

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2021
OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from ____ to ____

Commission File Number 001-33351

NEUROMETRIX, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

04-3308180

(I.R.S. 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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, \$0.0001 par value per share	NURO	The Nasdaq Stock Market LLC
Preferred Stock Purchase Rights		

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 6,645,397 shares of common stock, par value \$0.0001 per share, were outstanding as of October 20, 2021.



NeuroMetrix, Inc.
Form 10-Q
Quarterly Period Ended September 30, 2021

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

**NeuroMetrix, Inc.
Balance Sheets**

	<u>September 30, 2021</u> (Unaudited)	<u>December 31, 2020</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 23,213,537	\$ 5,226,213
Accounts receivable, net	639,766	334,297
Inventories	996,951	1,051,282
Prepaid expenses and other current assets	710,136	478,074
Total current assets	25,560,390	7,089,866
Fixed assets, net	204,939	183,494
Right to use asset	499,047	692,692
Other long-term assets	29,293	28,523
Total assets	\$ 26,293,669	\$ 7,994,575
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 316,969	\$ 142,316
Accrued expenses and compensation	1,028,373	998,442
Accrued product returns	46,000	545,000
Lease obligation, current	345,147	599,632
Total current liabilities	1,736,489	2,285,390
Lease obligation, net of current portion	329,169	461,410
Total liabilities	2,065,658	2,746,800
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Convertible preferred stock	1	1
Common stock, \$0.0001 par value; 25,000,000 shares authorized at September 30, 2021 and December 31, 2020; 6,645,397 and 3,793,739 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	665	379
Additional paid-in capital	222,387,601	202,129,195
Accumulated deficit	(198,160,256)	(196,881,800)
Total stockholders' equity	24,228,011	5,247,775
Total liabilities and stockholders' equity	\$ 26,293,669	\$ 7,994,575

The accompanying notes are an integral part of these interim financial statements.

NeuroMetrix, Inc.
Statements of Operations
(Unaudited)

	<u>Quarters Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Revenues	\$ 2,064,359	\$ 2,036,228	\$ 6,433,330	\$ 5,568,243
Cost of revenues	619,833	537,614	1,754,343	1,652,890
Gross profit	1,444,526	1,498,614	4,678,987	3,915,353
Operating expenses:				
Research and development	724,556	652,671	1,599,358	1,846,569
Sales and marketing	442,230	340,927	1,105,548	1,144,389
General and administrative	965,711	762,903	3,254,210	2,693,146
Total operating expenses	2,132,497	1,756,501	5,959,116	5,684,104
Loss from operations	(687,971)	(257,887)	(1,280,129)	(1,768,751)
Other income	882	774	1,673	2,323
Net loss	<u>\$ (687,089)</u>	<u>\$ (257,113)</u>	<u>\$ (1,278,456)</u>	<u>\$ (1,766,428)</u>
Net loss per common share applicable to common stockholders, basic and diluted	<u>\$ (0.12)</u>	<u>\$ (0.07)</u>	<u>\$ (0.28)</u>	<u>\$ (0.64)</u>

The accompanying notes are an integral part of these interim financial statements.

NeuroMetrix, Inc.
Statements of Changes in Stockholders' Equity
(Unaudited)

	Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Number of Shares	Amount	Number of Shares	Amount			
Balance at December 31, 2019	200	\$ 1	1,400,674	\$ 140	\$ 197,319,698	\$ (194,789,605)	\$ 2,530,234
Stock-based compensation expense	—	—	—	—	144,047	—	144,047
Issuance of common stock under at the market offering	—	—	256,078	25	453,432	—	453,457
Issuance of common stock to settle compensation obligations	—	—	31,000	3	43,748	—	43,751
Net loss	—	—	—	—	—	(657,371)	(657,371)
Balance at March 31, 2020	200	1	1,687,752	168	197,960,925	(195,446,976)	2,514,118
Stock-based compensation expense	—	—	—	—	128,862	—	128,862
Issuance of common stock under at the market offering	—	—	2,092,541	209	3,689,765	—	3,689,974
Issuance of common stock under employee stock purchase plan	—	—	4,364	1	7,605	—	7,606
Net loss	—	—	—	—	—	(851,944)	(851,944)
Balance at June 30, 2020	200	1	3,784,657	378	201,787,157	(196,298,920)	5,488,616
Stock-based compensation expense	—	—	—	—	140,269	—	140,269
Net loss	—	—	—	—	—	(257,113)	(257,113)
Balance at September 30, 2020	200	\$ 1	3,784,657	\$ 378	\$ 201,927,426	\$ (196,556,033)	\$ 5,371,772

	Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Number of Shares	Amount	Number of Shares	Amount			
Balance at December 31, 2020	200	\$ 1	3,793,739	\$ 379	\$ 202,129,195	\$ (196,881,800)	\$ 5,247,775
Stock-based compensation expense	—	—	—	—	68,863	—	68,863
Issuance of common stock under employee stock purchase plan	—	—	2,408	1	4,196	—	4,197
Net loss	—	—	—	—	—	(59,783)	(59,783)
Balance at March 31, 2021	200	1	3,796,147	380	202,202,254	(196,941,583)	5,261,052
Stock-based compensation expense	—	—	—	—	319,863	—	319,863
Issuance of common stock under at the market offering	—	—	1,207,681	121	3,766,727	—	3,766,848
Issuance of common stock under employee stock purchase plan	—	—	7,055	1	18,949	—	18,950
Vesting of restricted stock under option plan	—	—	13,911	3	(3)	—	—
Net loss	—	—	—	—	—	(531,584)	(531,584)
Balance at June 30, 2021	200	1	5,024,794	505	206,307,790	(197,473,167)	8,835,129
Stock-based compensation expense	—	—	—	—	196,361	—	196,361
Issuance of common stock under at the market offering	—	—	1,549,024	154	15,804,956	—	15,805,110
Issuance of common stock upon exercise of stock options	—	—	50,000	5	78,495	—	78,500
Vesting of restricted stock under option plan	—	—	10,877	1	(1)	—	—
Net loss	—	—	—	—	—	(687,089)	(687,089)
Balance at September 30, 2021	200	\$ 1	6,634,695	\$ 665	\$ 222,387,601	\$ (198,160,256)	\$ 24,228,011

The accompanying notes are an integral part of these interim financial statements.

NeuroMetrix, Inc.
Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (1,278,456)	\$ (1,766,428)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	103,594	67,772
Stock-based compensation	585,087	413,178
Settlement of compensation obligation	—	43,751
Impairment charge against right of use asset	126,748	280,000
Changes in operating assets and liabilities:		
Accounts receivable	(305,469)	(334,179)
Inventories	54,331	113,421
Collaboration receivable	—	189,008
Prepaid expenses, other current and long-term assets and lease obligation	(612,661)	(23,621)
Accounts payable	174,653	(533,302)
Accrued expenses and compensation	89,931	(694,668)
Accrued product returns	(499,000)	(103,000)
Net cash used in operating activities	<u>(1,561,242)</u>	<u>(2,348,068)</u>
Cash flows from investing activities:		
Purchases of fixed assets	(125,039)	—
Net cash used in investing activities	<u>(125,039)</u>	<u>—</u>
Cash flows from financing activities:		
Net proceeds from issuance of stock	19,673,605	4,151,037
Proceeds from debt issuance	—	773,200
Repayment of debt	—	(773,200)
Net cash provided by financing activities	<u>19,673,605</u>	<u>4,151,037</u>
Net increase in cash and cash equivalents	17,987,324	1,802,969
Cash and cash equivalents, beginning of period	5,226,213	3,126,206
Cash and cash equivalents, end of period	<u>\$ 23,213,537</u>	<u>\$ 4,929,175</u>
Supplemental disclosure of cash flow information:		
Common stock issued to settle employee compensation	<u>\$ —</u>	<u>\$ 43,751</u>

The accompanying notes are an integral part of these interim financial statements.

NeuroMetrix, Inc.
Notes to Unaudited Financial Statements
September 30, 2021

1. Business and Basis of Presentation

Our Business-An Overview

NeuroMetrix, Inc. (the Company) is an innovation-driven company focused on the development and global commercialization of non-invasive medical devices for the diagnosis and treatment of pain and neurological disorders. Revenues are derived from the sale of medical devices and after-market consumable products and accessories. The Company's products are cleared by the U.S. Food and Drug Administration (FDA) and regulators in foreign jurisdictions where appropriate. The Company has three commercial products. DPNCheck[®] is a diagnostic device that provides rapid, point-of-care detection of peripheral neuropathies. ADVANCE[®] is a diagnostic device that provides automated, in-office nerve conduction studies for the evaluation of focal neuropathies. Quell[®] is a wearable neurostimulation device indicated for symptomatic relief of lower extremity chronic pain that is available over-the-counter.

Unaudited Interim Financial Statements

The accompanying unaudited balance sheet as of September 30, 2021, unaudited statements of operations, changes in stockholders' equity for the quarters and nine months ended September 30, 2021 and 2020 and cash flows for the nine months ended September 30, 2021 and 2020 have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 8 of Regulation S-X. The accompanying balance sheet as of December 31, 2020 has been derived from audited financial statements prepared at that date but does not include all disclosures required by accounting principles generally accepted in the United States of America. In the opinion of management, the financial statements include all normal and recurring adjustments considered necessary for a fair presentation of the Company's financial position and operating results. Operating results for the nine months ended September 30, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2020 included in the Company's Annual Report on Form 10-K, as filed with the Securities and Exchange Commission, or the SEC, on January 29, 2021 (File No. 001-33351).

Revenues

Revenues include product sales, net of estimated returns. Revenue is measured as the amount of consideration the Company expects to receive in exchange for product transferred. Revenue is recognized when contractual performance obligations have been satisfied and control of the product has been transferred to the customer. In most cases, the Company has a single product delivery performance obligation. Accrued product returns are estimated based on historical data and evaluation of current information.

Accounts receivable are recorded at the amount the Company expects to collect, net of the allowance for doubtful accounts receivable. The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses based on customer past payment history, product usage activity, and recent communications with the customer. Individual customer balances which are over 90 days past due are reviewed individually for collectability and written-off when recovery is not probable. Allowance for doubtful accounts was \$25,000 as of September 30, 2021 and December 31, 2020.

One customer accounted for 25% and 29% of total revenues in the quarter and nine months ended September 30, 2021, respectively. Three customers accounted for 47% and two customers accounted for 34% of total revenues in the quarter and nine months ended September 30, 2020, respectively. Two customers accounted for 50% of accounts receivable as of September 30, 2021 and December 31, 2020.

Stock-based Compensation

Total compensation cost related to non-vested awards not yet recognized at September 30, 2021 was \$170,151. The total compensation costs are expected to be recognized over a weighted-average period of 1.3 years.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make significant estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during reporting periods. Actual results could differ from those estimates.

2. Comprehensive Loss

For the quarters and nine months ended September 30, 2021 and 2020, the Company had no components of other comprehensive loss other than net loss itself.

3. Net Loss Per Common Share

Basic and dilutive net loss per common share were as follows:

	Quarters Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss applicable to common stockholders	\$ (687,089)	\$ (257,113)	\$ (1,278,456)	\$ (1,766,428)
Weighted average number of common shares outstanding, basic and dilutive	5,818,449	3,784,657	4,597,580	2,755,903
Net loss per common share applicable to common stockholders, basic and diluted	\$ (0.12)	\$ (0.07)	\$ (0.28)	\$ (0.64)

Shares underlying the following potentially dilutive weighted average number of common stock equivalents were excluded from the calculation of diluted net loss per common share because their effect was anti-dilutive for each of the periods presented:

	Quarters Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Options	533,393	162,373	447,708	163,303
Warrants	—	—	—	23,040
Convertible preferred stock	62	62	62	62
Total	533,455	162,435	447,770	186,405

4. Inventories

Inventories consist of the following:

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
Purchased components	\$ 728,225	\$ 716,848
Finished goods	268,726	334,434
	<u>\$ 996,951</u>	<u>\$ 1,051,282</u>

5. Accrued Expenses and Compensation

Accrued expenses and compensation consist of the following:

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
Professional services	\$ 209,000	\$ 343,000
Compensation	494,361	49,837
Advertising and promotion	11,000	31,000
Warranty	33,100	49,600
Technology fees	—	450,000
Leasehold	60,000	—
Sales tax	111,984	24,493
Other	108,928	50,512
	<u>\$ 1,028,373</u>	<u>\$ 998,442</u>

6. Operating Leases

The Company's lease on its Woburn, Massachusetts corporate office and manufacturing facilities (the "Woburn Lease") extends through September 2025 with a monthly base rent of \$13,846 and a 5-year extension option. The Company's lease on its former corporate office in Waltham, Massachusetts (the "Waltham Lease") extends through February 2022 with an average monthly base rent of \$41,074 and a 5-year extension option. A letter of credit in the amount of \$226,731, secured by the Company's cash balances, was issued by a bank in favor of the Waltham Lease landlord. On August 15, 2021 the Company sublet the Waltham facility to a third party for a monthly base rent of \$20,929 for the remaining lease term. For the quarter and nine months ended September 30, 2021 the company recorded sublet income totaling \$34,560 within operating expenses on the Company's Statement of Operations. The Company had previously written off the value of its right-to-use asset in the Waltham facility. The impairment charges recorded within the Company's Statement of Operations for the quarters ended September 30, 2021 and 2020 were zero and \$76,000, respectively, and \$126,748 and \$280,000 for the nine months ended September 30, 2021 and 2020, respectively.

Future minimum lease payments under non-cancellable operating leases as of September 30, 2021 are as follows:

2021	\$ 163,790
2022	247,347
2023	165,785
2024	165,785
2025	117,431
Total minimum lease payments	<u>\$ 860,138</u>
Weighted-average discount rate, 14.7%	\$ 185,822
Lease obligation, current portion	345,147
Lease obligation, net of current portion	<u>329,169</u>
	<u>\$ 860,138</u>

Total recorded rent expense was \$18,932 and \$166,905, for the quarters ended September 30, 2021 and 2020, respectively. Total recorded rent expense was \$243,289 and \$500,713, for the nine months ended September 30, 2021 and 2020, respectively. The Company records rent expense on its facility leases on a straight-line basis over the lease term. Weighted average remaining operating lease term was 2.9 years as of September 30, 2021.

7. Fair Value Measurements

The following tables present information about the Company's assets and liabilities that are measured at fair value on a recurring basis for the periods presented and indicates the fair value hierarchy of the valuation techniques it utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable such as quoted prices, interest rates, and yield curves. Fair values determined by Level 3 inputs are unobservable data points for the asset or liability, and include situations where there is little, if any, market activity for the asset or liability. All Company assets and liabilities measured at fair value utilize Level 1 inputs.

	Fair Value Measurements at September 30, 2021 Using			
	September 30, 2021	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	\$ 20,453,185	\$ 20,453,185	\$ —	\$ —
Total	<u>\$ 20,453,185</u>	<u>\$ 20,453,185</u>	<u>\$ —</u>	<u>\$ —</u>

	December 31, 2020	Fair Value Measurements at December 31, 2020 Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	\$ 2,374,216	\$ 2,374,216	\$ —	\$ —
Total	\$ 2,374,216	\$ 2,374,216	\$ —	\$ —

As of September 30, 2021, the Company's cash equivalents consisted of money market accounts.

8. Stockholders' Equity

Preferred stock and convertible preferred stock consist of the following:

	September 30, 2021	December 31, 2020
Preferred stock, \$0.001 par value; 5,000,000 shares authorized at September 30, 2021 and December 31, 2020; no shares issued and outstanding at September 30, 2021 and December 31, 2020	\$ —	\$ —
Series B convertible preferred stock, \$0.001 par value; 147,000 shares designated at September 30, 2021 and December 31, 2020; 200 shares issued and outstanding at September 30, 2021 and December 31, 2020	\$ 1	\$ 1

2021 equity activity

In January 2021, the Company issued 2,408 shares of fully vested common stock, par value \$0.0001 per share ("common stock"), with a value of \$4,197 pursuant to the Company's 2010 Employee Stock Purchase Plan.

In May 2021, the Company issued 42,808 shares of restricted common stock with a value of \$125,000 under its 2004 Stock Option Plan. As of September 30, 2021, 24,788 shares were vested, 7,318 shares were forfeited in lieu of paying withholding taxes on the vesting of the restricted stock and 10,702 shares remain restricted.

In June 2021, the Company issued 7,055 shares of fully vested common stock with a value of \$18,950 pursuant to the Company's 2010 Employee Stock Purchase Plan.

In August 2021, the Company issued 50,000 shares of fully vested common stock with a value of \$78,500 upon the exercise of stock options pursuant to the Company's 2004 Stock Option Plan.

During the nine months ended September 30, 2021, the Company issued 2,756,705 shares of its common stock, under an at-the-market offering program ("ATM Agreement") for net proceeds of \$19,571,958. The ATM Agreement was entered into in 2020 and permits the sale and issuance of the Company's common stock subject to regulatory limitations imposed by the Securities and Exchange Commission and pursuant to a "shelf" registration statement on Form S-3.

2020 equity activity

In March 2020, the Company issued 31,000 shares of fully vested common stock with a value of \$43,751 pursuant to a Separation Agreement between the Company and an employee. The shares issued reflected the \$1.41 closing price of the Company's common stock as reported on the Nasdaq Capital Market on March 11, 2020.

In June 2020, the Company issued 4,364 shares of fully vested common stock with a value of \$7,606 pursuant to the Company's 2010 Employee Stock Purchase Plan.

During the nine months ended September 30, 2020, 2,348,619 shares of common stock were issued pursuant to the ATM Agreement for net proceeds of \$4,143,431.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion of our financial condition and results of operations in conjunction with our financial statements and the accompanying notes to those financial statements included elsewhere in this Quarterly Report on Form 10-Q. This discussion contains forward-looking statements that involve risks and uncertainties. For a description of factors that may cause our actual results to differ materially from those anticipated in these forward-looking statements, please refer to the below section of this Quarterly Report on Form 10-Q titled “Cautionary Note Regarding Forward-Looking Statements.” Unless the context otherwise requires, all references to “we”, “us”, the “Company”, or “NeuroMetrix” in this Quarterly Report on Form 10-Q refer to NeuroMetrix, Inc.

Overview

NeuroMetrix develops and commercializes health care products that utilize non-invasive neurostimulation. Our core expertise in biomedical engineering has been refined over two decades of designing, building and marketing medical devices that stimulate nerves and analyze nerve response for diagnostic and therapeutic purposes. We created the market for point-of-care nerve testing and were first to market with sophisticated wearable technology for symptomatic relief of chronic pain. Our business is fully integrated with in-house capabilities spanning research and development, manufacturing, regulatory affairs and compliance, sales and marketing, product fulfillment and customer support. We derive revenues from the sale of medical devices and after-market consumable products and accessories. Our products are sold in the United States and select overseas markets. They are cleared by the U.S. Food and Drug Administration (FDA) and regulators in foreign jurisdictions where appropriate. We have two principal product categories:

- Point-of-care neuropathy diagnostic tests
- Wearable neurostimulation devices

Peripheral neuropathies, also called polyneuropathies, are diseases of the peripheral nerves. They affect about 10% of adults in the United States, with the prevalence rising to 25-50% among individuals 65 years and older. Peripheral neuropathies are associated with loss of sensation, pain, increased risk of falling, weakness, and other complications. People with peripheral neuropathies generally have a diminished quality of life, poor overall health and higher mortality. The most common specific cause of peripheral neuropathies, accounting for about one-third of cases, is diabetes. Diabetes is a worldwide epidemic with an estimated affected population of over 400 million people. Within the United States there are over 30 million people with diabetes and another 80 million people with pre-diabetes. The annual direct cost of treating diabetes in the United States exceeds \$100 billion. Although there are dangerous acute manifestations of diabetes, the primary burden of the disease is in its long-term complications, which include cardiovascular disease, nerve disease and resulting conditions such as foot ulcers which may require amputation, eye disease leading to blindness, and kidney failure. The most common long-term complication of diabetes, affecting over 50% of the diabetic population, is peripheral neuropathy. Diabetic peripheral neuropathy (DPN) is the primary trigger for diabetic foot ulcers, which may progress to the point of requiring amputation. People with diabetes have a 15-25% lifetime risk of foot ulcers and approximately 15% of foot ulcers lead to amputation. Foot ulcers are the most expensive complication of diabetes with a typical cost of \$5,000 to \$50,000 per episode. In addition, between 16% and 26% of people with diabetes suffer from chronic pain in the feet and lower legs.

Early detection of peripheral neuropathies, such as DPN, is important because there are no treatment options once the nerves have degenerated. Today’s diagnostic methods for peripheral neuropathies range from a simple monofilament test for lack of sensory perception in the feet to a nerve conduction study performed by a specialist. Our DPNCheck nerve conduction technology provides a rapid, low cost, quantitative test for peripheral neuropathies, including DPN. It addresses an important medical need and is particularly effective in screening large populations. DPNCheck has been validated in numerous clinical studies.

Chronic pain is a significant public health problem. It is defined by the National Institutes of Health (NIH) as pain lasting more than 12 weeks. This contrasts with acute pain which is a normal bodily response to injury or trauma. Chronic pain conditions include low back pain, arthritis, fibromyalgia, neuropathic pain, cancer pain and many others. Chronic pain may be

triggered by an injury or there may be an ongoing cause such as disease or illness. There may also be no clear cause. Chronic pain can also lead to other health problems. These can include fatigue, sleep disturbance and mood changes which cause difficulty in carrying out important activities and may contribute to disability and despair. In general, chronic pain cannot be cured. Treatment of chronic pain is focused on reducing pain and improving function. The goal is effective pain management.

Chronic pain affects nearly 100 million adults in the United States and more than 1.5 billion people worldwide. The estimated incremental impact of chronic pain on health care costs in the United States is over \$250 billion per year and lost productivity is estimated to exceed \$300 billion per year. The most common approach to chronic pain management is pain medication. This includes over-the-counter (OTC) internal and external analgesics as well as prescription pain medications, both non-opioid and opioids. The approach to treatment is individualized, drug combinations may be employed, and the results are often inadequate. Side effects, including the potential for addiction are substantial. Increasingly, restrictions are being imposed on access to prescription opioids. Reflecting the complexity of chronic pain and the difficulty in treating it, we believe that inadequate relief leads 25% to 50% of pain sufferers to seek alternatives to prescription pain medications. These alternatives include nutraceuticals, acupuncture, chiropractic care, non-prescription analgesics, electrical stimulators, braces, sleeves, pads and other items. In total these pain relief products and services account for approximately \$20 billion in annual out-of-pocket spending in the United States.

Nerve stimulation is a long-established category of treatment for chronic pain. This treatment approach is available through implantable devices which have both surgical and ongoing risks, such as migration of the implanted nerve stimulation leads. Non-invasive approaches involving transcutaneous electrical nerve stimulation (TENS) have achieved limited efficacy in practice due to power limitations, ineffective dosing and low patient adherence. We believe that our Quell wearable technology for chronic pain is designed to address many of the limitations of traditional TENS.

Results of Operations

Comparison of Quarters Ended September 30, 2021 and 2020

Revenues

	Quarters Ended September 30,		Change	% Change
	2021	2020		
	(in thousands)			
Revenues	\$ 2,064.4	\$ 2,036.2	\$ 28.2	1.4 %

Revenues include sales of our wearable technologies for chronic pain and our nerve conduction technologies to physician offices, clinics, hospitals, other healthcare providers and insurers, as well as domestic and international distributors. Revenues comprise sales of medical devices as well as aftermarket electrodes and other supplies. Revenues were approximately \$2.0 million during the third quarter of 2021 and 2020.

Cost of Revenues and Gross Profit

	Quarters Ended September 30,		Change	% Change
	2021	2020		
	(in thousands)			
Cost of revenues	\$ 619.8	\$ 537.6	\$ 82.2	15.3 %
Gross profit	\$ 1,444.6	\$ 1,498.6	\$ (54.0)	(3.6)%

Gross margin was 70.0% in the third quarter of 2021 versus 73.6% in the same period in the prior year. The margin decline in 2021 was due to inventory charges related to sourcing components parts for our wearable neurostimulation device.

Operating Expenses

	Quarters Ended September 30,		Change	% Change
	2021	2020		
(in thousands)				
Operating expenses:				
Research and development	\$ 724.6	\$ 652.7	\$ 71.9	11.0 %
Sales and marketing	442.2	340.9	101.3	29.7 %
General and administrative	965.7	762.9	202.8	26.6 %
Total operating expenses	\$ 2,132.5	\$ 1,756.5	\$ 376.0	21.4 %

Research and Development

Research and development expense in the third quarter of 2021 increased by 11.0% from the same period in the prior year due to increases of \$117,000 in clinical and development costs and \$29,000 in personnel related costs offset by a decrease of \$33,000 in consulting costs and \$49,000 in facility and depreciation costs.

Sales and Marketing

Sales and marketing expense in the third quarter of 2021 increased by 29.7% from the same period in the prior year due to an increase of \$165,000 in personnel related costs offset by decreases of \$27,000 in facility and depreciation costs, \$32,000 in advertising spending and \$5,000 in consulting costs.

General and Administrative

General and administrative expense in the third quarter of 2021 increased by 26.6% from the same period in the prior year due to increases of \$29,000 in consulting costs, \$38,000 in outside professional service costs, \$41,000 in sales tax, insurance and other related costs and \$142,000 in personnel costs. A reduction in facility costs of \$55,000 offset the increases.

Other income

	Quarters Ended September 30,		Change	% Change
	2021	2020		
(in thousands)				
Other income	\$ 0.9	\$ 0.8	\$ 0.1	12.5 %

Other income primarily includes interest income.

Comparison of Nine Months Ended September 30, 2021 and 2020

Revenues

	Nine Months Ended September 30,		Change	% Change
	2021	2020		
	(in thousands)			
Revenues	\$ 6,433.3	\$ 5,568.2	\$ 865.1	15.5 %

Revenues include sales of our wearable technologies for chronic pain and our nerve conduction technologies to physician offices, clinics, hospitals, other healthcare providers and insurers, as well as domestic and international distributors. Revenues comprise sales of medical devices as well as aftermarket electrodes and other supplies. Revenues in the nine months ended September 30, 2021 were approximately \$865,000 higher than the nine months ended September 30, 2020, which was adversely affected by the economic effects of the COVID-19 pandemic.

Cost of Revenues and Gross Profit

	Nine Months Ended September 30,		Change	% Change
	2021	2020		
	(in thousands)			
Cost of revenues	\$ 1,754.3	\$ 1,652.9	\$ 101.5	6.1 %
Gross profit	\$ 4,679.0	\$ 3,915.4	\$ 763.6	19.5 %

Gross margin was 72.7% in the nine months ended September 30, 2021 versus 70.3% in the same period in the prior year. The margin improvement in 2021 was due to increased weighting of our nerve conduction testing technologies within total revenue.

Operating Expenses

	Nine Months Ended September 30,		Change	% Change
	2021	2020		
	(in thousands)			
Operating expenses:				
Research and development	\$ 1,599.4	\$ 1,846.6	\$ (247.2)	(13.4)%
Sales and marketing	1,105.5	1,144.4	(38.9)	(3.4)%
General and administrative	3,254.2	2,693.1	561.1	20.8 %
Total operating expenses	\$ 5,959.1	\$ 5,684.1	\$ 275.0	4.8 %

Research and Development

Research and development expense in the nine months ended September 30, 2021 decreased by 13.4% from the same period in the prior year due to the reversal of a \$450,000 technology fee accrual in the first quarter of 2021 and a decrease in facility costs of \$48,000 offset by increases of \$200,000 in clinical and development costs, \$38,000 in consulting costs and \$16,000 in personnel related costs.

Sales and Marketing

Sales and marketing expense in the nine months ended September 30, 2021 decreased by 3.4% from the same period in the prior year due to a \$76,000 reduction in personnel spending and a \$39,000 reduction in facility and depreciation costs offset by an increase in advertising spending of \$83,000.

General and Administrative

General and administrative expense in the nine months ended September 30, 2021 increased by 20.8% from the same period in the prior year due to increases of \$512,000 in non-cash personnel costs and \$108,000 in sales tax and fee related costs. This was offset by a reduction of \$55,000 in facility and depreciation costs.

Other income

	Nine Months Ended September 30,			
	2021	2020	Change	% Change
	(in thousands)			
Other income	\$ 1.7	\$ 2.3	\$ (0.6)	(26.1) %

Other income primarily includes interest income.

Liquidity and Capital Resources

Our principal source of liquidity is cash and cash equivalents of \$23.2 million at September 30, 2021. In addition to our cash resources, funding for our operations largely depends on revenues from the sale of our commercial products. A low level of market interest in our products, a decline in our consumables sales, unanticipated increases in our operating costs, and the effects of the COVID-19 pandemic could have an adverse effect on our liquidity and cash.

	September 30, 2021	December 31, 2020	Change	% Change
	(in thousands)			
Cash and cash equivalents	\$ 23,213.5	\$ 5,226.2	\$ 17,987.3	344.2 %

During the nine months ended September 30, 2021, our cash and cash equivalents increased by \$18.0 million reflecting \$1.6 million in cash used in operating activities and \$125.0 thousand in cash used in investing activities, offset by \$19.7 million in cash provided by financing activities.

In managing working capital, we focus on two important financial measurements:

	Quarters Ended September 30,		Year Ended
	2021	2020	December 31, 2020
Days sales outstanding (days)	24	23	15
Inventory turnover rate (times per year)	2.4	1.9	1.9

Days sales outstanding (DSO) reflect customer payment terms which vary from payment on order to 60 days from invoice date. DSO of 24 days during the quarter ended September 30, 2021 is consistent when compared to 23 days in the prior year period.

The inventory turnover rate increased to 2.4 turns in the third quarter of 2021 compared to 1.9 turns in the prior year period. The increase was due to higher sales in the third quarter of 2021 on approximately constant inventory levels.

The following sets forth information relating to our sources and uses of our cash:

	Nine Months Ended September 30,	
	2021	2020
	(in thousands)	
Net cash used in operating activities	\$ (1,561.2)	\$ (2,348.1)
Net cash used in investing activities	(125.0)	—
Net cash provided by financing activities	19,673.6	4,151.0
Net cash provided	<u>\$ 17,987.4</u>	<u>\$ 1,802.9</u>

If we raise additional funds by issuing equity or debt securities, either through the sale of securities pursuant to a registration statement or by other means, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. If we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us.

Cautionary Note Regarding Forward-Looking Statements

The statements contained in this Quarterly Report on Form 10-Q, including under the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and other sections of this Quarterly Report, 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, or the Exchange Act, including, without limitation, statements regarding our or our management’s expectations, hopes, beliefs, intentions or strategies regarding the future, such as our estimates regarding anticipated operating losses, future revenues and projected expenses, the effect of the COVID-19 pandemic on our operating capabilities, our future liquidity and our expectations regarding our needs for and ability to raise additional capital; our ability to manage our expenses effectively and raise the funds needed to continue our business; our belief that there are unmet needs for the management of chronic pain and in the diagnosis and treatment of diabetic neuropathy; our expectations surrounding our commercialized neurostimulation and neuropathy diagnostic products; our expected timing and our plans to develop and commercialize our products; our ability to meet our proposed timelines for the commercial availability of our products; our ability to obtain and maintain regulatory approval of our existing products and any future products we may develop; regulatory and legislative developments in the United States and foreign countries; the performance of our third-party manufacturers; our ability to obtain and maintain intellectual property protection for our products; the successful development of our sales and marketing capabilities; the size and growth of the potential markets for our products and our ability to serve those markets; our estimate of our customer returns of our products; the rate and degree of market acceptance of any future products; our reliance on key scientific management or personnel; the payment and reimbursement methods used by private or government third party payers; and other factors discussed elsewhere in this Quarterly Report on Form 10-Q. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “plan” and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. The forward-looking statements contained in this quarterly report are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in the section titled “Risk Factors” in our Annual Report on Form 10-K. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We do not use derivative financial instruments in our investment portfolio and have no foreign exchange contracts. Our financial instruments consist of cash and cash equivalents. We consider investments that, when purchased, have a remaining maturity of 90 days or less to be cash equivalents. The primary objectives of our investment strategy are to preserve principal, maintain proper liquidity to meet operating needs, and maximize yields. To minimize our exposure to an adverse shift in interest rates, we invest mainly in cash equivalents and short-term investments with a maturity of twelve months or less and maintain an average maturity of twelve months or less. We do not believe that a notional or hypothetical 10% change in interest rate percentages would have a material impact on the fair value of our investment portfolio or our interest income.

Item 4. Controls and Procedures

(a) *Evaluation of Disclosure Controls and Procedures.* Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of September 30, 2021, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

(b) *Changes in Internal Controls.* There were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control that occurred during the quarter ended September 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

While we are not currently a party to any material legal proceedings, we could become subject to legal proceedings in the ordinary course of business. We do not expect any such potential items to have a significant impact on our financial position.

Item 1A. Risk Factors

There have been no material changes in the risk factors described in “Item 1A. Risk Factors” of our Annual Report on [Form 10-K for the year ended December 31, 2020](#).

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

Exhibit No.	Description
4.1	Amendment No. 14 to Shareholder Rights Agreement by and between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent, dated July 20, 2021 (filed as Exhibit 4.1 to the Registrant’s Quarterly Report on Form 10-Q filed on July 22, 2021 and incorporated in this document by reference).
31.1	Certification of Principal Executive Officer Under Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended, and pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002. Filed herewith.
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended, and pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith.
32	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350. Furnished herewith.
101	The following materials from the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, formatted in XBRL (eXtensible Business Reporting Language): (i) Balance Sheets at September 30, 2021 and December 31, 2020, (ii) Statements of Operations for the quarters ended September 30, 2021 and 2020, (iii) Statements of Changes in Stockholders’ Equity for the quarters ended September 30, 2021 and 2020, (iv) Statements of Cash Flows for the quarters ended September 30, 2021 and 2020, and (v) Notes to Financial Statements.

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 thereunto duly authorized.

NEUROMETRIX, INC.

October 21, 2021

/s/ SHAI N. GOZANI, M.D., PH. D.

Shai N. Gozani, M.D., Ph. D.
Chairman, President and Chief Executive Officer

October 21, 2021

/s/ THOMAS T. HIGGINS

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

CERTIFICATION

I, Shai N. Gozani, M.D., Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of NeuroMetrix, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 21, 2021

/s/ SHAI N. GOZANI, M.D., PH. D.

Shai N. Gozani, M.D., Ph.D.

Chairman, President and Chief Executive Officer

CERTIFICATION

I, Thomas T. Higgins, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of NeuroMetrix, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 21, 2021

/s/ THOMAS T. HIGGINS

Thomas T. Higgins

Senior Vice President, Chief Financial Officer and Treasurer

CERTIFICATION

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of NeuroMetrix, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Quarterly Report for the quarter ended September 30, 2021 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ SHAI N. GOZANI, M.D., PH. D.

Shai N. Gozani, M.D., Ph.D.

Chairman, President and Chief Executive Officer

/s/ THOMAS T. HIGGINS

Thomas T. Higgins

Senior Vice President, Chief Financial Officer and Treasurer

October 21, 2021

This certification is being furnished and not filed, and shall not be incorporated into any document for any purpose, under the Securities Exchange Act of 1934 or the Securities Act of 1933.