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): May 9, 2024

NEUROBO PHARMACEUTICALS, INC.
(Exact name of Registrant as Specified in Its Charter)

Delaware	001-37809	47-2389984
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

545 Concord Avenue, Suite 210
Cambridge, Massachusetts 02138
(Address of principal executive offices, 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 2.02 Results of Operations and Financial Condition.

On May 9, 2024, NeuroBo Pharmaceuticals, Inc. (the "***Company***") issued a press release announcing its financial results for the first quarter ended March 31, 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.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 2.02, and Exhibit 99.1 hereto, 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 liability of that section, nor shall it be deemed incorporated by reference in any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release dated May 9, 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: May 9, 2024

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

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

Dosed First Patient in the Single Ascending Dose Part 1 of the Phase 1 Clinical Trial of DA-1726 in Obesity, With Top-Line Data Readout Expected in the Third Quarter of 2024

Anticipate First Patient to be Dosed in the Multiple Ascending Dose Part 2 of the Phase 1 Clinical Trial of DA-1726 in the Third Quarter of 2024

Part 2 of the Phase 2a Trial of DA-1241 for the Treatment of MASH Underway After Enrollment of Part 1 Completed, With Data Expected in the Fourth Quarter of 2024

Cash of $16.0 Million, Expected to Fund the Company Into the Fourth Quarter of 2024

CAMBRIDGE, May 9, 2024 – NeuroBo Pharmaceuticals, Inc. (Nasdaq: NRBO), a clinical-stage biotechnology company focused on transforming cardiometabolic diseases, today announced financial results for the first quarter ended March 31, 2024 and provided a corporate update.

“During the first quarter and subsequently, we continued to diligently advance the clinical development of our two, next generation cardiometabolic assets, with promising therapeutic potential in the obesity and metabolic dysfunction-associated steatohepatitis (MASH) markets,” stated Hyung Heon Kim, President and Chief Executive Officer of NeuroBo. “This past month, we began dosing patients in our first-in-human, 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), in obesity. Based on pre-clinical evidence generated to date, we strongly believe that DA-1726 may offer a superior tolerability profile compared to currently available GLP-1 agonists, due to its unique ratio of GLP1R and glucagon receptors, reducing food intake while increasing energy expenditure, leading to improved patient outcomes. Looking ahead for DA-1726, we eagerly anticipate presenting new, compelling pre-clinical data at the American Diabetes Association 84th Scientific Sessions in June of this year. We anticipate reporting top-line data from the single ascending dose (SAD) Part 1 in the third quarter of this year and also expect to dose the first patient in the multiple ascending dose (MAD) Part 2 in the third quarter of this year, with the expectation for the top-line data from the MAD Part 2 in the first quarter of 2025."

Mr. Kim continued, “Additionally, just after quarter end, 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. This milestone followed closely on the heels of the Safety Review Committee (SRC) approval, allowing the study to continue without modification, an early indication of the safety of DA-1241. Part 2 of this trial, in combination with sitagliptin, a DPP4 inhibitor, continues to enroll patients. Pre-clinical safety data, reported in January, showed promising results for DA-1241 for this combination therapy. Notably, two poster presentations, with new pre-clinical evidence on DA-1241 in combination with semaglutide (Segovia®), will be 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

- April 2024: Dosed the first patient in the SAD Part 1 of its two-part 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 into Part 1 with a 1:2:1 ratio into 3 treatment groups: DA-1241 50 mg, DA-1241 100 mg, or placebo.
- March 2024: Received SRC approval to continue the two-part Phase 2a trial of DA-1241 for the treatment of MASH without modification following a blinded safety review of the first six months of study conduct.
- March 2024: Announced the appointment of Marshall Woodworth as Chief Financial Officer, following his tenure as Acting Chief Financial Officer.
- February 2024: Received first site Institutional Review Board (IRB) approval for Alexander Prezioso, M.D., Investigator, Clinical Pharmacology of Miami, in Hialeah, FL, to proceed with the Phase 1 clinical trial of DA-1726 for the treatment of obesity.
- February 2024: Announced that the FDA has cleared its Investigational New Drug (IND) application for the Phase 1 clinical trial of DA-1726 in obesity.
- January 2024: Reported positive pre-clinical safety data of DA-1241 in combination with sitagliptin, a DPP4 inhibitor. The pre-clinical results demonstrated that once daily oral administration in rats, of sitagliptin alone (180 mg/kg/day), DA-1241 alone (100 mg/kg/day), or sitagliptin in combination with DA-1241 (up to 180/100 mg/kg/day sitagliptin+DA-1241) for 13 weeks, was well tolerated with no adverse effects. Additionally, opened enrollment for Part 2 of its Phase 2a clinical trial of DA-1241 when co-administered with sitagliptin for the treatment of MASH.

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. Initiation of the multiple ascending dose (MAD) study Part 2 is expected in the third quarter of 2024 and the top-line data expected in the first quarter of 2025.
- **DA-1241 in MASH:** Full enrollment of the two-part Phase 2a clinical trial of DA-1241 in MASH is expected in the third quarter of 2024. Top-line results are expected to be available in the fourth quarter of 2024.

First Quarter Financial and Operating Results

- **Research and Development (R&D) Expenses** were approximately $4.9 million for the three months ended March 31, 2024, as compared to approximately $0.6 million for the three months ended March 31, 2023. The increase of approximately $4.3 million was primarily attributable to increased development activities for DA-1241 and DA-1726. Specifically, the $4.3 million increase in R&D expenses was primarily attributable to (i) $3.9 million in higher expenditures for investigational drug manufacturing costs, non-clinical and preclinical services, clinical trials and consulting and (ii) $0.4 million in higher employee compensation and benefits.

- **General and Administrative Expenses** were approximately $2.0 million for the three months ended March 31, 2024, compared to approximately $1.9 million for the three months ended March 31, 2023. The increase of approximately $0.1 million was primarily attributable to $0.2 million in higher non-cash stock-based compensation, partially offset by $0.1 million in lower legal and professional fees.

- **Other Income (Expense)** was approximately $0.2 million for the three months ended March 31, 2024, compared to approximately ($0.1 million) for the three months ended March 31, 2023. The change was primarily attributable to $0.2 million of interest income earned on our cash balance for the three months ended March 31, 2024, of which there was none for the three months ended March 31, 2023.

- **Net Loss** for the three months ended March 31, 2024, was approximately $6.7 million, or $1.32 per basic and diluted share, based on 5,089,408 weighted average shares of common stock, basic and diluted, compared with a net loss of approximately $2.6 million, or $0.51 per basic and diluted share, based on 5,059,003 weighted average shares of common stock, basic and diluted, for the three months ended March 31, 2023.

- **Cash** was approximately $16.0 million as of March 31, 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 fourth quarter of 2024 and we are currently exploring various financing alternatives.

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 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 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 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, except as required by law.

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- Tables to Follow -

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

	As of	
	March 31, 2024 (Unaudited)	December 31, 2023
Assets		
Current assets:		
Cash	$ 15,988	$ 22,435
Prepaid expenses and other current assets	776	77
Total current assets	16,764	22,512
Property and equipment, net	47	46
Right-of-use asset	186	202
Other assets	21	21
Total assets	$ 17,018	$ 22,781
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable (including related party payable of $794 and $0 as of March 31, 2024 and December 31, 2023, respectively)	$ 2,079	$ 821
Accrued liabilities (including related party payable of $175 and $789 as of March 31, 2024 and December 31, 2023, respectively)	3,948	4,414
Warrant liabilities	728	658
Lease liability, short-term	70	67
Total current liabilities	6,825	5,960
Lease liability, long-term	117	136
Total liabilities	6,942	6,096
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value per share; 10,000 shares authorized as of March 31, 2024 and December 31, 2023; no shares issued or outstanding as of March 31, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value per share, 100,000 shares authorized as of March 31, 2024 and December 31, 2023; 4,906 shares issued and outstanding as of March 31, 2024 and December 31, 2023	5	5
Additional paid–in capital	125,050	124,945
Accumulated deficit	(114,979)	(108,265)
Total stockholders' equity	10,076	16,685
Total liabilities and stockholders' equity	$ 17,018	$ 22,781

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

	Three Months Ended March 31,	
	2024	2023
Operating expenses:		
Research and development	$ 4,904	$ 637
General and administrative	1,977	1,883
Total operating expenses	6,881	2,520
Loss from operations	(6,881)	(2,520)
Other income (expense):		
Change in fair value of warrant liabilities	(70)	(84)
Interest income	237	—
Total other income	167	(84)
Loss before income taxes	(6,714)	(2,604)
Provision for income taxes	—	—
Net loss and comprehensive loss	(6,714)	(2,604)
Loss per share of common stock, basic and diluted	$ (1.32)	$ (0.51)
Weighted average shares of common stock, basic and diluted	5,089,408	5,059,003