

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, 2022
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 the 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: 7,757,226 shares of common stock, par value \$0.0001 per share, were outstanding as of October 19, 2022.

NeuroMetrix, Inc.
Form 10-Q
Quarterly Period Ended September 30, 2022

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PART I – FINANCIAL INFORMATION**Item 1. Financial Statements****NeuroMetrix, Inc.
Balance Sheets**

	<u>September 30, 2022</u> (Unaudited)	<u>December 31, 2021</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 1,772,005	\$ 22,572,104
Held-to-maturity securities	19,054,654	—
Accounts receivable, net	702,459	310,818
Inventories	1,057,239	706,553
Prepaid expenses and other current assets	845,649	598,384
Total current assets	<u>23,432,006</u>	<u>24,187,859</u>
Fixed assets, net	175,840	198,703
Right of use asset	398,144	475,230
Other long-term assets	26,400	26,400
Total assets	<u>\$ 24,032,390</u>	<u>\$ 24,888,192</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 539,379	\$ 284,036
Accrued expenses and compensation	1,134,659	814,155
Accrued product returns	10,000	39,000
Lease obligation, current	148,391	228,506
Total current liabilities	<u>1,832,429</u>	<u>1,365,697</u>
Lease obligation, net of current portion	233,693	306,709
Total liabilities	<u>2,066,122</u>	<u>1,672,406</u>
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, 2022 and December 31, 2021; 7,137,519 and 6,694,296 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	714	669
Additional paid-in capital	224,853,549	222,378,373
Accumulated deficit	(202,887,996)	(199,163,257)
Total stockholders' equity	<u>21,966,268</u>	<u>23,215,786</u>
Total liabilities and stockholders' equity	<u>\$ 24,032,390</u>	<u>\$ 24,888,192</u>

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>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Revenues	\$ 1,968,003	\$ 2,064,359	\$ 6,408,695	\$ 6,433,330
Cost of revenues	693,571	619,833	1,888,566	1,754,343
Gross profit	1,274,432	1,444,526	4,520,129	4,678,987
Operating expenses:				
Research and development	1,074,954	724,556	2,701,330	1,599,358
Sales and marketing	810,209	442,230	2,235,646	1,105,548
General and administrative	1,102,260	965,711	3,468,452	3,254,210
Total operating expenses	2,987,423	2,132,497	8,405,428	5,959,116
Loss from operations	(1,712,991)	(687,971)	(3,885,299)	(1,280,129)
Other income	106,737	882	160,560	1,673
Net loss	<u>\$ (1,606,254)</u>	<u>\$ (687,089)</u>	<u>\$ (3,724,739)</u>	<u>\$ (1,278,456)</u>
Net loss per common share applicable to common stockholders, basic and diluted	<u>\$ (0.23)</u>	<u>\$ (0.12)</u>	<u>\$ (0.53)</u>	<u>\$ (0.28)</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, 2020	200	\$ 1	3,807,555	\$ 380	\$ 202,129,194	\$ (196,881,800)	\$ 5,247,775
Stock-based compensation expense	—	—	—	—	68,863	—	68,863
Issuance of common stock under at the market offering	—	—	2,408	1	4,196	—	4,197
Net loss	—	—	—	—	—	(59,783)	(59,783)
Balance at March 31, 2021	200	1	3,809,963	381	202,202,253	(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 equity plan	—	—	13,911	3	(3)	—	—
Net loss	—	—	—	—	—	(531,584)	(531,584)
Balance at June 30, 2021	200	1	5,038,610	\$ 506	206,307,789	(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 equity plan	—	—	10,877	1	(1)	—	—
Net loss	—	—	—	—	—	(687,089)	(687,089)
Balance at September 30, 2021	200	\$ 1	6,648,511	\$ 666	\$ 222,387,600	\$ (198,160,256)	\$ 24,228,011

	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, 2021	200	\$ 1	6,664,296	\$ 669	\$ 222,378,373	\$ (199,163,257)	\$ 23,215,786
Stock-based compensation expense	—	—	—	—	37,632	—	37,632
Issuance of common stock under at the market offering	—	—	292,500	29	1,943,023	—	1,943,052
Vesting of restricted stock under equity plan	—	—	1,759	3	(3)	—	—
Net loss	—	—	—	—	—	(958,562)	(958,562)
Balance at March 31, 2022	200	1	6,958,555	701	224,359,025	(200,121,819)	24,237,908
Stock-based compensation expense	—	—	—	—	109,340	—	109,340
Issuance of common stock under employee stock purchase plan	—	—	2,503	—	7,829	—	7,829
Issuance of common stock to settle compensation obligation	—	—	50,213	5	215,412	—	215,417
Vesting of restricted stock under equity plan	—	—	3,120	7	(7)	—	—
Net loss	—	—	—	—	—	(1,159,923)	(1,159,923)
Balance at June 30, 2022	200	1	7,014,391	\$ 713	224,691,599	(201,281,742)	23,410,571
Stock-based compensation expense	—	—	—	—	161,951	—	161,951
Vesting of restricted stock under equity plan	—	—	16,578	1	(1)	—	—
Net loss	—	—	—	—	—	(1,606,254)	(1,606,254)
Balance at September 30, 2022	200	\$ 1	7,030,969	\$ 714	\$ 224,853,549	\$ (202,887,996)	\$ 21,966,268

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

NeuroMetrix, Inc.
Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (3,724,739)	\$ (1,278,456)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	39,170	103,594
Stock-based compensation	308,923	585,087
Issuance of common stock to settle compensation obligations	26,019	—
Impairment charge against right of use asset	—	126,748
Loss on disposal of fixed assets	6,875	—
Accretion of interest income on held-to-maturity securities	(133,278)	—
Changes in operating assets and liabilities:		
Accounts receivable	(391,641)	(305,469)
Inventories	(350,686)	54,331
Prepaid expenses and other current and long-term assets	(383,310)	(612,661)
Accounts payable	255,343	174,653
Accrued expenses and compensation	569,902	89,931
Accrued product returns	(29,000)	(499,000)
Net cash used in operating activities	(3,806,422)	(1,561,242)
Cash flows from investing activities:		
Purchases of held-to-maturity securities	(18,921,376)	—
Purchases of fixed assets	(23,182)	(125,039)
Net cash used in investing activities	(18,944,558)	(125,039)
Cash flows from financing activities:		
Net proceeds from issuance of stock	1,950,881	19,673,605
Net cash provided by financing activities	1,950,881	19,673,605
Net (decrease) increase in cash and cash equivalents	(20,800,099)	17,987,324
Cash and cash equivalents, beginning of period	22,572,104	5,226,213
Cash and cash equivalents, end of period	\$ 1,772,005	\$ 23,213,537
Supplemental disclosure of cash flow information:		
Issuance of common stock to settle compensation obligation	\$ 189,398	\$ —

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

NeuroMetrix, Inc.
Notes to Unaudited Financial Statements
September 30, 2022

1. Business and Basis of Presentation

Our Business-An Overview

NeuroMetrix, Inc. (the "Company" or "NeuroMetrix") develops and commercializes health care products that utilize non-invasive neurostimulation. Revenues are derived from the sale of medical devices and after-market consumable products and accessories. The Company's 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. The Company has two primary products. DPNCheck® is a diagnostic device that provides rapid, point-of-care detection of peripheral neuropathies. Quell® is a wearable neuromodulation technology indicated for treatment of fibromyalgia symptoms and chronic lower extremity pain.

The Company held cash, cash equivalents and held-to-maturity securities totaling \$20.8 million as of September 30, 2022. The Company has a history of operating losses and has financed its operations primarily from sales of equity, sales of its products and third party development collaboration payments. The Company believes that its present balance of cash and held-to-maturity securities resources coupled with cash inflows from product sales will enable the Company to fund its operations for at least the next twelve months from the date of issuance of the financial statements. Actual cash requirements could differ from management's projections for many reasons. These include the effects of the Covid-19 pandemic on sales, procurement of production materials, and maintenance of critical staffing. They could also include changes the Company may make to its business strategy that affect operating expenses, regulatory developments, changes to research and development spending plans; and other items affecting the Company's projected uses of cash.

Unaudited Interim Financial Statements

The accompanying unaudited balance sheet as of September 30, 2022, unaudited statements of operations, changes in stockholders' equity for the quarters and nine months ended September 30, 2022 and 2021 and cash flows for the nine months ended September 30, 2022 and 2021 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, 2021 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, 2022 are not necessarily indicative of the results that may be expected for the year ending December 31, 2022 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2021 included in the Company's Annual Report on Form 10-K, as filed with the Securities and Exchange Commission, or the SEC, on January 28, 2022 (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, 2022 and December 31, 2021.

Two customers accounted for 32% and one customer accounted for 34% of total revenues in the quarter and nine months ended September 30, 2022, respectively. One customer accounted for 25% and 29% of total revenues in the quarter and nine months ended September 30, 2021, respectively. One customer accounted for 26% and two customers accounted for 35% of accounts receivable as of September 30, 2022 and December 31, 2021, respectively.

Held-To-Maturity Securities

The Company's investments in held-to-maturity securities consist of investment grade U.S. Treasury obligations, commercial paper and corporate bonds with maturity dates of less than 365 days. The Company has the ability and intention to hold these securities until maturity. Accordingly, these securities are recorded in the Company's balance sheet at amortized cost and interest is recorded within other income on the Company's statement of operations. The market value of the held-to-maturity securities at September 30, 2022 was \$18,937,643.

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, 2022 and 2021, 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,	
	2022	2021	2022	2021
Net loss applicable to common stockholders	\$ (1,606,254)	\$ (687,089)	\$ (3,724,739)	\$ (1,278,456)
Weighted average number of common shares outstanding, basic and dilutive	7,025,254	5,818,449	6,976,548	4,597,580
Net loss per common share applicable to common stockholders, basic and diluted	\$ (0.23)	\$ (0.12)	\$ (0.53)	\$ (0.28)

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:

	September 30,	
	2022	2021
Options	525,468	504,045
Unvested restricted stock awards	106,550	10,702
Unvested restricted stock units	207,233	—
Convertible preferred stock	62	62
Total	839,313	514,809

4. Inventories

Inventories consist of the following:

	<u>September 30, 2022</u>	<u>December 31, 2021</u>
Purchased components	\$ 461,349	\$ 422,093
Finished goods	595,890	284,460
	<u>\$ 1,057,239</u>	<u>\$ 706,553</u>

5. Accrued Expenses and Compensation

Accrued expenses and compensation consist of the following:

	<u>September 30, 2022</u>	<u>December 31, 2021</u>
Professional services	\$ 277,000	\$ 109,000
Compensation	522,044	440,474
Consulting	125,000	5,000
Warranty	18,000	28,400
Leasehold	—	60,000
Sales tax	143,136	108,788
Other	49,479	62,493
	<u>\$ 1,134,659</u>	<u>\$ 814,155</u>

6. Operating Leases

The Company's lease on its Woburn, Massachusetts corporate office and manufacturing facility extends through September 2025 with a monthly base rent of \$13,846 and a 5-year extension option.

Future minimum lease payments under this non-cancellable operating lease as of September 30, 2022 are as follows:

2022	\$ 41,446
2023	165,785
2024	165,785
2025	117,431
Total minimum lease payments	<u>\$ 490,447</u>
Discount rate, 15%	\$ 108,363
Lease obligation, current portion	148,391
Lease obligation, net of current portion	233,693
	<u>\$ 490,447</u>

The Company's lease on its former corporate office in Waltham, Massachusetts expired in February 2022. During the first quarter of 2021, the Company recorded an impairment charge of \$126,748 on that idle facility which was being offered for sublet. In the first quarter of 2022, a \$60,000 reduction in rent expense was recorded upon return of the facility to the lessor. The letter of credit issued by a bank in favor of the Waltham facility was released. For the nine months ended September 30, 2022, the Company recorded sublet income totaling \$22,795 within operating expenses on the Company's statement of operations.

Total recorded rent expense was \$46,102 and \$18,932, for the quarters ended September 30, 2022 and 2021, respectively. Total recorded rent expense was \$116,959 and \$243,289 for the nine months ended September 30, 2022 and 2021, respectively. The Company records rent expense on its facility lease on a straight-line basis over the lease term. The remaining operating lease term was 3.0 years as of September 30, 2022.

7. Fair Value Measurements

Assets and liabilities that are measured at fair value are presented below. All Company assets and liabilities measured at fair value utilize Level 1 inputs (i.e. quoted prices (unadjusted) in active markets for identical assets or liabilities).

	September 30, 2022	Fair Value Measurements at September 30, 2022 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	\$ 1,230,690	\$ 1,230,690	\$ —	\$ —
Total	\$ 1,230,690	\$ 1,230,690	\$ —	\$ —

	December 31, 2021	Fair Value Measurements at December 31, 2021 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	\$ 20,317,736	\$ 20,317,736	\$ —	\$ —
Total	\$ 20,317,736	\$ 20,317,736	\$ —	\$ —

The Company's cash equivalents consist of money market accounts.

8. Stockholders' Equity

Preferred stock and convertible preferred stock consist of the following:

	September 30, 2022	December 31, 2021
Preferred stock, \$0.001 par value; 5,000,000 shares authorized at September 30, 2022 and December 31, 2021; no shares issued and outstanding at September 30, 2022 and December 31, 2021	\$ —	\$ —
Series B convertible preferred stock, \$0.001 par value; 147,000 shares designated at September 30, 2022 and December 31, 2021; 200 shares issued and outstanding at September 30, 2022 and December 31, 2021	\$ 1	\$ 1

2022 equity activity

In January 2022, the Company issued 292,500 shares of common stock under an at-the-market (ATM) equity offering program with net proceeds of \$1,943,052 and issued 20,000 restricted stock awards under its 2004 Stock Option Plan with a value of \$104,200. In April 2022, the Company issued 76,000 shares of restricted common stock under its 2022 Equity Incentive Plan with a value of \$326,000 to employees as long term incentives (LTI) and issued 50,213 shares of fully vested common stock with a value of \$215,417 in settlement of management incentive compensation. In May 2022, the Company issued 161,764 restricted stock units with a value of \$550,000 as LTI to its management and directors under its 2022 Equity

Incentive Plan. In June 2022, the Company issued 2,503 shares of fully vested common stock with a value of \$7,829 pursuant to the Company's Employee Stock Purchase Plan. For the quarter ended September 30, 2022, the Company issued 57,972 restricted stock units with a value of \$202,008 under its 2022 Equity Incentive Plan. As of September 30, 2022, the Company had 106,550 unvested shares of restricted common stock and 207,233 unvested restricted stock units. Total compensation cost related to non-vested awards not yet recognized at September 30, 2022 was \$1,224,278. These unrecognized costs are expected to be recognized over a weighted-average period of 2.3 years. Subsequently from October 1, 2022 to October 19, 2022 the Company issued 623,834 shares of Common Stock under its ATM program with net proceeds of \$1,890,721.

2021 equity activity

In January 2021, the Company issued 2,408 shares of fully vested common stock with a value of \$4,197 pursuant to the Company's 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 of these shares were vested, 7,318 shares were forfeited to settle withholding taxes on the vesting and 10,702 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 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 the ATM for net proceeds of \$19,571,958.

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.

Our Business

Our mission is to reduce the impact of neurological disorders and pain syndromes on individuals and on population health through innovative non-invasive medical devices.

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 proprietary and encompass point-of-care neuropathy diagnostic tests and wearable neurotherapeutic devices.

DPNCheck is our testing technology for peripheral neuropathies. It is designed to address unmet physician needs in the assessment of peripheral neuropathy risk, particularly in value-based care models such as Medicare Advantage. The technology is well-suited to this task given its ease of use, rapid testing, quantitative results, and overall high sensitivity and specificity. DPNCheck has been evaluated in numerous clinical studies. It contributes attractive gross margins and has posted average revenue growth exceeding 20% over the past five years through December 31, 2021. We believe there is significant, accessible opportunity to expand DPNCheck usage. Towards that goal, we are investing in commercial resources and in the technology itself. Our next generation DPNCheck technology, targeted for commercial launch in late 2022, will further enhance the user experience and improve our manufacturing efficiency.

Quell is our wearable neuromodulation technology for chronic pain and associated syndromes. Patients control and personalize the technology via a mobile phone app and their utilization and certain clinical metrics may be tracked in the Quell Health Cloud. Quell has been sold over-the-counter (OTC) for the management of lower extremity chronic pain. Its technological sophistication, combined with our extensive consumer experience and the compelling results of recent clinical studies provide the opportunity to leverage the technology platform into a portfolio of Quell-based prescription (Rx) wearable neurotherapeutics. The first product in that portfolio is a Quell fibromyalgia indication which received De Novo authorization for marketing from the FDA in May 2022.

ADVANCE is our legacy neurodiagnostic technology primarily used for the diagnosis and screening of Carpal Tunnel Syndrome (CTS). The technology has been marketed since 2008. While we no longer market ADVANCE devices, we continue to provide disposable electrodes to a loyal base of hand surgeons and manufacturers for industrial health use.

Recent Developments

Breakthrough Device Designation for Quell fibromyalgia indication - In 2021, Quell received Breakthrough Device Designation (BDD) from the FDA for a fibromyalgia indication. A pivotal clinical study of Quell for fibromyalgia was completed, and the indication was authorized for marketing by the FDA under a De Novo regulatory filing. We plan a limited commercial launch in late 2022 to guide our marketing approach. We plan a similar approach with other disease indications involving chronic pain and associated syndromes. These include chemotherapy induced peripheral neuropathy (CIPN) and, potentially, chronic overlapping pain conditions (COPC) and restless leg syndrome (RLS). Sales of the current OTC version of Quell to new customers ended in October 2022 in advance of the launch of the Quell fibromyalgia indication. Our focus continues to be on the development of a Quell prescription portfolio for disease-specific indications where we have unique product offerings without direct, non-pharmaceutical competition.

Breakthrough Device Designation for Chronic Chemotherapy CIPN indication - In January 2022, Quell received BDD from the FDA for reducing moderate to severe symptoms of chemotherapy induced peripheral neuropathy that have persisted for at least six months following the end of chemotherapy. A National Cancer Institute (NCI) funded, multi-center, double blind, randomized, sham-controlled trial of Quell in CIPN is currently ongoing. The study is expected to complete by the end of 2022. Depending on the outcome of the trial, we hope to be positioned for an FDA filing in 2023.

Equity sales – We secured \$1.95 million in net proceeds from equity sales in the first half of 2022. We maintain a debt-free, primarily common stock equity capital structure, and adequate funding resources to support operations and our growth initiatives.

COVID-19 - The COVID-19 pandemic adversely affected our business. It is difficult to quantify the disruption to our markets and customers; however, we believe the effects were more pronounced in the diagnostic testing markets for DPNCheck and ADVANCE, and less pronounced in the consumer retail markets for Quell. Generally, we see continued purchases of testing consumables by existing diagnostic customers but with less predictability than in the past. Also, our growth via new customer acquisition has been lower due to marketing challenges resulting from COVID-19 restrictions.

We have been able to maintain our business operations during the past two years while prioritizing employee safety. On-premises staffing in production and fulfillment has successfully met our business requirements. Other functional areas including R&D, sales and marketing, and administration have been a blend of on-premises and remote work. These functional areas have been disadvantaged to a degree by the pandemic.

We plan to continue with our present blend of staff activity until we have greater clarity on the opportunities and risks of a more personally interactive business model. The extent to which COVID-19 affects future operations will depend on new developments, which are uncertain and cannot be predicted with confidence, including the pandemic duration and potential new strains of the virus, severity, vaccination effectiveness, and treatments available to those with severe COVID-19 symptoms. Also uncertain are the potential effects on our business of the economic impacts from the pandemic recovery including inflation, electronic parts and components availability, labor availability and costs, and other issues.

Results of Operations

Comparison of Quarters Ended September 30, 2022 and 2021

	Quarter ended September 30,		Increase (Decrease)	
	2022	2021	Amount	Percent
Revenues	\$ 1,968,003	\$ 2,064,359	\$ (96,356)	(4.7)%
Gross profit	\$ 1,274,432	\$ 1,444,526	\$ (170,094)	(11.8)%
– % of revenues	64.8 %	70.0 %		(5.2)%
Operating expenses	\$ 2,987,423	\$ 2,132,497	\$ 854,926	40.1 %
Other income, net	\$ 106,737	\$ 882	\$ 105,855	12,001.7 %
Net loss	\$ (1,606,254)	\$ (687,089)	\$ 919,165	133.8 %
Net loss per common share	\$ (0.23)	\$ (0.12)	\$ 0.11	91.7 %

Revenues

Revenues for the third quarter of 2022 decreased by \$96 thousand or 4.7% from the third quarter of 2021. DPNCheck contributed the majority of revenues in both quarters. It posted a revenue reduction of 6% in the third quarter of 2022, attributable to lower biosensor shipments. Quell revenue increased in the third quarter of 2022. Our legacy ADVANCE revenues also declined due to continuing erosion of the customer base.

Gross Profit

Gross profit for the third quarter of 2022 decreased by \$170 thousand or 11.8% from the third quarter of 2021. The decrease reflected the decline in revenues exacerbated by increases in cost of goods sold to secure essential electronic components for the manufacture of our devices.

Operating Expenses

Operating expenses increased in the third quarter of 2022 by \$855 thousand or 40.1% from the third quarter of 2021. The increase reflects investment in our DPNCheck initiatives to drive future growth, including the expansion of our commercial capabilities and bringing to market our next generation testing technology. The increase also includes regulatory and development costs related to the Quell disease-specific indications portfolio.

Research and development spending in the third quarter of 2022 of \$1,075 thousand was \$350 thousand higher than the third quarter of 2021 attributable to expanded outside engineering services. Sales and marketing spending of \$810 thousand increased by \$368 thousand over the third quarter of 2021. The increase was mainly attributable to personnel costs of \$247 thousand greater than the prior year quarter reflecting costs of both the DPNCheck and Quell Fibromyalgia commercial teams. General and administrative costs of \$1.1 million in the third quarter of 2022 increased by \$137 thousand primarily due to higher personnel costs.

Net loss

The net loss in the third quarter of 2022 increased by \$919 thousand from the third quarter of 2021. Similarly, net loss per common share increased to \$0.23 per common share in the third quarter of 2022 from \$0.12 per common share in the third quarter of 2021. The increase in the number of our common shares outstanding in the third quarter of 2022 partially offset the per share effect of a greater net loss in that period.

Comparison of Nine Months Ended September 30, 2022 and 2021

	Nine months ended September 30,		Increase (Decrease)	
	2022	2021	Amount	Percent
Revenues	\$ 6,408,695	\$ 6,433,330	\$ (24,635)	(0.4)%
Gross profit	\$ 4,520,129	\$ 4,678,987	\$ (158,858)	(3.4)%
– % of revenues	70.5 %	72.7 %		(2.2)%
Operating expenses	\$ 8,405,428	\$ 5,959,116	\$ 2,446,312	41.1 %
Other income, net	\$ 160,560	\$ 1,673	\$ 158,887	9,497.1 %
Net loss	\$ (3,724,739)	\$ (1,278,456)	\$ 2,446,283	191.3 %
Net loss per common share	\$ (0.53)	\$ (0.28)	\$ 0.25	89.3 %

Revenues

Revenues for the nine months ended September 30, 2022 decreased by \$25 thousand or 0.4% from the nine months ended September 30, 2021. DPNCheck contributed the majority of revenues in both periods. It posted revenue growth of 7.6% in the nine months ended September 30, 2022, primarily attributable to increased biosensor shipments both domestic and international. Quell revenue declined in the nine months ended September 30, 2022 with lower advertising spending and an emphasis on product line profitability. Our legacy ADVANCE revenues also declined with the continuing erosion of the customer base.

Gross Profit

Gross profit for the nine months ended September 30, 2022 decreased by \$159 thousand or 3.4% from the nine months ended September 30, 2021. Gross profit as a percent of revenue decreased by 2.2 percentage points between the comparable periods primarily due to incremental costs to secure essential electronic components for the manufacture of our devices.

Operating Expenses

Operating expenses increased in the nine months ended September 30, 2022 by \$2.5 million or 41.1% from the nine months ended September 30, 2021. The increase includes a research and development benefit in 2021 of \$450 thousand from reversal of previously accrued technology fees upon the expiry of the relevant statute of limitations. Excluding the one-time research and development benefit in 2021, the increase in operating expenses between the periods was \$1.9 million or 33%. The increase in spending reflects investment in DPNCheck initiatives to drive future growth, including the expansion of DPNCheck commercial capabilities and product initiatives for the Medicare Advantage market. The increase also reflects regulatory and product development investments related to the emerging Quell portfolio for disease-specific indications.

Research and development spending in the nine months ended September 30, 2022 of \$2.7 million was \$1.1 million higher than the nine months ended September 30, 2021. Adjusting for the one-time technology credit in 2021, the research and development spending increase of \$650 thousand or 40% encompasses product development efforts for both DPNCheck and Quell. Sales and marketing spending of \$2.2 million increased by \$1.1 million due to the addition of a new commercial team for DPNCheck and pre-launch spending related to Quell Fibromyalgia. General and administrative costs of \$3.5 million increased by \$214 thousand or 6.6% primarily due to inflation.

Net loss

The net loss for the nine months ended September 30, 2022 increased by \$2,446 thousand from 2021. Similarly, net loss per common share increased to (\$0.53) per common share in the nine months ended September 30, 2022 from (\$0.28) per common share in the nine months ended September 30, 2021. The increase in the number of common shares outstanding in the nine months ended September 30, 2022 partially offset the effect of a greater net loss in that period.

Liquidity and Capital Resources

The following table contains certain key performance indicators we believe depict our liquidity and cash flow position:

	September 30,		December 31,
	2022	2021	2021
Cash, cash equivalents and held-to-maturity securities	\$ 20,826,659	\$ 23,213,537	\$ 22,572,104
Working capital	\$ 21,599,577	\$ 23,823,901	\$ 22,822,162
Current ratio	12.8	14.7	17.7
Days sales outstanding	28.6	24.0	14.1
Inventory turnover	2.9	2.4	2.7

Our primary sources of liquidity are cash, cash equivalents, held-to-maturity securities, revenues from the sales of our products, and net proceeds from equity sales. Our expected cash outlays relate to funding operations. We believe that our resources are sufficient to fund our cash requirements over at least the next twelve months from the date of issuance of the financial statements.

As of September 30, 2022, we held \$20.8 million in cash, cash equivalents, and held-to-maturity securities. Working capital was \$21.5 million, and the current ratio was 12.8. The Company had no term debt or borrowings.

Days sales outstanding (DSO) reflect our customer payment terms which vary from payment on order to 60 days from shipment date. The increase in DSO at September 30, 2022 in comparison with December 31, 2021 reflects the timing of shipments during the nine months ended September 30, 2022. The inventory turnover rate reflects changes in stocking levels relative to cost of revenues in the prior year quarter and prior year-end.

Cash Flows

	Nine months ended September 30,		Change
	2022	2021	
Net cash provided by (used in):			
Operating activities	\$ (3,806,422)	\$ (1,561,242)	\$ 2,245,180
Investing activities	(18,944,558)	(125,039)	18,819,519
Financing activities	1,950,881	19,673,605	(17,722,724)
Net change in cash and cash equivalents	<u>\$ (20,800,099)</u>	<u>\$ 17,987,324</u>	

Operating activities

Operations cash usage in the nine months ended September 30, 2022 increased by \$2.2 million from the comparable period in 2021. This reflects the increased net loss and variances in the components of working capital.

Investing activities

Investing activities in the nine months ended September 30, 2022 primarily reflect the deployment of cash to purchase investment grade, held-to-maturity securities in the amount of \$18.9 million. The cash deployed is invested short term, and while it is not forecasted to be essential to the Company's near-term operations requirements, provides a cushion if necessary.

Financing activities

Equity sales in the nine months ended September 30, 2022 contributed \$1.95 million. Common shares were sold to investors utilizing the Company's at-the-market (ATM) facility.

We maintain a shelf registration statement covering the sales of shares of our common stock and other securities, and giving us the opportunity to raise funding when needed or otherwise considered appropriate at prices and on terms to be determined at the time of any such offerings. Pursuant to the instructions to Form S-3, we have the ability to sell shares under the shelf registration statement, during any 12-month period, in an amount less than or equal to one-third of the aggregate market value of our common stock held by non-affiliates. 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.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our unaudited financial statements, which have been prepared in accordance with generally accepted accounting principles for interim financial information. The preparation of these unaudited financial statements requires us to make estimates and assumptions about future events that affect the amounts reported in our financial statements. Actual results may differ from these estimates. The critical accounting policies and the significant judgments and estimates used in the preparation of our unaudited financial statements for the three and nine months ended September 30, 2022, were consistent with those discussed in our Annual Report on Form 10-K for the year ended December 31, 2021.

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, 2022, 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, 2022 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, 2021](#).

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

None.

Item 6. Exhibits

Exhibit No.	Description
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.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document). Filed herewith.
101.SCH	Inline XBRL Taxonomy Extension Schema Document. Filed herewith.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document. Filed herewith.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document. Filed herewith.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document. Filed herewith.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document. Filed herewith.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101). Filed herewith.

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 20, 2022

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

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

October 20, 2022

/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 20, 2022

/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 20, 2022

/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, 2022 (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 20, 2022

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.