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 9, 2023

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.)

200 Berkeley Street, Office 19th Floor
Boston, Massachusetts 02116
(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 August 9, 2023, NeuroBo Pharmaceuticals, Inc. (the ***"Company"***) issued a press release announcing its financial results for the second quarter ended June 30, 2023 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.

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 August 9, 2023
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 9, 2023

By: /s/ Joseph Hooker
Joseph Hooker
Interim President and Chief Executive Officer

Exhibit 99.1

NeuroBo Pharmaceuticals Reports Second Quarter 2023 Financial Results and Provides Corporate Update

Dosing of First Patient in Phase 2a Clinical Trial of DA-1241 Expected September 2023

Cash and Cash Equivalents of $28.7 Million, Expected to Fund the Company into 2024, Through Multiple Clinical Milestones

BOSTON, August 9, 2023 – NeuroBo Pharmaceuticals, Inc. (Nasdaq: NRBO), a clinical-stage biotechnology company on a quest to transform cardiometabolic diseases, today announced financial results for the second quarter ended June 30, 2023 and provided a corporate strategic update.

“During the second quarter and thereafter, we have made significant progress advancing the development of our two promising cardiometabolic assets, which address the underserved nonalcoholic steatohepatitis (NASH) market and the significant obesity and type 2 diabetes (T2D) markets,” stated Joe Hooker, Interim President and Chief Executive Officer of NeuroBo. “Notably, in May, we received U.S. Food and Drug Administration (FDA) approval of our Investigational New Drug (IND) application for DA-1241, a novel G-Protein-Coupled Receptor 119 (GPR119) agonist, for the treatment of NASH. This was followed, just recently, with receipt of first site Institutional Review Board (IRB) approval for the Phase 2a clinical trial of DA-1241. We look forward to working closely with our contract research organization (CRO) partner and our site investigators, with the goal to dose the first patient next month. We believe that the mechanism of action of DA-1241 will translate into a new and effective treatment for NASH. In preclinical studies, DA-1241 demonstrated a beneficial effect on liver inflammation and fibrosis, lipid metabolism and glucose metabolism, and was shown to be safe and well tolerated in Phase 1a/1b studies in healthy volunteers and patients with T2D. As previously announced, the two-part design will provide optionality for an interim analysis in the first half of 2024, and we anticipate a full data readout in the second half of 2024.

“Additionally, in June, positive preclinical data was presented at the American Diabetes Association's 83rd Scientific Sessions, demonstrating that our second asset, DA-1726, a novel oxyntomodulin (OXM) analogue which acts as a glucagon-like peptide-1 receptor (GLP1R) and glucagon receptor (GCGR) dual agonist, elicits superior weight loss efficacy compared to Semaglutide (SEMA) and Tirzepatide (TIR) and effective glycemic control in mice models. We intend to advance DA-1726 through the IND process during the second half of this year. If accepted by the FDA, we plan to initiate a Phase 1a safety study in the first half of 2024, with a data readout expected in the second half of 2024. Based on the preclinical evidence demonstrating superior body weight loss compared with other selective GLP1R agonists, we are optimistic about the potential of DA-1726 to address the significant obesity market.”

Mr. Hooker added, “We have also made progress toward our goal of evaluating potential out-licensing and acquisition opportunities for our four legacy therapeutic programs and recently announced signing of a term sheet with MThera Pharma Co., Ltd. (MTHERA) to out-license the worldwide rights, outside of Korea, for NB-01 for the treatment of painful diabetic neuropathy. With MTHERA's deep knowledge of

manufacturing, evaluating the quality of, and researching natural medicines and botanical drugs, we consider it the optimal partner to progress the clinical development of NB-01. Meanwhile, we continue to evaluate potential opportunities for our three remaining legacy therapeutic programs, ANA001, NB-02 and Gemcabene. With a cash cushion of $28.7 million at quarter end to fund operations through multiple, near-term value creating milestones, we are enthusiastic about the potential of our cardiometabolic assets and look forward to continued execution to drive shareholder value."

Second Quarter 2023 and Subsequent Highlights

- August 2023: Received the first site IRB approval for Zeid Kayali, M.D., Medical Director at Inland Empire Liver Foundation, in Rialto, CA, to proceed with the Phase 2a clinical trial of DA-1241, a novel GPR119 agonist, for the treatment of NASH. The dosing of the first patient in part one of the two-part, Phase 2a clinical trial is expected to occur in September of 2023.

- August 2023: Signed a term sheet with MTHERA to out-license the worldwide rights, excluding Korea, for NB-01, for the treatment of painful diabetic neuropathy, and allowing MTHERA to conduct research in order to seek new patents for NB-01 and conduct clinical trials, including, but not limited to, a potential Phase 3 clinical trial in the United States for the future commercialization of NB-01.

- June 2023: Presented preclinical data on DA-1726, a novel OXM analogue functioning as a GLP1R and GCGR dual agonist, showing an ability to elicit superior weight loss efficacy compared to SEMA and TIR. Additionally, DA-1276 has shown effective glycemic control. The data was presented in one ePoster theater discussion and two general poster presentations at the American Diabetes Association's 83rd Scientific Sessions.

- May 2023: Appointed Mark A. Glickman, a highly accomplished pharmaceutical industry executive with more than 30 years of industry experience, to the Board of Directors.

- May 2023: Received FDA clearance for the Company's IND application for a two-part, Phase 2a clinical trial of DA-1241 for the treatment of NASH.

Second Quarter 2023 Financial and Operating Results

- **Research and Development (R&D) Expenses** were approximately $2.4 million for the three months ended June 30, 2023 as compared to approximately $1.0 million for the three months ended June 30, 2022. The approximate $1.4 million increase was primarily related to costs as the Company prepared for the clinical trial of DA-1241, set to begin in the third quarter of 2023, including increases in drug manufacturing and toxicology studies of $0.7 million and $0.6 million, respectively. The increase is also partially attributable to related clinical study and overhead costs in the aggregate of $0.1 million.

  For the six months ended June 30, 2023, R&D expenses were approximately $3.0 million, as compared to approximately $1.9 million for the six months ended June 30, 2022. The approximate $1.1 million increase was primarily related to costs as the Company prepared for the clinical trial of DA-1241 set to begin in the third quarter of 2023, including increases in toxicology studies and related to drug manufacturing of $0.9 million and $0.6 million, respectively. The increase is partially offset by a decrease in clinical trial costs of $0.4 million, as the Company was finishing the ANA 001 study during the six months ended June 30, 2022, and a decrease in drug manufacturing for the Company's legacy assets of $0.1 million.

- **General and Administrative Expenses** were approximately $1.4 million for the three months ended June 30, 2023, as compared to approximately $2.2 million for the three months ended June 30, 2022. The decrease of approximately $0.8 million in the current period was primarily due to a decrease in professional fees of $0.5 million related to the exploration of business opportunities during the three months ended June 30, 2022, as well as a decrease in insurance costs of approximately $0.2 million, and a decrease in stock-based compensation of $0.2 million, offset primarily by increases in employee payroll and executive consultants in the aggregate of $0.1 million.

  For the six months ended June 30, 2023, G&A expenses were approximately $3.3 million, as compared to approximately $4.2 million for the six months ended June 30, 2022. The decrease of approximately $0.9 million in the current period was primarily due to a decrease in professional fees of $0.3 million related to the exploration of business opportunities during the six months ended June 30, 2022, as well as a decrease in insurance costs of approximately $0.4 million, and a decrease in stock-based compensation of $0.5 million, offset primarily by increases in employee payroll and executive consultants in the aggregate of $0.3 million.

- **Net Loss** for the three months ended June 30, 2023 was $0.7 million, or $0.02 per basic and diluted share, based on 40,472,026 weighted average shares of common stock outstanding, compared with a net loss of $3.3 million, or $3.72 per basic and diluted share, based on 888,693 weighted average shares of common stock outstanding for the three months ended June 30, 2022.

  Net Loss for the six months ended June 30, 2023 was $3.3 million, or $0.08 per basic and diluted share, based on 40,472,026 weighted average shares of common stock outstanding, compared with a net loss of $6.2 million, or $6.95 per basic and diluted share, based on 888,693 weighted average shares of common stock outstanding for the six months ended June 30, 2022.

- **Cash and Cash Equivalents** were $28.7 million as of June 30, 2023, compared with $33.4 million as of December 31, 2022. The company expects its cash position will be adequate to fund operations into 2024.

About NeuroBo Pharmaceuticals

NeuroBo Pharmaceuticals, Inc. is a clinical-stage biotechnology company on a quest to transform cardiometabolic diseases. The company is currently developing DA-1241 for the treatment of Non-Alcoholic Steatohepatitis (NASH) 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, which promotes the release of key gut peptides GLP-1, GIP, and PYY. In preclinical studies, DA-1241 demonstrated 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 acts 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, including without limitation, statements about the closing of the offering of securities. 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 our ability to execute on our commercial strategy, the timeline for regulatory submissions, regulatory steps and potential regulatory approval of our 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 ability to integrate the new product candidates into NeuroBo's business in a timely and cost-efficient manner; the cooperation of our contract manufacturers, clinical study partners and others involved in the development of our current and future product candidates; our ability to initiate and complete clinical trials on a timely basis; our ability to recruit sites and subjects for our clinical trials; costs related to the license agreement, known and unknown, including costs of any litigation or regulatory actions relating to the license agreement; our ability to out-license or sell assets related to our legacy programs; 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.

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- Tables to Follow -

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

	June 30, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash	$ 28,688	$ 33,364
Prepaid expenses	486	168
Total current assets	29,174	33,532
Property and equipment, net	5	2
Total assets	$ 29,179	$ 33,534
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 967	$ 708
Accrued liabilities	2,041	280
Warrant liabilities	975	10,796
Total current liabilities	3,983	11,784
Total liabilities	3,983	11,784
Commitments and contingencies (Note 4)		
Stockholders' equity		
Preferred stock, $0.001 par value per share; 10,000,000 shares authorized as of June 30, 2023 and December 31, 2022; no shares issued or outstanding as of June 30, 2023 and December 31, 2022.	—	—
Common stock, $0.001 par value per share, 100,000,000 shares authorized as of June 30, 2023 and December 31, 2022; 38,241,685 and 25,436,019 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively.	38	25
Additional paid–in capital	124,291	117,520
Accumulated deficit	(99,133)	(95,795)
Total stockholders' equity	25,196	21,750
Total liabilities and stockholders' equity	$ 29,179	$ 33,534

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 2,364	$ 982	$ 3,001	$ 1,902
General and administrative	1,442	2,237	3,325	4,192
Total operating expenses	3,806	3,219	6,326	6,094
Loss from operations	(3,806)	(3,219)	(6,326)	(6,094)
Other income (expense):				
Change in fair value of warrant liabilities	3,072	—	2,988	—
Other expense	—	(84)	—	(84)
Loss before income taxes	(734)	(3,303)	(3,338)	(6,178)
Provision for income taxes	—	—	—	—
Net loss	(734)	(3,303)	(3,338)	(6,178)
Other comprehensive loss, net of tax	—	(3)	—	(4)
Comprehensive loss	$ (734)	$ (3,306)	$ (3,338)	$ (6,182)
Loss per share:				
Net loss per share, basic and diluted	$ (0.02)	$ (3.72)	$ (0.08)	$ (6.95)
Weighted average shares of common stock outstanding:				
Basic and diluted	40,472,026	888,693	40,472,026	888,693