)	(16,767)	(3,338)
Provision for income taxes	—	—	—	—
Net loss and comprehensive net loss	(10,053)	(734)	(16,767)	(3,338)
Loss per share of common stock, basic and diluted	\$ (1.85)	\$ (0.15)	\$ (3.19)	\$ (0.66)
Weighted average shares of common stock, basic and diluted	5,428,906	5,059,003	5,259,939	5,059,003