
**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): March 28, 2024



NEUROBO PHARMACEUTICALS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware (State or other jurisdiction	001-37809 (Commission	47-2389984 (IRS Employer
of incorporation)	File Number)	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 March 28, 2024, NeuroBo Pharmaceuticals, Inc. (the “*Company*”) issued a press release announcing its financial results for the year ended December 31, 2023. 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 March 28, 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: March 28, 2024

By: /s/ Hyung Heon Kim

Hyung Heon Kim

President and Chief Executive Officer



NeuroBo Pharmaceuticals Reports Year End 2023 Financial Results and Provides Corporate Update

Received First Site Institutional Review Board (IRB) Approval to Proceed With the Phase 1 Trial of DA-1726 in Obesity

Phase 1 Trial of DA-1726 Expected to Dose First Patient in Second Quarter of 2024

Received Safety Review Committee (SRC) Approval Recommending That the Two-Part Phase 2a Trial of DA-1241 for the Treatment of MASH Continue Without Modification

Data from the Phase 2a Trial of DA-1241 Expected in the Second Half of 2024

Cash of \$22.4 Million, Expected to Fund the Company Into the Fourth Quarter of 2024

CAMBRIDGE, March 28, 2024 – NeuroBo Pharmaceuticals, Inc. (Nasdaq: NRBO), a clinical-stage biotechnology company focused on transforming cardiometabolic diseases, today announced financial results for the year ended December 31, 2023 and provided a corporate strategic update.

“Throughout 2023 and into the first quarter of 2024, we made remarkable progress advancing the clinical development of our two, next generation cardiometabolic assets, which address the significant metabolic dysfunction-associated steatohepatitis (MASH) and obesity markets,” stated Hyung Heon Kim, President and Chief Executive Officer of NeuroBo. “Most recently, we received Safety Review Committee (SRC) approval, recommending that the Phase 2a clinical trial for DA-1241, a novel G-Protein-Coupled Receptor 119 (GPR119) agonist for treating MASH, continue without modification. The SRC recommendation was based on no significant safety trends found in the first six months of study conduct, which is an early indication of the safety of DA-1241. Pre-clinical safety data, reported in January, showed promising results for DA-1241 in combination with sitagliptin, a DPP4 inhibitor. Enrollment for Part 2 has also begun, indicating a strong commitment to the timely development of our pipeline programs. As previously reported, based on the pre-clinical evidence to date, DA-1241 has been shown to effectively improve hepatic and systemic inflammation, with the sitagliptin combination therapy showing synergistic anti-inflammatory effects. The drug has also been shown to be well tolerated in both healthy volunteers and patients with type 2 diabetes mellitus (T2DM). We continue to believe that DA-1241 has the potential to be a safe and effective treatment for MASH and look forward to reporting full trial data in the second half of this year.

“Our second asset, DA-1726, a novel oxyntomodulin (OXM) analogue acting as a GLP1R and GCGR dual agonist, is currently in preparations for a Phase 1 study for the treatment of obesity. In February of this year, shortly after the U.S. Food and Drug Administration (FDA) cleared our Investigational New Drug (IND) application for the clinical trial, we received our first site Institutional Review Board (IRB) approval to proceed with the Phase 1 clinical trial. Importantly, in preclinical testing, DA-1726 showed superior weight loss compared to semaglutide (Wegovy®), and its administration resulted in similar weight reduction even while consuming more food compared to tirzepatide (Zepbound™). Additionally, DA-1726 has shown improvements in hepatic steatosis, inflammation, and fibrosis. Given this data, we believe DA-1726’s balanced combination of reduced food intake and increased energy expenditure can potentially be a safe

and effective therapy for obesity. We have begun screening patients with the goal of randomizing the first patient in the second quarter of this year and anticipate reporting top-line data from the single ascending dose (SAD) Part 1 in the first half of 2025, and from the multiple ascending dose (MAD) Part 2 in the second half of 2025.

Mr. Kim concluded, "It is an exciting time at NeuroBo and to add to this, I would like to welcome Marshall Woodworth, who was recently appointed as our permanent Chief Financial Officer. He has already made a significant impact on the company and its financial operations and his continued contributions to the team will be key as we continue to execute on the clinical development of our two promising cardiometabolic assets."

Fourth Quarter 2023 and Subsequent Highlights

- March 2024: Received SRC approval recommending that the two-part Phase 2a trial of DA-1241 for the treatment of MASH continue 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 trial DA-1726 in obesity, previously submitted in December 2023.
- 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, the company announced it had opened enrollment for Part 2 of its Phase 2a clinical trial of DA-1241 when co-administered with sitagliptin for the treatment of MASH.
- December 2023: Effected a 1-for-8 reverse stock split to regain compliance with the Nasdaq minimum bid price requirement. On January 8, 2024, company received notification from Nasdaq that it had regained compliance.
- November 2023: Appointed James P. Tursi, M.D., a pharmaceutical industry veteran, to its Board of Directors and as a member of the Board's Nominating and Governance Committee.

Anticipated Clinical Milestones

- **DA-1241 in MASH:** Full data from the Phase 2a clinical trial of DA-1241 in MASH is expected to be available in the second half of 2024.
- **DA-1726 in Obesity:** Initiation of a Phase 1 single ascending dose (SAD) study and multiple ascending dose (MAD) study, expected in the second quarter of 2024. Top-line data from the single ascending dose (SAD) Part 1 is expected in the first half of 2025 and from the multiple ascending dose (MAD) Part 2 in the second half of 2025.

Full Year 2023 Financial and Operating Results

- **Research and Development (R&D) Expenses** were approximately \$9.2 million for the year ended December 31, 2023, as compared to approximately \$2.8 million for the year ended December 31,
-

2022. The increase of approximately \$6.4 million was primarily attributable to (i) \$6.3 million in higher expenditures for investigational drug manufacturing costs, non-clinical and pre-clinical services, clinical trials and consulting, (ii) \$0.1 million in higher stock-based compensation, and (iii) \$0.1 million in higher employee compensation and benefits.

- **General and Administrative Expenses** were approximately \$6.7 million for the year ended December 31, 2023, compared to approximately \$8.6 million for the year ended December 31, 2022. The decrease of approximately \$1.9 million was primarily due to (i) \$0.9 million in lower insurance cost, (ii) \$0.7 million in lower stock-based compensation, (iii) \$0.3 million in lower legal and professional fees, and (iv) \$0.3 million in lower employee compensation and benefits. The decreases were partially offset by an increase of \$0.2 million in state non-income taxes and fees as well as public company costs.
- **Total Operating Expenses** were approximately \$15.9 million for the year ended December 31, 2023, compared to approximately \$19.6 million for the year ended December 31, 2022. The approximately \$3.7 million decrease was primarily attributable to (i) \$8.2 million in lower acquired in-process R&D expenses and (ii) \$1.9 million in lower general and administrative expenses. The decreases were partially offset by \$6.4 million in higher R&D expenses.
- **Other Income** was approximately \$3.4 million for the year ended December 31, 2023, compared to approximately \$5.7 million for the year ended December 31, 2022. The decrease was primarily attributable to a decrease of \$5.0 million in gain related to the change in fair value of warrant liabilities. The decrease was partially offset by \$0.5 million of interest income recorded in 2023 and \$2.3 million of financing and other expenses incurred in 2022.
- **Net Loss** for the year ended December 31, 2023, was \$12.5 million, or \$2.46 per basic and diluted share, based on 5,071,101 weighted average shares of common stock outstanding, compared with a net loss of \$14.0 million, or \$43.42 per basic and diluted share, based on 321,703 weighted average shares of common stock outstanding for the year ended December 31, 2022.
- **Cash** was \$22.4 million as of December 31, 2023, compared with \$33.4 million as of December 31, 2022. The company expects its cash position will be adequate to fund operations into the fourth quarter of 2024.

About NeuroBo Pharmaceuticals

NeuroBo Pharmaceuticals, Inc. is a clinical-stage biotechnology company focused on transforming cardiometabolic diseases. The company is currently developing DA-1241 for the treatment of Metabolic Dysfunction-Associated Steatohepatitis (MASH) and Type 2 diabetes mellitus (T2DM), and is developing DA-1726 for the treatment of obesity. DA-1241 is a novel G-protein-coupled receptor 119 (GPR119) agonist that promotes the release of key gut peptides GLP-1, GIP, and PYY. In preclinical 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. 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.

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”, “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; 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 our contract manufacturers, clinical study partners and others involved in the development of NeuroBo’s current and future product candidates; potential negative interactions between our 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; our 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; effects of changes in applicable laws or regulations; effects of changes to NeuroBo’s stock price on the terms of the license agreement and any future fundraising; and other risks and uncertainties described in our filings with the SEC. Forward-looking statements speak only as of the date when made. NeuroBo does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Contacts:

NeuroBo Pharmaceuticals

Marshall H. Woodworth
Chief Financial Officer
+1-857-299-1033
marshall.woodworth@neurobopharma.com

Rx Communications Group

Michael Miller
+1-917-633-6086
mmiller@rxir.com

- Tables to Follow -

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

	As of December 31,	
	2023	2022
Assets		
Current assets:		
Cash	\$ 22,435	\$ 33,364
Prepaid and other current assets	77	168
Total current assets	22,512	33,532
Property and equipment, net	46	2
Right-of-use asset	202	—
Other assets	21	—
Total assets	\$ 22,781	\$ 33,534
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 821	\$ 708
Accrued liabilities	4,414	280
Warrant liabilities	658	10,796
Lease liability, short-term	67	—
Total current liabilities	5,960	11,784
Lease liability, long-term	136	—
Total liabilities	6,096	11,784
Commitments and contingencies (Note 4)		
Stockholders' equity		
Preferred stock, \$0.001 par value per share; 10,000,000 shares authorized as of December 31, 2023 and 2022; no shares issued or outstanding as of December 31, 2023 and 2022.	—	—
Common stock, \$0.001 par value per share, 100,000,000 shares authorized as of December 31, 2023 and 2022; 4,906,032 and 3,179,502 shares issued and outstanding as of December 31, 2023 and 2022, respectively.	5	25
Additional paid-in capital	124,945	117,520
Accumulated deficit	(108,265)	(95,795)
Total stockholders' equity	16,685	21,750
Total liabilities and stockholders' equity	\$ 22,781	\$ 33,534

NeuroBo Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2023	2022
Operating expenses:		
Research and development	\$ 9,158	\$ 2,778
Acquired in-process research and development	—	8,210
General and administrative	6,728	8,640
Total operating expenses	15,886	19,628
Loss from operations	(15,886)	(19,628)
Other income (expense):		
Change in fair value of warrant liabilities	2,955	7,935
Interest income	461	—
Financing expense	—	(2,191)
Other expense	—	(83)
Total other income	3,416	5,661
Loss before income taxes	(12,470)	(13,967)
Provision for income taxes	—	—
Net loss	\$ (12,470)	\$ (13,967)
Loss per share of common stock, basic and diluted	\$ (2.46)	\$ (43.42)
Weighted average shares of common stock, basic and diluted	5,071,101	321,703
Comprehensive loss:		
Net loss	\$ (12,470)	\$ (13,967)
Other comprehensive loss, net of tax	—	(4)
Comprehensive loss	\$ (12,470)	\$ (13,971)