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): November 7, 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)	(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 November 7, 2024, NeuroBo Pharmaceuticals, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 2024 and providing a corporate 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 November 7, 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: November 7, 2024

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

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

Reported Positive Top-Line Data From the SAD Part 1 of Its Phase 1 Clinical Trial Evaluating DA-1726 for the Treatment of Obesity, Revealing Favorable Safety, Tolerability and Dose-Linear Pharmacokinetics

$21.7 Million in Cash at End of Third Quarter Expected to Fund the Company Into the Third Quarter of 2025

Top-Line Results from the Phase 2a Trial of DA-1241 for the Treatment of MASH Expected in December of 2024

Top-Line Data From the MAD Part 2 of the Phase 1 Trial of DA-1726 Expected in the First Quarter of 2025

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

CAMBRIDGE, Mass., November 7, 2024 – NeuroBo Pharmaceuticals, Inc. (Nasdaq: NRBO), a clinical-stage biotechnology company focused on transforming cardiometabolic diseases, today announced financial results for the third quarter ended September 30, 2024 and provided a corporate update.

"The third quarter was punctuated by the positive top-line results from the single ascending dose (SAD) Part 1 of our 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, revealing it to be safe and tolerable as well as demonstrating dose-linear pharmacokinetics (PK)," stated Hyung Heon Kim, President and Chief Executive Officer of NeuroBo. "Based on the excellent safety data from the SAD Part 1, we are currently engaged in the addition of one or more cohorts to further investigate the maximum tolerated dose, enabling us to fully harness the potential of DA-1726. Based on the pre-clinical data available, along with DA-1726's balanced activation of GLP1R and glucagon receptors, which enhances energy expenditure, we maintain our belief that it can emerge as a best-in-class obesity treatment, offering a more favorable tolerability profile compared to existing GLP-1 agonists and those in late-stage clinical trials. Importantly, the drug's strong safety profile also enabled the accelerated initiation of the multiple ascending dose (MAD) study, for which we expect to report top-line results from the planned cohorts during the first quarter of 2025.

"To further differentiate DA-1726, early in the quarter, we signed a joint research agreement, together with our collaboration partner, Dong-A ST and ImmunoForge, to develop a long-acting once monthly formulation of the drug. Additionally, we continue to plan for an early proof-of-concept, multicenter, randomized, double-blind, placebo-controlled Part 3 of the Phase 1 clinical trial to evaluate the efficacy and safety of DA-1726 in obese, otherwise healthy subjects, reflecting our strong commitment to rapidly advancing the clinical development of this promising cardiometabolic asset. Part 3 is anticipated to begin upon the completion of Part 2."

Mr. Kim continued, “After recently announcing the last patient last visit in our Phase 2a clinical trial for DA-1241, a novel G-Protein-Coupled Receptor 119 (GPR119) agonist, in subjects with presumed metabolic dysfunction-associated steatohepatitis (MASH), our next clinical milestone is the full data readout expected in December of this year. As a reminder, the trial is exploring the efficacy of DA-1241 independently, as well as in combination with sitagliptin, a DPP-4 inhibitor, which we believe will show synergistic effects compared to DA-1241, alone. Based on 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.”

Third Quarter 2024 and Subsequent Highlights

- November 2024: Completed the last patient last visit in its two-part, Phase 2a clinical trial evaluating the efficacy and safety of DA-1241 for the treatment of MASH.
- September 2024: Announced positive top-line safety, tolerability and dose-linear PK data from the SAD Part 1 of its Phase 1 clinical trial evaluating DA-1726 for the treatment of obesity. A total of 45 obese, otherwise healthy participants were randomized in a double-blind, 6:3 ratio of DA-1726 or placebo. Single ascending doses were found to be safe and well tolerated, with no serious adverse events. Only 5 subjects in the DA-1726 treatment group reported adverse events compared with 3 subjects in the placebo group. A dose-linear PK profile was observed across the investigated dose range. Additional cohorts are being added to the SAD Part 1 to explore the maximum tolerated dose.
- August 2024: Completed enrollment in the SAD Part 1 of the Phase 1 clinical trial evaluating DA-1726 for the treatment of obesity.
- 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 the Company’s four legacy assets, for the 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.

Anticipated Clinical Milestones

- **DA-1726 in Obesity:** The last patient visit in the multiple ascending dose (MAD) study Part 2 is expected in the fourth quarter of 2024 and top-line data is expected in the first quarter of 2025. The planned Phase 1 Part 3 will evaluate early proof of concept, with the first patient expected to be enrolled during the third quarter of 2025, followed by 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 December of 2024.

Third Quarter Financial and Operating Results

- **Research and Development (R&D) Expenses** were approximately $4.5 million for the three months ended September 30, 2024, as compared to approximately $2.3 million for the three months ended September 30, 2023. The increase of approximately $2.2 million was primarily related to increased R&D activities for DA-1241 and DA-1726 for the three months ended September 30, 2024 related to the Phase 2a clinical trial for DA-1241 and Phase 1 trial for DA-1726. Specifically, the $2.2 million increase in R&D expenses was attributable to (i) $1.9 million in higher expenditures for clinical trials, non-clinical and preclinical services, and consulting and (ii) $0.3 million in higher employee compensation and benefits. Included in R&D expenses for the three months ended September 30, 2024 was $0.7 million of non-clinical and preclinical expenses incurred under the Shared Services Agreement with Dong-A ST as compared to $0.4 million for the three months ended September 30, 2023.

  R&D expenses were approximately $17.5 million for the nine months ended September 30, 2024, as compared to approximately $5.3 million for the nine months ended September 30, 2023. The approximately $12.2 million increase was primarily related to increased R&D activities related to Phase 2a clinical trial for DA-1241 and a Phase 1 trial for DA-1726 for the nine months ended September 30, 2024 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 $12.2 million increase in R&D expenses was attributable to (i) $11.2 million in higher expenditures for clinical trials, investigational drug manufacturing costs, non-clinical and preclinical services, and consulting and (ii) $1.0 million in higher employee compensation and benefits. Included in R&D expenses for the nine months ended September 30, 2024 was $4.3 million of investigational drug manufacturing costs and non-clinical and preclinical expenses incurred under the Shared Services Agreement with Dong-A ST as compared to $2.2 million for the nine months ended September 30, 2023.

- **General and Administrative (G&A) Expenses** were approximately $1.7 million for the three months ended September 30, 2024, compared to approximately $1.6 million for the three months ended September 30, 2023. The increase of approximately $0.1 million was primarily attributable to $0.2 million in higher employee compensation and benefits, partially offset by $0.1 million in lower legal and professional fees.

  G&A expenses were approximately $5.7 million for the nine months ended September 30, 2024, as compared to approximately $4.9 million for the nine months ended September 30, 2022. The approximately $0.8 million increase was primarily attributable to $0.9 million in higher employee compensation and benefits, partially offset by $0.1 million in lower legal and professional fees.

- **Total Other Income** was approximately $0.6 million for the three months ended September 30, 2024, as compared to approximately $0.1 million for the three months ended September 30, 2023. The approximately $0.5 million increase was attributable to the recording of a gain of $0.3 million related to the change in fair value of warrant liabilities for the three months ended September 30, 2024 compared to a loss of $0.1 million for the three months ended September 30, 2023, and $0.1 million in higher interest income earned on our cash balance.

Total other income was approximately $0.8 million for the nine months ended September 30, 2024, as compared to approximately $3.1 million for the nine months ended September 30, 2023. The approximately $2.3 million decrease was primarily attributable to $2.8 million in lower gain related to the change in fair value of warrant liabilities, partially offset by $0.5 million of higher interest income earned on our cash balance.

- **Net Loss** for the three months ended September 30, 2024, was approximately $5.7 million, or $0.55 per basic and diluted share, based on 10,214,087 weighted average shares of common stock, basic and diluted, compared with a net loss of approximately $3.8 million, or $0.75 per basic and diluted share, based on 5,075,817 weighted average shares of common stock, basic and diluted, for the three months ended September 30, 2023.

  Net loss for the nine months ended September 30, 2024, was approximately $22.4 million, or $3.24 per basic and diluted share, based on 6,922,338 weighted average shares of common stock, basic and diluted, compared with a net loss of approximately $7.2 million, or $1.41 per basic and diluted share, based on 5,064,670 weighted average shares of common stock, basic and diluted, for the nine months ended September 30, 2023.

- **Cash** was approximately $21.7 million as of September 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 third quarter of 2025.

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	
	September 30, 2024 (Unaudited)	December 31, 2023
Assets		
Current assets:		
Cash	$ 21,669	$ 22,435
Prepaid expenses and other current assets	266	77
Total current assets	21,935	22,512
Property and equipment, net	39	46
Right-of-use asset	151	202
Other assets	21	21
Total assets	$ 22,146	$ 22,781
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,017	$ 821
Clinical trial accrued liabilities	3,354	3,033
Accrued expenses and other current liabilities	654	592
Warrant liabilities	564	658
Related party payable	3,450	789
Lease liability, short-term	75	67
Total current liabilities	9,114	5,960
Lease liability, long-term	79	136
Total liabilities	9,193	6,096
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value per share; 10,000 shares authorized as of September 30, 2024 and December 31, 2023; no shares issued or outstanding as of September 30, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value per share, 100,000 shares authorized as of September 30, 2024 and December 31, 2023; 8,609 and 4,906 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	9	5
Additional paid–in capital	143,628	124,945
Accumulated deficit	(130,684)	(108,265)
Total stockholders' equity	12,953	16,685
Total liabilities and stockholders' equity	$ 22,146	$ 22,781

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 4,517	$ 2,292	$ 17,495	$ 5,293
General and administrative	1,742	1,601	5,729	4,926
Total operating expenses	6,259	3,893	23,224	10,219
Loss from operations	(6,259)	(3,893)	(23,224)	(10,219)
Other income (expense):				
Change in fair value of warrant liabilities	297	(87)	94	2,901
Interest income	310	162	711	162
Total other income	607	75	805	3,063
Loss before income taxes	(5,652)	(3,818)	(22,419)	(7,156)
Provision for income taxes	—	—	—	—
Net loss and comprehensive net loss	(5,652)	(3,818)	(22,419)	(7,156)
Loss per share of common stock, basic and diluted	$ (0.55)	$ (0.75)	$ (3.24)	$ (1.41)
Weighted average shares of common stock, basic and diluted	10,214,087	5,075,817	6,922,338	5,064,670