
**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 13, 2023

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 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 13, 2023, NeuroBo Pharmaceuticals, Inc. (the “*Company*”) issued a press release announcing its financial results for the third quarter ended September 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 November 13, 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: November 13, 2023

By: /s/ Hyung Heon Kim

Hyung Heon Kim

President and Chief Executive Officer



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

DA-1726 Phase 1 IND Filing Expected by Year End 2023

Board Strengthened with Recent Appointment of Industry Veteran, James P. Tursi, M.D.

Cash and Cash Equivalents of \$25.8 Million, Expected to Fund the Company Into the Fourth Quarter of 2024, Through Multiple Potential Value Creating Milestones

BOSTON, November 13, 2023 – NeuroBo Pharmaceuticals, Inc. (Nasdaq: NRBO), a clinical-stage biotechnology company on a quest to transform cardiometabolic diseases, today announced financial results for the third quarter ended September 30, 2023 and provided a corporate strategic update.

“During the third quarter, we continued to advance the clinical development of our two, next generation cardiometabolic assets, which address the significant nonalcoholic steatohepatitis (NASH) and obesity markets,” stated Hyung Heon Kim, President and Chief Executive Officer of NeuroBo. “Of note, we received first site Institutional Review Board (IRB) approval and subsequently dosed the first patient in our Phase 2a clinical trial of DA-1241, a novel G-Protein-Coupled Receptor 119 (GPR119) agonist, for the treatment of NASH, marking the achievement of a significant milestone for our most advanced asset and reflecting our strong commitment to the timely development of our pipeline programs. The two-part design of this study provides us with the option for an interim analysis, expected in the first half of next year and we anticipate the full data readout in the second half of 2024. Based on strength of the data from our Phase 1a/1b studies in healthy volunteers and patients with Type 2 diabetes (T2D), in which 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, we believe that the mechanism of action of this promising cardiometabolic asset will translate into a safe and effective treatment for NASH, a disease with no current treatment options.

“As it relates to 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, DA-1726 has shown highly encouraging results in preclinical testing including reduced food intake via activation of the GLP-1 receptor as well as increased energy expenditure via glucagon activation. Specifically, in obese mouse models, DA-1241 elicits similar weight loss efficacy compared to Tirzepatide, even while consuming more food, and has exhibited superior weight loss compared to Semaglutide, while also showing further improvements in hepatic steatosis, inflammation, and fibrosis. As a result, we believe DA-1726 will be an effective therapy to address the growing obesity market. We intend to continue to advance DA-1726 through the Investigational New Drug (IND) process during the fourth quarter of this year. If the IND is accepted by the U.S. Food and Drug Administration (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.”

Mr. Kim continued, “Operationally, we are in a strong position, with \$25.8 million in cash and cash equivalents at September 30, 2023, which is expected to fund operations at least into the fourth quarter of next year, through multiple potential value creating milestones. As previously reported, in August, we signed 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 and we continue to consider strategies to monetize our remaining legacy assets, ANA001, NB-02 and Gemcabene, including potential out-licensing and acquisition opportunities.”

Third Quarter 2023 and Subsequent Highlights

- 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 Committee.
- September 2023: Dosed the first patient in the Phase 2a clinical trial of DA-1241, a novel G-Protein-Coupled Receptor 119 (GPR119) agonist, for the treatment of NASH, at The Pinnacle Edinberg/South Texas Research Institute in Edinburg, Texas, under the supervision of Principal Investigator, Dr. David Ramirez.
- August 2023: Appointed current Board member, Hyung Heon Kim, as the Company’s President and Chief Executive Officer.
- 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, for the treatment of NASH.
- 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.

Anticipated Clinical Milestones

- **DA-1241 in NASH:** Data from an interim analysis of the Phase 2a clinical trial of DA-1241 in NASH expected to be available in the first half of 2024. The full data readout is expected in the second half of 2024.
- **DA-1726 in Obesity:** IND submission for a Phase 1 single ascending dose (SAD) study and multiple ascending dose (MAD) study, expected by year end 2023. Initiation of the Phase 1a safety study targeted for the first half of 2024, pending IND acceptance by the FDA, with a data readout expected in the second half of 2024.

Third Quarter 2023 Financial and Operating Results

- **Research and Development (R&D) Expenses** were approximately \$2.3 million for the three months ended September 30, 2023 as compared to approximately \$0.6 million for the three months ended September 30, 2022. The increase of approximately \$1.7 million was primarily due to costs related to the Company’s clinical trial of DA-1241 which was initiated in the third quarter of 2023, including increases in clinical trial costs and toxicology studies of \$1.3 million and \$0.4 million, respectively.

For the nine months ended September 30, 2023, R&D expenses were approximately \$5.3 million, as compared to approximately \$2.5 million for the nine months ended September 30, 2022. The increase of approximately \$2.8 million was primarily due to costs related to the Company’s clinical trial of DA-1241 which was initiated in the third quarter of 2023, including increases in clinical trial costs, toxicology studies and related drug manufacturing of \$0.9 million, \$1.6 million, and \$0.5 million,

respectively. The increase was partially offset by a decrease of \$0.2 million in general research and development overhead, as the Company was finishing the ANA001 study.

- **General and Administrative Expenses** were approximately \$1.6 million for the three months ended September 30, 2023, compared to approximately \$2.5 million for the three months ended September 30, 2022. The decrease of approximately \$0.9 million was primarily due to a decrease in professional fees of \$0.7 million related to the exploration of business opportunities during the three months ended September 30, 2022, as well as a decrease in insurance costs of approximately \$0.2 million.

For the nine months ended September 30, 2023, G&A expenses were approximately \$4.9 million, as compared to approximately \$6.7 million for the nine months ended September 30, 2022. The decrease of approximately \$1.8 million was primarily due to a decrease in professional fees of \$1.0 million chiefly related to the exploration of business opportunities during the nine months ended September 30, 2022, as well as a decrease in insurance costs of approximately \$0.7 million and a decrease in stock-based compensation of \$0.5 million, offset partially by increases in payroll and executive consultant fees in the aggregate of \$0.4 million.

- **Net Loss** for the three months ended September 30, 2023 was \$3.8 million, or \$0.09 per basic and diluted share, based on 40,606,537 weighted average shares of common stock outstanding, compared with a net loss of \$3.1 million, or \$3.50 per basic and diluted share, based on 888,693 weighted average shares of common stock outstanding for the three months ended September 30, 2022.

Net Loss for the nine months ended September 30, 2023 was \$7.2 million, or \$0.18 per basic and diluted share, based on 40,517,356 weighted average shares of common stock outstanding, compared with a net loss of \$9.3 million, or \$10.45 per basic and diluted share, based on 888,693 weighted average shares of common stock outstanding for the nine months ended September 30, 2022.

- **Cash and Cash Equivalents** were \$25.8 million as of September 30, 2023, compared with \$33.4 million as of December 31, 2022. The company expects its cash position will be adequate to fund operations at least into the fourth quarter of 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 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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NeuroBo Pharmaceuticals, Inc.

Marshall Woodworth, Acting Chief Financial Officer

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- Tables to Follow -

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

	September 30, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash	\$ 25,837	\$ 33,364
Prepaid expenses	308	168
Total current assets	26,145	33,532
Property and equipment, net	41	2
Right-of-use asset	218	—
Other assets	21	—
Total assets	\$ 26,425	\$ 33,534
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,981	\$ 708
Accrued liabilities	1,614	280
Warrant liabilities	1,062	10,796
Lease liability, short-term	65	—
Total current liabilities	4,722	11,784
Lease liability, long-term	153	—
Total liabilities	4,875	11,784
Commitments and contingencies (Note 4)		
Stockholders' equity		
Preferred stock, \$0.001 par value per share; 10,000,000 shares authorized as of September 30, 2023 and December 31, 2022; no shares issued or outstanding as of September 30, 2023 and December 31, 2022.	—	—
Common stock, \$0.001 par value per share, 100,000,000 shares authorized as of September 30, 2023 and December 31, 2022; 38,429,185 and 25,436,019 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively.	38	25
Additional paid-in capital	124,463	117,520
Accumulated deficit	(102,951)	(95,795)
Total stockholders' equity	21,550	21,750
Total liabilities and stockholders' equity	\$ 26,425	\$ 33,534

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

	For the Three Months Ended		For the Nine Months Ended	
	September 30,		September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 2,292	\$ 571	\$ 5,293	\$ 2,473
General and administrative	1,601	2,533	4,926	6,725
Total operating expenses	3,893	3,104	10,219	9,198
Loss from operations	(3,893)	(3,104)	(10,219)	(9,198)
Other income (expense):				
Change in fair value of warrant liabilities	(87)	—	2,901	—
Interest income	162	—	162	—
Other expense	—	(9)	—	(93)
Loss before income taxes	(3,818)	(3,113)	(7,156)	(9,291)
Provision for income taxes	—	—	—	—
Net loss	(3,818)	(3,113)	(7,156)	(9,291)
Other comprehensive loss, net of tax	—	—	—	(4)
Comprehensive loss	\$ (3,818)	\$ (3,113)	\$ (7,156)	\$ (9,295)
Loss per share:				
Net loss per share, basic and diluted	\$ (0.09)	\$ (3.50)	\$ (0.18)	\$ (10.45)
Weighted average shares of common stock outstanding:				
Basic and diluted	40,606,537	888,693	40,517,356	888,693