

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): July 27, 2023

NEUROMETRIX, INC.

(Exact name of registrant as specified in charter)

Delaware

001-33351

04-3308180

(State or other jurisdiction
of incorporation)

(Commission File Number)

(IRS Employer
Identification No.)

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 July 27, 2023, NeuroMetrix, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2023. 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

[99.1](#) Press Release of NeuroMetrix, Inc. dated July 27, 2023.

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: July 27, 2023

/s/ **THOMAS T. HIGGINS**

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

NeuroMetrix Reports Q2 2023 Business Highlights

WOBURN, Mass., July 27, 2023 (Globe NewsWire) -- NeuroMetrix, Inc. (Nasdaq: NURO) today reported business and financial highlights for the quarter and six months period ended June 30, 2023. The Company's mission is to reduce the impact of neurological disorders and pain syndromes through innovative non-invasive medical devices.

"We have taken an important step to expand the availability of Quell[®] Fibromyalgia in key U.S. markets," said Shai N. Gozani, M.D., Ph.D., Chief Executive Officer of NeuroMetrix. "This follows positive evidence of physician and patient traction from our strategic launch this year. Also, we were encouraged by recently reported results from a phase 2 randomized controlled trial (RCT) of Quell in chemotherapy induced peripheral neuropathy (CIPN), which may help address a large unmet need. We are finalizing our CIPN regulatory strategy. These developments highlight the growth opportunities for our Quell prescription neurotherapeutics portfolio."

Dr. Gozani continued, "We believe that there remains an attractive growth opportunity for DPNCheck[®] despite the recent instability in the Medicare Advantage market created by changes in risk-adjustment announced by the Centers for Medicare and Medicaid Services (CMS) earlier this year. We will continue to develop the DPNCheck market through a patient and flexible strategy that carefully deploys resources in line with emerging opportunities."

Recent Business Highlights:

- The Company reported positive results from its strategic launch of Quell Fibromyalgia. There were 123 unique prescribers during Q2 compared to 92 during Q1. The cumulative number of Quell Fibromyalgia prescriptions that have been written increased to 490 in Q2 from 234 in Q1, with approximately 60% of prescriptions filled by patients. The cumulative number of month-refills increased to 348 in Q2 from 141 in Q1.
- In light of the encouraging early Quell Fibromyalgia experience, the Company announced a sales force expansion to drive further adoption. The next stage of the commercialization process will focus on the Texas, California and Florida markets.
- The University of Rochester School of Medicine and Dentistry reported results of an NIH-funded multi-center randomized sham-controlled trial of Quell for CIPN. Subjects with moderate to severe CIPN symptoms of hot/burning pain, sharp/shooting pain or muscle cramping experienced about a 50% reduction in symptoms for active Quell treatment compared to about 30% for sham Quell treatment. The Company expects to make a 510(k) filing with the FDA in Q4 of this year. The use of Quell for moderate to severe CIPN received a FDA breakthrough designation in January 2022.
- Several Quell clinical trials are active and enrolling, including for fibromyalgia-like long COVID, chronic overlapping pain conditions (COPC) and peripheral edema. These indications represent potential new or expanded labels for the Quell prescription neurotherapeutics platform.
- The University of Sheffield diabetes research group reported results of a prospective study of abnormal sural nerve function, detected using DPNCheck and a complimentary technology, which predicts all-cause mortality in type 2 diabetes, even after adjusting for cardiovascular and other risk factors. Hence, early-stage diagnosis using DPNCheck is vital to identifying the risk of potentially devastating health complications.
- Two large recently published clinical studies support the clinical utility of DPNCheck in screening people with diabetes. Ke and colleagues developed an algorithm to predict progression to vision threatening diabetic retinopathy based on DPNCheck testing. Fukuda and colleagues analyzed the correlation of diabetic peripheral neuropathy to kidney function and found that DPNCheck test results were an independent predictor of kidney disease.

Financial Results:

Financial results in Q2 2023 were in line with the Company's expectations. This follows the Q1 2023 disruption to the Medicare Advantage market by CMS with its changes to Risk Adjustment Data Validation (RADV) and to risk adjustment calculations. Revenue in Q2 2023 of \$1.7 million was lower by \$0.5 million or 23% from Q2 2022 primarily due to reduced sales volume for DPNCheck in the Medicare Advantage market. The gross margin rate of 68% in Q2 2023 was flat with Q2 2022. Operating expenses of \$2.7 million were approximately level with the prior year quarter. The Q2 2023 net loss was \$1.5 million (\$0.19 per share) versus a net loss of \$1.2 million (\$0.17 per share) in Q2 2022.

Revenues in H1 2023 of \$3.4 million were lower by \$1.1 million or 24% from H1 2022. Net loss of \$3.1 million or (\$0.40) per share in H1 2023 increased from \$2.1 million or (\$0.30) per share in H1 2022.

The Company ended the period with \$19.6 million in cash and securities.

Company to Host Live Conference Call and Webcast

NeuroMetrix will host a conference call at 8:00 a.m. Eastern today, July 27, 2023. 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 www.neurometrix.com.

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,	
	2023	2022	2023	2022
Revenues	\$ 1,655,744	\$ 2,138,301	\$ 3,380,515	\$ 4,440,692
Cost of revenues	536,486	686,121	1,062,858	1,194,995
Gross profit	1,119,258	1,452,180	2,317,657	3,245,697
Operating expenses:				
Research and development	753,509	915,799	1,452,934	1,626,376
Sales and marketing	744,963	566,598	1,560,835	1,425,437
General and administrative	1,244,241	1,180,101	2,637,412	2,366,192
Total operating expenses	2,742,713	2,662,498	5,651,181	5,418,005
Loss from operations	(1,623,455)	(1,210,318)	(3,333,524)	(2,172,308)
Other income	86,426	50,395	222,321	53,823
Net loss	<u>\$ (1,537,029)</u>	<u>\$ (1,159,923)</u>	<u>\$ (3,111,203)</u>	<u>\$ (2,118,485)</u>

NeuroMetrix, Inc.
Condensed Balance Sheets
(Unaudited)

	June 30, 2023	December 31, 2022
Cash, cash equivalents and securities	\$ 19,627,209	\$ 21,199,727
Other current assets	2,662,197	2,907,260
Noncurrent assets	484,097	562,628
Total assets	<u>\$ 22,773,503</u>	<u>\$ 24,669,615</u>
Current liabilities	\$ 1,209,929	\$ 1,106,412
Lease obligation, net of current portion	152,143	207,516
Stockholders' equity	21,411,431	23,355,687
Total liabilities and stockholders' equity	<u>\$ 22,773,503</u>	<u>\$ 24,669,615</u>