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 6, 2024

NEUROMETRIX, INC.

(Exact name of registrant as specified in charter)

Delaware	001-33351	04-3308180		
(State or other jurisdiction		(IRS Employer		
of incorporation)	(Commission File Number)	Identification No.)		

(Commission File Number)

4B Gill Street, Woburn, Massachusetts (Address of principal executive offices)

01801 (Zip Code)

(781) 890-9989

(Registrant's telephone number, including area code)

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 (see General Instruction A.2. below):

□ 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))

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 6, 2024, NeuroMetrix, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2024. The full text of the press release and the related attachment are furnished as Exhibit 99.1 hereto and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

- <u>99.1</u> Press Release of NeuroMetrix, Inc. dated August 6, 2024.
- 104 Cover Page Interactive Data File (embedded within the 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.

NEUROMETRIX, INC.

Date: August 6, 2024

/s/ THOMAS T. HIGGINS

Thomas T. Higgins Senior Vice President, Chief Financial Officer and Treasurer

NeuroMetrix Reports Q2 2024 Business Highlights and Update on Review of Strategic Options

WOBURN, Mass., August 6, 2024 (Globe NewsWire) -- NeuroMetrix, Inc. (Nasdaq: NURO) today reported financial and business highlights for the quarter and six months ended June 30, 2024. The Company's mission is to reduce the impact of neurological disorders and pain syndromes through innovative non-invasive medical devices.

In February of this year, the Company announced that it had initiated a review of strategic options with an objective of enhancing shareholder value. Over the past six months, the Company has invested considerable effort in evaluating a number of specific strategic directions and also making financial, operational and commercial optimizations.

- In collaboration with a financial advisor, the Company conducted an extensive survey of potential transactions. Detailed diligence was performed on multiple opportunities; however, the Company determined that none of these opportunities were in the best interests of its shareholders at this time.
- The Company implemented a substantial reduction-in-force at the end of Q1 to lower operating expenses by over \$0.5M per quarter.
- The Company has been exploring opportunities to monetize certain assets to offset operating cash consumption. Particular attention has been placed on international markets that are not central to the Company's domestic sales focus.
- The Company engaged in discussions with one of its largest shareholders that led to the addition of Joshua S. Horowitz as a new independent director and termination of its at-the-market (ATM) equity facility in April 2024.

The Company believes it is in the best interests of shareholders that the strategic review process continues. There can be no assurance that this process will result in the Company pursuing or consummating any particular transaction or other strategic outcome. The Company has not set a timetable for completion of this evaluation process and may not disclose further developments unless disclosure is appropriate or necessary.

Business Highlights:

- Quell revenue increased by 47% to \$192,000 in Q2 2024 from \$131,000 in Q2 2023. Quell revenue includes sales of Quell Fibromyalgia (prescription) and Quell Relief (OTC). The increase was entirely from growth in the fibromyalgia indication, which offset a decrease in OTC revenue due to a commercial pause initiated in late 2022. The Company is planning to restart OTC sales in Q4 2024.
- A total of 540 Quell starter kits (fibromyalgia and OTC) were sold and there were 3,682 1-month refills ordered, for both indications, in Q2 2024. This represented starter kit growth of 165% and refill growth of 13% from Q2 2023.
- Following engagement with the FDA, the Company decided to proceed with a De Novo submission for a chemotherapy induced peripheral neuropathy (CIPN) indication for Quell technology. The filing is expected to be made in Q4 2024, which may enable a commercial launch into the oncology market as early as Q4 2025.

- DPNCheck revenue of \$536,000 in Q2 2024 declined by \$869,000 or 62% from Q2 2023. The primary DPNCheck market, Medicare Advantage (MA), is in the final year of the CMS phase-out of risk-adjustment compensation for many types of patient screening, including peripheral neuropathy. The resulting decline in domestic DPNCheck sales has not yet been offset by alternative markets that the Company is pursuing. International sales of DPNCheck also declined from the prior year quarter due to excess inventory at the Japan distributor. The Company believes this situation is transient, and these biosensor orders should resume later this year.
- Several scientific abstracts demonstrating the diagnostic accuracy and positive clinical outcomes of DPNCheck in patients with diabetic peripheral neuropathy (DPN) were presented at the Japanese Diabetes Society meeting in May 2024 and the <u>American Diabetes Association Scientific Sessions</u> in June 2024.
- The Company received Health Canada approval to market DPNCheck 2.0, the latest generation of its point-of-care neurodiagnostic technology.
- The Company implemented a wind down of its legacy ADVANCE business, which has been managed for cash flow for the past 5 years. This will free up resources and reduce IT overhead that had become an operational burden relative to the product's declining financial contribution.

"Quell prescription and OTC indications represent a substantial growth opportunity. The deliberate and strategic launch of Quell Fibromyalgia has provided valuable market insight and clarified tactics. Our initial approach of direct-to-physician promotion has now been broadened with a direct-to-patient telemedicine option. In addition, our original patient cash-pay approach is now complemented by a reimbursed Veterans Administration (VA) channel. We are also planning to reactivate our OTC business for lower extremity chronic pain. These steps should lead to continued top line growth with steadily improving gross and operating margins," said Shai N. Gozani, M.D., Ph.D., Chairman and CEO of NeuroMetrix. "In addition, our efforts to expand beyond Medicare Advantage and return the DPNCheck business to growth continue. We are optimistic about several opportunities and hope to have meaningful updates later this year."

Financial Results:

Revenue in Q2 2024 of \$0.8 million was lower by \$0.9 million or 54% from Q2 2023. The decline in revenue was attributable to the DPNCheck product line which contracted by \$0.9 million or 62%, primarily due to changes in Medicare Advantage risk-adjustment compensation. The gross margin rate of 64% in Q2 2024 declined from 68% in Q2 2023 due primarily to an unfavorable shift in product mix and lower production volumes. Operating expenses were \$2.3 million in Q2 2024, a decrease of \$0.4 million from the comparable period in 2023. Reduced personnel costs, partially offset by professional service fees associated with the strategic review, contributed to lower operating expenses. The Q2 2024 net loss was \$1.5 million (\$0.74 per share). This compares to a net loss of \$1.5 million or (\$1.56 per share) in Q2 2023. Shares outstanding were approximately 2.0 million at the end of Q2 2024.

Revenues in H1 2024 of \$1.9 million were lower by \$1.5 million or 45% from H1 2023. Net loss of \$4.5 million or (\$2.37) per share in H1 2024 increased from \$3.1 million or (\$3.20) per share in H1 2023.

Company to Host Live Conference Call and Webcast

NeuroMetrix will host a conference call at 8:00 a.m. Eastern today, August 6, 2024. Participants who wish to access the call live via telephone and be able to ask questions must register in advance here. Upon registering, a dial-in and unique PIN will be provided on screen and via email to join the call. An audio-only webcast of the call may be accessed in the "Investors Relations" section of the Company's website at www.NeuroMetrix.com. A replay of the call will be available for one year on the Company's website under the "Investor Relations" tab.

About NeuroMetrix

NeuroMetrix is a commercial stage healthcare company that develops and commercializes neurotechnology devices to address unmet needs in the chronic pain and diabetes markets. The Company's products are wearable or hand-held medical devices enabled by proprietary consumables and software solutions that include mobile apps, enterprise software and cloud-based systems. The Company has two commercial brands. Quell[®] is a wearable neuromodulation platform. DPNCheck[®] is a point-of-care screening test for peripheral neuropathy. For more information, visit <u>www.neurometrix.com</u>.

Safe Harbor Statement

The statements contained in this press release include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including, without limitation, statements regarding the company's or management's expectations regarding the business, as well as events that could have a meaningful impact on the company's revenues and cash resources. While the company believes the forward-looking statements contained in this press release are accurate, there are a number of factors that could cause actual events or results to differ materially from those indicated by such forward-looking statements, including, without limitation, estimates of future performance, and the ability to successfully develop, receive regulatory clearance, commercialize and achieve market acceptance for any products. There can be no assurance that future developments will be those that the company has anticipated. Such forward-looking statements involve known and unknown risks, uncertainties and other factors including those risks, uncertainties and factors referred to in the company's most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, as well as other documents that may be filed from time to time with the Securities and Exchange Commission or otherwise made public. The company is providing the information in this press release only as of the date hereof, and expressly disclaims any intent or obligation to update the information included in this press release or revise any forward-looking statements.

Source: NeuroMetrix, Inc.

Thomas T. Higgins SVP and Chief Financial Officer neurometrix.ir@neurometrix.com

NeuroMetrix, Inc. Statements of Operations (Unaudited)

	Quarters Ended June 30,		Six Months Ended June 30,				
	 2024		2023		2024		2023
Revenues	\$ 769,148	\$	1,655,744	\$	1,862,704	\$	3,380,515
Cost of revenues	 277,229		536,486		853,768		1,062,858
Gross profit	491,919		1,119,258		1,008,936		2,317,657
Operating expenses:							
Research and development	266,932		753,509		1,210,484		1,452,934
Sales and marketing	435,014		744,963		1,496,743		1,560,835
General and administrative	 1,618,628		1,244,241		3,384,355		2,637,412
Total operating expenses	 2,320,574		2,742,713		6,091,582		5,651,181
Loss from operations	(1,828,655)		(1,623,455)		(5,082,646)		(3,333,524)
Other income	 340,723		86,426		565,140		222,321
Net loss	\$ (1,487,932)	\$	(1,537,029)	\$	(4,517,506)	\$	(3,111,203)

NeuroMetrix, Inc. Condensed Balance Sheets (Unaudited)

	 June 30, 2024	December 31, 2023		
Cash, cash equivalents and securities	\$ 16,429,956	\$	17,997,151	
Other current assets	2,046,633		2,857,291	
Noncurrent assets	453,194		569,999	
Total assets	\$ 18,929,783	\$	21,424,441	
Current liabilities	\$ 1,589,750	\$	1,240,639	
Lease obligation, net of current portion	28,210		92,485	
Stockholders' equity	17,311,823		20,091,317	
Total liabilities and stockholders' equity	\$ 18,929,783	\$	21,424,441	