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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 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	**04-3308180**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

4B Gill Street, Woburn, Massachusetts	**01801**
(Address of Principal Executive Offices)	(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		**The Nasdaq Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

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) during the preceding 12 months (or for such shorter period that the registrant was required to submit 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 definitions 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of June 30, 2022, the last business day of the registrant’s most recently completed second fiscal quarter, the aggregate market value of the voting stock held by non-affiliates of the registrant was $25,918,726 based on the closing sale price of the common stock as reported on the Nasdaq Capital Market on June 30, 2022.

As of March 21, 2023, there were 7,791,538 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K: Certain information required by Part III of this Annual Report on Form 10-K is incorporated from the Registrant’s Proxy Statement for the Annual Meeting of Stockholders to be held on May 2, 2023, or the 2023 Annual Meeting of Stockholders.

NEUROMETRIX, INC.

ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2022

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PART I

The statements contained in this Annual Report on Form 10-K, including under the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other sections of this Annual 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 (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, our future liquidity; 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 Quell and DPNCheck; 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; 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 Annual Report on Form 10-K or any document incorporated by reference herein. 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 Annual Report on Form 10-K 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." 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. Unless the context otherwise requires, all references to "we", "us", the "Company", or "NeuroMetrix" in this Annual Report on Form 10-K refer to NeuroMetrix, Inc.

ITEM 1. BUSINESS

Our Business — An Overview

NeuroMetrix is a commercial stage neurotechnology company based in Woburn, Massachusetts. The Company's mission is to improve individual and population health through innovative medical devices and technology solutions for neurological disorders and pain syndromes. 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 are fully integrated with in-house capabilities spanning research and development, manufacturing, regulatory affairs and compliance, sales and marketing, product fulfillment and customer support. We hold extensive, proprietary intellectual property.

NeuroMetrix created the market for point-of-care nerve testing and introduced sophisticated wearable technology for chronic pain syndromes. Nearly five million patients have been served with our products. Revenue is derived from the sale of medical devices and after-market consumable products and accessories in the United States and select overseas markets. Products are authorized by the U.S. Food and Drug Administration (FDA) and regulators in foreign jurisdictions where appropriate. We have two principal product categories:

- Diagnostic technology - point-of-care peripheral neuropathy assessment
- Therapeutic technology – wearable neuromodulation for chronic pain syndromes

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 over 30% 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 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 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 multiple 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 contributing 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. 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, inadequate 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.

Business Strategy

Our leading commercial products, and the focus of our strategic attention, are DPNCheck and Quell.

DPNCheck is our well-established testing technology for peripheral neuropathies. This technology has been evaluated in multiple clinical studies. It contributes attractive gross margins and has posted an average growth rate of 16.5% over the past five years. During 2022 we invested in the expansion of our DPNCheck commercial staff. This included adding personnel resources in sales, marketing and training with the goal of accelerating revenue in the Medicare Advantage market sector. We now have a commercial team with deep experience in the Medicare Advantage sector which is growing rapidly and is expected to exceed traditional Medicare fee-for-service within the next two years. This sector is dominated by large healthcare providers where the typical sales cycle is quite long. Accordingly, we expect to see the early revenue impacts from our expanded commercial team in the second half of 2023.

During 2023 we will encourage the existing DPNCheck installed base to transition to our next generation technology, DPNCheck 2.0 which was released in late 2022. This new device enhances the user experience and improves testing efficiency while continuing to deliver quantitative test results and high overall sensitivity and specificity. It also replaces electric and other parts in the predecessor device which may have become obsolete. Our DPNCheck product development efforts in 2023 will focus on the software ecosystem connecting user testing at the clinic level to the overall business enterprise via a DPNCheck data cloud, and also facilitating linkages between clinic testing and patient electronic medical records (EMR). This integration project is complex and costly; however, it is essential to expanding usage of DPNCheck, particularly in large organizations.

Quell is our wearable neuromodulation technology for chronic pain. It has been refined over the past seven years with over 200,000 chronic pain patients and is protected by over 20 U.S. utility patents. 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. The degree of technological sophistication, combined with our extensive consumer experience and the compelling results of clinical studies gives us the opportunity to leverage this technology base into a portfolio of Quell-based prescription (Rx) wearable neurotherapeutics.

In 2021 Quell received Breakthrough Device Designation from the FDA for a fibromyalgia indication. A pivotal double-blind, randomized, sham-controlled clinical study of Quell - Fibromyalgia has since been completed, and a De Novo marketing authorization was obtained from the FDA in 2022. Quell – Fibromyalgia is indicated for use as an aid for reducing the symptoms of fibromyalgia in adults with high pain sensitivity. This prescription product was introduced at the American College of Rheumatology 2022 Annual Meeting followed by a strategic commercial launch initiated in December 2022 to broaden market awareness and our understanding of market dynamics.

Quell also received FDA Breakthrough Device Designation in early 2022 for the treatment of chronic Chemotherapy Induced Peripheral Neuropathy (CIPN). A CIPN double-blind, randomized, sham-controlled clinical study employing Quell and funded by the National Cancer Institute (NCI) and the National Institute of Health (NIH) recently completed enrollment. Study results are expected to be published during in the first half of 2023. Positive results from that study would position us for a DeNovo filing with FDA similar to our approach with Quell – Fibromyalgia and, if successful, to an early 2024 launch of our second product in the portfolio of Quell-based prescription wearable therapeutics. We plan a similar approach with other disease indications involving chronic pain. These potentially include Chronic Low Back Pain, Post-Acute Sequelae of COVID 19, Chronic Overlapping Pain Conditions (COPC), Restless Leg Syndrome (RLS) and others.

ADVANCE is our legacy, point-of-care neurodiagnostic technology primarily used for the diagnosis and screening for carpal tunnel syndrome (CTS). The technology has been marketed since 2008. Sales of ADVANCE devices were discontinued several years ago and we continue to provide disposable electrodes to a customer base of hand surgeons and manufacturers for industrial health use.

Research and Development for Competitive Advantage

Our products are proprietary and were developed in-house by our research and development team. We believe that continual product innovation, focusing on our unique competency of precision neurostimulation, is essential to profitable growth and competitive advantage. Our 2023 research and development efforts are focused in two areas important to our future: 1) expanding our enterprise integration and population health analytics tools for DPNCheck users; and 2) further developing the Quell technology platform of disease-specific wearable neuromodulation products for chronic pain symptoms.

Business Model

Our product technologies consist of a medical device used in conjunction with a consumable electrode or biosensor. Other accessories and consumables are also available to customers. Our goal is the development of active, installed user bases regularly ordering or subscribing to aftermarket products. Our DPNCheck, Quell and ADVANCE products all conform to this business model.

Primary Marketed Products

DPNCheck

DPNCheck is a fast, accurate, and quantitative nerve conduction test that is used to evaluate peripheral neuropathies (also called polyneuropathies or systemic neuropathies) such as DPN. It is designed to be used by primary care physicians, endocrinologists, podiatrists and other clinicians at the point-of-care to objectively detect, stage, and monitor peripheral neuropathies. The device measures nerve conduction velocity and response amplitude of the sural nerve, a nerve in the lower leg and ankle. These parameters are recognized as sensitive and specific biomarkers of peripheral neuropathies. DPNCheck is comprised of: (1) an electronic hand-held device and (2) a single patient-use biosensor (limited biosensor re-use is allowed in certain international markets). In addition, we provide users with PC-based software that links to the device via a USB connection thereby allowing physicians to generate reports, manage their test data and integrate with enterprise systems including EMR.

DPNCheck is a modified version of our previously marketed NC-stat nerve testing device that has the same clinical indications with respect to peripheral neuropathies. While lower in cost than the original device, DPNCheck has the same functionality with respect to sural nerve testing. Approximately 4.3 million patient studies have been performed using our NC-stat technology. Our nerve testing technology has been the subject of over 50 peer-reviewed publications, including over 30 studies specifically addressing the accuracy and clinical utility of the DPNCheck device in the assessment of DPN and other peripheral neuropathies. Cumulatively through 2022, approximately 8,400 DPNCheck devices have been shipped to customers.

Quell

Quell is a wearable device for symptomatic relief and management of chronic pain indications. It incorporates a collection of proprietary approaches designed to optimize the effectiveness of nerve stimulation. These include high power electrical stimulation hardware with precise control, algorithms that automatically determine therapeutic stimulation intensity and compensate for nerve desensitization, and automated detection of user sleep and appropriate adjustment of stimulation level. Quell is comprised of (1) an electronic device that is placed in a flexible band worn on the upper calf, (2) an electrode that attaches to the device and is the interface between the device and the skin, and (3) a smartphone app to control the device and visualize, understand and optimize data relating to chronic pain and health. The app is integrated with the Quell Health Cloud for storage of user data, data analytics and scientific research. An Apple Watch® app provides many of the functions of the smartphone app with the convenience of a smartwatch. The Quell device is lightweight and can be worn during the day while active, and at night while sleeping. It has been authorized by the FDA for symptomatic relief and management of lower extremity chronic pain and as an aid for reducing the symptoms of fibromyalgia in adults with high pain sensitivity. Cumulatively through 2022, approximately 204,000 Quell devices have been shipped to customers.

ADVANCE

The ADVANCE System is our legacy neurodiagnostics business. It is a comprehensive platform for the performance of nerve conduction studies. The ADVANCE System is comprised of (1) the ADVANCE device and related modules, (2) various types of electrodes, and (3) a communication hub that enables a physician’s office to network the device to their office computers and to our servers for data archiving and report generation. The ADVANCE System is used with proprietary nerve specific electrode arrays. These electrode arrays combine multiple individual electrodes and embedded microelectronic components into a single patient-use disposable unit. We currently market a number of different nerve-specific electrode arrays but have discontinued sale of ADVANCE devices.

Historically, the ADVANCE System was marketed to a broad range of physician specialties including neurologists, orthopedic surgeons, primary care physicians, and endocrinologists, and utilized for a variety of different clinical indications including assessment of CTS, low back and leg pain, and DPN. It is most commonly used in the assessment of CTS. Over 20

peer-reviewed studies have been published on the use of this technology in this clinical application. As of December 31, 2022, we had an installed base of approximately 90 active customers for the ADVANCE System.

The following chart summarizes our previously and currently marketed products.

Product	Time on Market	Technology	Primary Clinical Indications	No. Patients Tested/Treated
Quell	Q2 2015 – present	Transcutaneous Electrical Nerve Stimulation	Symptomatic and management relief of lower extremity chronic pain (OTC) and fibromyalgia (Rx)	> 204,000
SENSUS	Q1 2013 – Q4 2020	Transcutaneous Electrical Nerve Stimulation	Symptomatic relief and management of chronic pain (Rx)	> 11,000
DPNCheck	Q4 2011 – present	Nerve Conduction	Evaluation of peripheral neuropathies	> 2,300,000
ADVANCE	Q2 2008 – present	Nerve Conduction	Evaluation of entrapment and systemic neuropathies	> 1,950,000 (ADVANCE and NC-stat)
NC-stat	Q2 1999 – Q3 2010	Nerve Conduction	Evaluation of entrapment and systemic neuropathies	

Customers

DPNCheck customers include managed care organizations, endocrinologists, podiatrists and primary care physicians in the United States and distributors in Europe, Japan, China and the Middle East. Through December 31, 2022, over 8,400 DPNCheck devices have been shipped to customers. Quell customers are primarily consumers in the United States. Cumulatively through December 31, 2022, approximately 204,000 Quell devices have been shipped. Our legacy ADVANCE System customers include approximately 90 active accounts covering occupational health, primary care, internal medicine, orthopedic and hand surgeons, pain medicine physicians, neurologists, physical medicine and rehabilitation physicians, and neurosurgeons.

At December 31, 2022, two customers accounted for 31% of accounts receivable and one customer accounted for 32% of revenue.

Sales, Marketing, and Distribution

Our U.S. sales efforts for DPNCheck primarily focus on Medicare Advantage organizations and providers who assume financial responsibility and the associated risks for the health care costs of their patients. We believe that DPNCheck presents an attractive clinical case with detection of peripheral neuropathy allowing for earlier clinical intervention to help mitigate the effects of peripheral neuropathy on both patient quality of life and cost of care. Also, the diagnosis and documentation of peripheral neuropathy provided by DPNCheck helps clarify the patient health profile which, in turn, may have a direct, positive effect on Medicare Advantage reimbursement through the Hierarchical Condition Category (HCC) system. Outside the United States, DPNCheck is sold in Japan by our distribution partner Fukuda Denshi Co., Ltd. and in China by Omron Medical (Beijing) Ltd. Sales and marketing efforts for DPNCheck are led by our Senior Vice President, Population Health and Value Based Care.

Quell – Fibromyalgia is available in the United States via HealthWarehouse.com, an on-line pharmacy. A prescription is required for purchase. The Company is conducting a strategic launch of this product to optimize its marketing strategy. Quell (OTC) for lower extremity chronic pain is no longer available to new customers. Sales and marketing efforts for Quell are led by our National Sales Director, Neuromodulation.

Customer Service handles domestic ADVANCE sales and support. A small network of independent distributors in several European countries and Canada support ADVANCE in their jurisdictions.

Manufacturing and Supply

We perform final assembly and servicing of our Quell and DPNCheck devices at our manufacturing facility in Massachusetts. The ADVANCE device which is no longer in production but for which we continue to sell accessories, is serviced by us. Outside suppliers provide the sub-assemblies and components that we use in manufacturing Quell and DPNCheck, as well as our consumable products including biosensors and electrodes. Reflecting the relatively small volumes of our products being manufactured and sold, we do not have alternative suppliers for many of the key components of our products. Rather we rely on regular contact and close working relationships with local suppliers developed over many years. In outsourcing, we target companies that meet FDA, International Organization for Standardization (ISO), and other quality standards supported by internal policies and procedures. Supplier performance is maintained and managed through a corrective action program ensuring all product requirements are met or exceeded. Following the receipt of products or product components from our third-party manufacturers, we conduct the necessary inspection, final assembly, packaging, and labeling at our manufacturing facility. We believe that our manufacturing relationships minimize our capital investment, provide us with manufacturing expertise, and helps control costs.

A New England regional supplier has been manufacturing devices and providing sub-assemblies to us since 2005. The supplier currently manufactures sub-assemblies for Quell and DPNCheck. A supplier based in the central United States has been manufacturing ADVANCE electrodes for us since 1999. A full-service original equipment manufacturer (OEM) also based in the central United States and specializing in medical and cosmetic devices, manufactures DPNCheck biosensors and Quell electrodes.

We are registered with the FDA and subject to compliance with FDA quality system regulations. As a registered device manufacturer, we undergo regularly scheduled FDA quality system inspections, are subject to periodic inspections by state agencies and, if deemed necessary by the FDA, additional inspections may occur. We are also ISO registered and undergo annual quality system audits by a European agency. ADVANCE and DPNCheck are cleared for marketing within the United States, Canada and the European Union. DPNCheck is also cleared for marketing in Japan, China and Mexico. Quell is authorized for marketing in the United States.

Research and Development

We believe that we have research and development (R&D) capability that is unique to the industry with over two decades of experience in developing diagnostic and therapeutic devices involving the precision stimulation and measurement of nerve signals for clinical purposes. Our company has extensive experience in neurophysiology, biomedical instrumentation, signal processing, biomedical sensors, and information systems.

Our R&D team works closely with marketing and customers to design products that are focused on improving clinical outcomes. The team of eight engineers includes one who holds an M.D. degree. Our founder and Chief Executive Officer leads R&D and coordinates our clinical program. He holds both M.D. and Ph.D. degrees.

R&D efforts planned for 2023:

- *DPNCheck* . During 2022 we completed the upgrade and market release of our DPNCheck 2.0 device which delivers an improved user experience and also addresses manufacturing issues and replaces electronic and other parts that may have become obsolete. In 2023 our DPNCheck focus will shift to development of the software ecosystem beyond the patient test itself to covering the broader healthcare enterprise. The primary features of this program will be development of a DPNCheck data cloud where test information would be aggregated for an enterprise-wide view of testing, and also to enable the transmission of patient data to EMR.

- *Quell Prescription Wearable Therapeutic Initiative*. In 2022 we secured regulatory approval for Quell-Fibromyalgia and addressed technology enhancements essential for commercial launch which was initiated at the end of the year. The next therapeutic target for the technology will be Quell - Chemotherapy Induced Peripheral Neuropathy (CIPN), which was the subject of a pivotal clinical study supported by the NIH and NCI. This study was a multi-center, double

blind, randomized, sham-controlled trial of Quell in CIPN. A total of 150 patients were enrolled, with subjects randomized to an active or sham Quell device for 6-weeks. The primary outcome measure is the baseline to 6-week change in the EORTC-CIPN20 (a composite measure of CIPN symptoms and functional impairments). Other outcomes include individual CIPN symptoms and objective measures of central descending pain inhibition, lower limb sensation threshold, and balance. Enrollment in the study was completed late in 2022 and study results are expected in the first half of 2023.

- *Clinical studies for our wearable technology.* We plan to continue efforts to build the body of evidence from external clinical studies that is foundational to our Quell initiative.

Clinical Program

Our clinical program operates under the direction of our Chief Executive Officer. This may from time-to-time be comprised of internal, collaborative, and external clinical studies. Internal clinical studies are designed and implemented directly by us for the purposes of product design and early clinical validation. Collaborative studies are conducted together with leading researchers around the world to provide clinical validation and to explore the clinical utility of our products. External studies are entirely independent of us, although in many cases the researchers request unrestricted grants for financial and/or material support, such as for devices and consumables. External studies may examine the clinical performance and utility of our products or our products may be used as outcomes measures. We actively seek to publish clinical study results in leading peer-reviewed journals while also encouraging our clinical collaborators and clinical study grant recipients to do the same. During 2023 we expect that our clinical program will be limited to external studies.

Competition

The Quell technology falls within the crowded TENS category which encompasses a wide number of neurostimulation devices, the majority of which are imported from Asia-based manufacturers. However, we believe there is no direct competition to our Quell technology with the level of power, sophistication, and user features for the symptomatic relief of chronic pain. The most common approach to chronic pain is pain medication. This includes over-the-counter drugs (such as Advil and Motrin), and prescription drugs including anti-convulsants (such as Lyrica and Neurontin) and anti-depressants (such as Cymbalta and Elavil). Topical creams may also be used (such as Zostrix and Bengay). With severe pain, narcotic or opioid pain medications may be prescribed (such as codeine, fentanyl, morphine, and oxycodone). 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.

Reflecting the difficulty in treating chronic pain, inadequate relief leads many pain sufferers to turn to the over-the-counter market for supplements or alternatives to prescription pain medications. These include non-prescription medications, topical creams, lotions, TENS devices, dietary products, braces, sleeves, pads and other items. In the United States, over $4 billion is spent annually on such pain relief products.

Nerve stimulation is an established treatment for chronic pain. It is available through implantable spinal cord stimulation; however, this approach requires surgery and has attendant risks. Non-invasive approaches to neurostimulation have achieved limited success in practice due to device limitations, inadequate dosing and low patient adherence. We believe that our Quell – Fibromyalgia wearable technology whose prescription indications make it the only FDA authorized non-pharmaceutical treatment for fibromyalgia, and its personalization features including app control, high power and automation, and digital health integration characteristics place it in a unique neurostimulation category without direct competition. Further, we expect that our initiative to build a portfolio of Quell-based prescription wearable neurotherapeutics will, if successful, significantly reduce or eliminate direct competition from TENS devices.

We believe that DPNCheck is currently the only objective and standardized test for peripheral neuropathies widely available at the point-of-care. The American Diabetes Association and other organizations recommend at least annual evaluation of all people with diabetes for DPN. Due to cost and availability, the evaluation is typically performed using a simple (5.07/10g) monofilament. The method is subjective and only identifies late stage neuropathy where intervention is generally limited to foot care. Experts in the field have indicated that there is an unmet need for a practical, objective, and

sensitive test for diabetic neuropathy that can be widely deployed in the regular care of all people with diabetes. Monofilaments (5.07/10g) are a commodity sold by multiple medical supply companies.

There are several companies that sell neurodiagnostic devices that may compete with our ADVANCE System. These companies include Cadwell Laboratories, Inc. and Natus Medical Incorporated, both of which have substantially greater financial resources than NeuroMetrix. Natus Medical Incorporated and Cadwell Laboratories, Inc. have effective worldwide distribution channels for supplying medical instruments to neurologists and physical medicine and rehabilitation physicians.

Intellectual Property

We rely on a combination of patents, trademarks, copyrights, trade secrets, and other intellectual property laws, nondisclosure agreements and other measures to protect our proprietary technology, intellectual property rights, and know-how. We hold issued utility patents covering a number of important aspects of our Quell, SENSUS, DPNCheck and ADVANCE products. We believe that in order to have a competitive advantage, we must develop and maintain the proprietary aspects of our technologies. We also require our employees, consultants and advisors, whom we expect to work on our products, to agree to disclose and assign to us all inventions conceived, or developed using our property, or which relate to our business. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain and use information that we regard as proprietary.

Patents

As of December 31, 2022, we had 50 issued U.S. patents, 50 issued foreign patents, and 33 patent applications. Our wearable therapeutic products have 24 issued U.S. utility patents, 19 foreign utility patents, 10 issued U.S. design patents plus 24 issued foreign design patents. We also have 32 patent applications related to our wearable therapeutic products (12 U.S. and 20 foreign). For our DPNCheck diagnostic device, 11 utility patents (4 U.S. and 7 foreign) were issued that cover the core technology.

With regard to our legacy neurodiagnostic products, our issued design patents began to expire in 2015, and our issued utility patents began to expire in 2017. We have additional patents and patent applications directed to other novel inventions that extend patent terms into 2023 to 2031.

The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. Patent litigation can involve complex factual and legal questions, and its outcome is uncertain. Any claim relating to infringement of patents that is successfully asserted against us may require us to pay substantial damages. Even if we were to prevail, any litigation could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. Our success will also depend in part on our not infringing patents issued to others, including our competitors and potential competitors. If our products are found to infringe the patents of others, our development, manufacture, and sale of these potential products could be severely restricted or prohibited. In addition, our competitors may independently develop similar technologies. Because of the importance of our patent portfolio to our business, we may lose market share to our competitors if we fail to protect our intellectual property rights.

A patent infringement suit brought against us may force us or any strategic partners or licensees to stop or delay developing, manufacturing, or selling potential products that are claimed to infringe a third-party's intellectual property, unless that party grants us rights to use its intellectual property. In such cases, we may be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all. Even if we were able to obtain rights to the third-party's intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

Trademarks

We hold domestic registrations for the trademarks NEUROMETRIX, Quell, stylized Q, Quell Health Cloud, DPNCheck, SENSUS, NC-stat, ADVANCE, and NC-stat DPNCheck. We use a trademark for Wearable Pain Relief Technology and Therapy Autopilot. We hold certain foreign registrations for the marks NEUROMETRIX, Quell, OptiTherapy, and NC-stat.

Third-Party Reimbursement

Procedures performed with our neurodiagnostic medical devices including ADVANCE and DPNCheck may be paid for by third-party payers, including government health programs, such as Medicare, and private insurance and managed care organizations. The 2023 Physicians Fee Schedule published by the Centers for Medicare & Medicaid Services (CMS) includes CPT 95905 for nerve conduction studies performed with pre-configured electrode arrays such as those used with the DPNCheck device and the ADVANCE System.

We believe that physicians are generally receiving reimbursement under CPT 95905 from Medicare for nerve conduction studies performed for carpal tunnel syndrome using pre-configured electrode arrays that meet the medical necessity requirements in their local Medicare region but that commercial insurers are generally not providing reimbursement. Reimbursement by third-party payers is an important element of success for medical device companies. We do not foresee a significant near-term improvement in reimbursement for procedures performed with ADVANCE and DPNCheck.

In the United States, some insured individuals receive their medical care through managed care programs which monitor and, for payment purposes, often require pre-approval of the services that a member's provider prescribes. Some managed care programs pay their providers a predetermined annual payment per member which puts the providers at financial risk for the services provided to their members. Our United States sales efforts for DPNCheck are focused on the Medicare Advantage program. The Medicare Advantage program is administered by CMS and operated by private managed care organizations or insurers referred to as Medicare Advantage organizations ("MAOs"). CMS pays these MAOs capitated fees that are adjusted under CMS's risk adjustment model, which uses health status indicators, or risk scores, to ensure the adequacy of payment. Members with higher risk codes generally require more healthcare resources than those with lower risk codes. In turn, the MAOs fully absorbs the risk of patient health care costs. MAOs may share a portion of the risk with provider organizations such as independent practice associations (IPAs) with whom they contract to provide medical services to their members. Proper assessment of each member's health status and accurate coding helps to assure that MAOs receive capitation fees consistent with the cost of insuring these members. Nerve conduction testing can provide valuable, early identification of peripheral neuropathy leading to clinical interventions that can reduce health care costs. Also, these tests provide valuable input regarding each member's health risk status which can result in more appropriate capitated payments from CMS.

The Medicare Advantage program is currently experiencing uncertainty due to changes in several aspects of the Medicare Advantage program recently proposed by the CMS. On January 30, 2023, CMS issued a final rule regarding the MA Risk Adjustment Data Validation (RADV) program that is used to recover improper risk adjustment payments made to MAOs. Also, on February 1, 2023, CMS issued its 2024 Medicare Advantage Advance Notice, which proposed substantial changes to the Hierarchical Condition Categories (HCC) risk adjustment model for calendar year 2024. The proposal includes changes that limit HCC codes for some types of peripheral neuropathies. The eventual impact of these factors and related uncertainty is unclear; however, there could be a material effect on future DPNCheck revenues and margins.

We believe that the overall escalating cost of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry to reduce the costs of products and services.

Our success in selling DPNCheck and ADVANCE will depend upon, among other things, our customers receiving, and our potential customers' expectation that they will receive sufficient reimbursement or patient capitated premium adjustments from third-party payers for procedures or therapies using these products. We expect that Quell will generally not be reimbursed by third party payers in the near future. See "Risk Factors," *"If health care providers are unable to obtain sufficient reimbursement or other financial incentives from third-party health care payers related to the use of our products other than Quell, their adoption and our future product sales will be materially adversely affected."*

FDA and Other Governmental Regulation

FDA Regulation

Our products are medical devices that are subject to extensive regulation by the U.S. FDA under the Federal Food, Drug, and Cosmetic Act (FDCA), and the regulations promulgated thereunder, as well as by other regulatory bodies in the United States and abroad. The FDA classifies medical devices into one of three classes based on the risks associated with the medical device and the controls deemed necessary to reasonably ensure the device's safety and effectiveness. Those three classes are:

- Class I, the lowest risk products, which require compliance with medical device general controls, including labeling, establishment registration, device product listing, adverse event reporting and, for some products, adherence to good manufacturing practices through the FDA's quality system regulations;
- Class II, comprising moderate-risk devices, which also require compliance with general controls and in some cases, so-called special controls that may include performance standards, particular labeling requirements, or post-market surveillance obligations; typically a Class II device also requires pre-market review and clearance by FDA of a pre-market notification (also referred to as a "510(k) application") as well as adherence to the quality system regulations/good manufacturing practices for devices; and
- Class III, high-risk devices that are often implantable or life-sustaining, which also require compliance with the medical device general controls and quality system regulations, but which generally must be approved by FDA before entering the market, through a more-lengthy pre-market approval (PMA) application. Approved PMAs can include post-approval conditions and post-market surveillance requirements, analogous to some of the special controls that may be imposed on Class II devices.

Before being introduced into the U.S. market, our products must obtain marketing clearance or approval from FDA through the 510(k) pre-market notification process, the *de novo* classification process (summarized below under *De Novo Classification Process* (the PMA process), unless they are determined to be Class I devices or to otherwise qualify for an exemption from one of these available forms of pre-market review and authorization by the FDA. To date, our products have all been classified as Class II, moderate-risk medical devices and have been subject to the 510(k) review and clearance process. See "Risk Factors," *"We are subject to extensive regulation by the FDA which could restrict the sales and marketing of Quell, DPNCheck and ADVANCE, as well as other products for which we may seek FDA clearance or approval, and could cause us to incur significant costs."*

510(k) Pre-Market Notification Process

Class II devices typically require pre-market review and clearance by the FDA, which is accomplished through the submission of a 510(k) pre-market notification before the device may be marketed. To obtain 510(k) clearance, we must demonstrate that a new device is substantially equivalent to another device with 510(k) clearance or grandfathered status, or to a device that was reclassified from Class III to Class II or Class I - this device to which the new device is compared is called the "predicate device." In some cases, we may be required to perform clinical trials to support a claim of substantial equivalence. If clinical trials are required, we may be required to submit an application for an investigational device exemption (IDE), which must be cleared by the FDA prior to the start of a clinical investigation, unless the device and clinical investigation are considered non-significant risk by the FDA or are exempt from the IDE requirements. Whether or not an IDE is required for a clinical study involving a medical device, an appropriate Institutional Review Board (IRB) must review and approve the study protocol before it is initiated. It generally takes three months from the date of the pre-market notification submission to obtain a final 510(k) clearance decision from the FDA, but it can be significantly longer.

After a medical device receives a 510(k) clearance letter, which authorizes commercial marketing of the new device for one or more specific indications for use, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires the submission of a new 510(k) notification or could require *de novo* classification or a PMA. The FDA allows each company to make this determination, but the FDA can review the decision as part of routine compliance audits of the company. If the FDA disagrees with a company's decision not to seek prior FDA authorization, the FDA may require the company to seek additional 510(k) clearance or pre-market approval. The FDA also can require the company to cease marketing and/or recall the medical device in question until its regulatory status is resolved.

De Novo Classification Process

If the FDA determines that a new, previously unclassified medical device or its intended use is not substantially equivalent to a predicate device, the device is automatically placed into Class III, requiring the submission of a PMA. Devices that cannot be cleared through the 510(k) process due to lack of a predicate device but would be considered low or moderate risk (in other words, they do not rise to the level of requiring the approval of a PMA because any risks associated with the device could be mitigated through general controls and/or special controls) may be eligible for the 510(k) De Novo classification process. If a product is classified as Class II through the *De Novo* classification process, then that device may serve as a predicate device for subsequent 510(k) pre-market notifications.

FDA has issued a Guidance document that formally codifies requirements for the medical device De Novo process and the procedures and criteria for product developers to file a De Novo classification request. FDA's activities to create predictability,

consistency, and transparency for innovative medical device developers may benefit the medical technology industry as a whole.

PMA Application Process

If a medical device does not qualify for the 510(k) pre-market notification process and is not eligible for classification as a low or moderate-risk device through the *De Novo* process, the device is deemed to be Class III and a company must submit a PMA application to seek authorization for its commercial sale. A PMA requires more extensive pre-filing testing than is required in the 510(k) application and is more costly, lengthy and uncertain. The PMA review and approval process can take one to three years or longer, from the time the PMA application is filed with the FDA. Under a PMA, the company must demonstrate to the FDA that the new medical device is safe and effective for its intended purpose. A PMA typically includes extensive pre-clinical and clinical trial data, and information about the device, its design, manufacture, labeling and components. Before approving a PMA, the FDA generally also performs an on-site inspection of manufacturing facilities for the product to ensure compliance with the FDA's quality system regulation (QSR).

If FDA approves the PMA, the approved indications may be more limited than those originally sought. In addition, FDA's approval order may include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution and post-market study requirements. Failure to comply with the post-approval conditions can result in adverse enforcement or administrative actions, including the withdrawal of the approval. Approval of a new PMA application or a PMA supplement may be required before making certain types of modifications to the device, including to its labeling, intended use or indication, or manufacturing process, especially when such modifications have the potential to affect safety and effectiveness.

Post-Marketing Compliance Obligations

Regardless of which pre-market pathway a medical device uses to reach the U.S. market, after a device is placed on the market, numerous regulatory requirements continue to apply. These include:

- the FDA's QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other good manufacturing practice and quality assurance procedures during all aspects of the manufacturing process (unless a device category is exempt from this requirement by the FDA, such as in the case of many Class I devices);
- labeling regulations and FDA prohibitions against the promotion of products for uncleared or unapproved uses (known as off-label uses), as well as requirements to provide adequate information on both risks and benefits;
- medical device reporting regulations, which require that manufacturers report to FDA any event that the company learns of in which a device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections and device recalls or removals if undertaken to reduce a risk to health by the device or to remedy a violation of the FDA caused by the device that may present a risk to health;
- post-market surveillance regulations, which apply to Class II or III devices if the FDA has issued a post-market surveillance order and the failure of the device would be reasonably likely to have serious adverse health consequences, the device is expected to have significant use in the pediatric population, the device is intended to be implanted in the human body for more than one year, or the device is intended to be used to support or sustain life and to be used outside a user facility;
- regular and for-cause inspections by FDA to review a manufacturer's facility and its compliance with applicable FDA requirements; and
- the FDA's recall authority, whereby it can ask, or order, device manufacturers to recall from the market a product that is in violation of applicable laws and regulations.

Regulatory Approvals and Clearances

The ADVANCE System received 510(k) clearance as a Class II medical device in April 2008 for its intended use by physicians to perform nerve conduction studies and needle electromyography procedures.

The NC-stat System is also a Class II medical device and has been the subject of several 510(k) clearances, most recently in July 2006 (K060584). The NC-stat System is cleared for use to stimulate and measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies. Our NC-stat DPNCheck, or DPNCheck, device is a technical modification to the 510(k) cleared NC-stat device and has the same intended use, and therefore does not raise safety or effectiveness questions that would require a separate 510(k) submission under the FDA's published guidance on 510(k) requirements for modified devices.

As transcutaneous electrical nerve stimulators, the SENSUS and Quell pain therapy devices are Class II medical devices that received 510(k) clearance from the FDA in August 2012 and July 2014, respectively. In November 2012, the FDA provided 510(k) clearance for the disposable electrode used in conjunction with the SENSUS device, and in July 2013, the FDA provided 510(k) clearance for the use of SENSUS during sleep. The intended use of the SENSUS pain management therapeutic system is the symptomatic relief and management of chronic pain. The SENSUS device is no longer marketed and, where possible, we have transitioned SENSUS customers to Quell. In July 2014, our Quell device received 510(k) clearance for over-the-counter use and in November 2014, our Quell disposable electrode received 510(k) clearance for over-the-counter use. In January 2016, a number of new features were added to Quell and received 510(k) clearance, most notably use with an optional mobile app that contains several convenience features. The intended use of the Quell pain management therapeutic system is the symptomatic relief and management of chronic pain. The Quell device may also be used during nighttime sleep.

Quell – Fibromyalgia is a transcutaneous electrical nerve stimulator employing our core Quell technology. Its intended use was not substantially equivalent to an existing predicate device; however, it was considered low to moderate risk. FDA accepted the eligibility of Quell – Fibromyalgia as a 510 (k) De Novo submission and provided the device with De Novo authorization in May 2022.

Federal Trade Commission Regulatory Oversight

We are subject to Federal Trade Commission (FTC) regulatory oversight. Under the Federal Trade Commission Act (FTC Act), the FTC is empowered, among other things, to (a) prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce; (b) seek monetary redress and other relief for conduct injurious to consumers; and (c) gather and compile information and conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce. The FTC has very broad enforcement authority, and failure to abide by the substantive requirements of the FTC Act and other consumer protection laws can result in administrative or judicial penalties, including civil penalties, or injunctions affecting the manner in which Quell could be marketed in the future.

Manufacturing Facilities

Our facility, and the facilities utilized by our contract sub-assembly manufacturer, have been inspected by FDA in the past, and observations were noted. There were no findings that involved a significant violation of regulatory requirements. The responses to these observations have been accepted by the FDA and we believe that we and our contract manufacturers are in substantial compliance with the FDA Quality System Regulation (QSR). We expect that our facility and our subcontract facilities will be inspected again as required by the FDA. If the FDA finds significant violations, we could be subject to fines, recalls, requirements to halt manufacturing, or other administrative or judicial sanctions.

Medical Device Single Audit Program (MDSAP)

The International Medical Device Regulators Forum (IMDRF) recognized that a global approach to auditing and monitoring the manufacturing of medical devices could improve their safety and oversight on an international scale. The IMDRF established a work group which developed specific documents to advance a Medical Device Single Audit Program (MDSAP).

The Medical Device Single Audit Program allowed MDSAP recognized Auditing Organizations to conduct a single regulatory audit of a medical device manufacturer to satisfy the relevant requirements of the regulatory authorities participating in the program.

MDSAP participating international partners include:

- MDSAP Members
  - Therapeutic Goods Administration of Australia
  - Brazil's Agência Nacional de Vigilância Sanitária
  - Health Canada
  - Japan's Ministry of Health, Labour and Welfare, and the Japanese Pharmaceuticals and Medical Devices Agency
  - U.S. Food and Drug Administration
- MDSAP Official Observers:
  - The World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) Programme
  - European Union (EU)
- MDSAP Affiliate Members:
  - Republic of Korea's Ministry of Food and Drug Safety

Based on its evaluation of the MDSAP Final Pilot Report, the MDSAP Regulatory Authority Council (the international MDSAP governing body) determined that the MDSAP Pilot had satisfactorily demonstrated the viability of the Medical Device Single Audit Program.

In July 2022, NeuroMetrix underwent a MDSAP audit by the registrar TÜV SÜD. There were several observations noted during the MDSAP audit to which the Company has responded and are presently under review with TÜV SÜD. The FDA accepts MDSAP audit reports as a substitute for routine Agency inspections.

Human Capital Resources

As of December 31, 2022, we had 27 full time employees. Of these employees, eight were in research and development, eight in sales and marketing, five in production/distribution, and six in general and administrative services. One employee holds both M.D. and Ph.D. degrees and one employee holds an M.D. degree. Our employees are not represented by a labor union and are not subject to a collective bargaining agreement. We have never experienced a work stoppage and believe that we have good employee relations.

We recruit employees with the skills and training relevant to functional responsibilities. As a small, innovative company focused on profitable growth, we believe that our future success largely depends on our continued ability to attract and retain highly skilled employees. We assess the likelihood that a particular candidate will contribute to the Company's overall goals, and beyond their specifically assigned tasks. Depending on the position, our recruitment reach can be national as well as local. We aim to provide market-based compensation and stretch incentives. We work to retain our employees for many years, as evidenced by the average 11 plus years' tenure of our workforce. New employees are provided industry-relevant compliance training and are introduced to our Code of Business Conduct and Ethics, with which all employees are required to annually confirm compliance. During 2021 and 2022, as we worked to manage through the effects of the pandemic, all employees were retained at full salary and, where possible, were provided the option of working remotely or at our Woburn facility with appropriate safeguards.

Available Information

Access to our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to these reports filed with or furnished to the Securities and Exchange Commission, or SEC, may be obtained through the Investor Relations section of our website at *www.neurometrix.com/investor* as soon as reasonably practical after we electronically file or furnish these reports. We do not charge for access to and viewing of these reports. Information on our Investor Relations page and on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein by reference. In addition, the SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. Also, our filings with the SEC may be accessed through the SEC's website at *www.sec.gov.* All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Corporate Information

NeuroMetrix was founded in June 1996 by our President and Chief Executive Officer, Shai N. Gozani, M.D., Ph.D. We were originally incorporated in Massachusetts in 1996 and were reincorporated in Delaware in 2001. Our offices and production facilities are located at 4-B Gill Street, Woburn, Massachusetts 01801. Our website is *www.neurometrix.com.*

ITEM 1A. Risk Factors

You should carefully consider the following risks and all other information contained in this Annual Report on Form 10-K and our other public filings before making any investment decisions with respect to our securities. If any of the following risks occurs, our business, prospects, reputation, results of operations, or financial condition could be harmed. In that case, the trading price of our securities could decline, and our stockholders could lose all or part of their investment. This Annual Report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of specific factors, including the risks described below and elsewhere in this Annual Report on Form 10-K.

Summary of Risk Factors

Our business is subject to numerous risks and uncertainties, including those highlighted in this section below, that represent challenges that we face in connection with the successful implementation of our strategy. The occurrence of one or more of the events or circumstances described in more detail in the risk factors below, alone or in combination with other events or circumstances, may have an adverse effect on our business, prospects, reputation, results of operations, or financial condition. Such risks include, but are not limited to:

- We have incurred significant operating losses since inception and cannot assure you that we will achieve profitability.
- Our future capital needs are uncertain. Our operations could be curtailed if we are unable to obtain the required additional funding when needed. The terms of any financings may not be advantageous to us.
- We hold an investment portfolio of securities that could experience losses.
- Our financial condition and results of operations may be adversely affected by a resurgence of the coronavirus.
- We are focused on growing sales of DPNCheck, our test for peripheral neuropathy, and Quell, our wearable device for chronic pain. We cannot assure you that we will be successful with these products or future product candidates or product enhancements in our development pipeline.
- Our current and future revenue is dependent upon commercial acceptance of our products in the marketplace. If our products are not accepted by prescribers and customers, our operations will be materially and adversely affected.
- If health care providers are unable to obtain sufficient reimbursement or other financial incentives from third-party health care payers related to the use of our products other than Quell, their adoption and our future product sales will be materially adversely affected.
- The clinical study process is lengthy and expensive with uncertain outcomes. Results of earlier studies may not be predictive of future clinical study results, or the safety profile for such products or products under development.
- We rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing our product candidates.
- We depend on several single source manufacturers to produce components of our products. Any material adverse changes in our relationships with these manufacturers, or material supply chain delays, could prevent us from delivering products to our customers in a timely manner and may adversely impact our future revenues or costs.
- If our manufacturers are unable to supply us with an adequate supply of product components, we could lose customers, our potential future growth could be limited and our business could be harmed.
- The success of our business depends upon our ability to advance our pipeline products to commercialization.
- Our ability to achieve profitability depends in part on maintaining or increasing our gross margins on product sales which we may not be able to achieve.
- If we lose any of our officers or key employees, our management and technical expertise could be weakened significantly.
- If we are unable to recruit, hire and retain skilled and experienced personnel, our ability to manage and expand our business will be harmed, which would impair our future revenues and profitability.
- Failure to develop or enter into relationships to sell products other than our existing products or enhance our existing products could have an adverse effect on our business prospects.
- If we are unable to develop new products or enhance existing products, we may be unable to attract or retain customers.
- We currently compete, and may in the future need to compete, against other medical device and consumer companies with greater resources, more established distribution channels and other competitive advantages, and the success of these competitors may harm our ability to generate revenues.

- Security breaches and other disruptions could compromise our information and expose us to liability, which could cause our business and reputation to suffer.
- If future clinical studies or other articles are published, or physician associations or other organizations announce positions that are unfavorable to our products, our sales efforts and revenues may be negatively affected.
- If we expand in foreign markets, we will be affected by new business risks that may adversely impact our financial condition or results of operations.
- We are subject to extensive regulation by the FDA and other federal and state regulators which could restrict the sales and marketing of Quell, DPNCheck and ADVANCE, as well as other products for which we may seek FDA clearance or approval, and could cause us to incur significant costs.
- If we or our manufacturers fail to comply with the FDA's quality system regulation, the manufacturing and distribution of our products could be interrupted, and our product sales and operating results could suffer.
- We are subject to Federal Trade Commission regulatory oversight. Exercise of this regulatory oversight could lead to an outcome which would constrain our marketing of Quell, cause us to incur significant costs and penalties, and adversely affect our financial results.
- Our products may be subject to recalls, even after receiving FDA clearance or approval, which would harm our reputation, business and financial results.
- We are subject to federal and state laws prohibiting "kickbacks" and false or fraudulent claims, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.
- If we are found to have violated laws protecting the confidentiality of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities, damage our reputation and harm our business.
- The use of our products could result in product liability claims that could be expensive, damage our reputation and harm our business.
- Our products are complex in design, and defects may not be discovered prior to shipment to customers, which could result in warranty obligations or product liability or other claims, reducing our revenues and increasing our costs and liabilities.
- The patent rights we rely upon to protect the intellectual property underlying our products may not be adequate, which could enable third parties to use our technology and would harm our ability to compete in the market.
- Other rights and measures we have taken to protect our intellectual property may not be adequate, which would harm our ability to compete in the market.
- We may need to initiate lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive and, if we lose, could cause us to lose some of our intellectual property rights, which would harm our ability to compete in the market.
- Claims that our products infringe on the proprietary rights of others could adversely affect our ability to sell our products and increase our costs.
- We identified a material weakness in our internal control over financial reporting. If our remediation measures are ineffective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to report our financial condition or results of operations accurately or in a timely manner and we may be unable to maintain compliance with applicable stock exchange listing requirements, which may adversely affect investor confidence in us and, as a result, materially and adversely affect our business and the value of our common stock.
- Future sales of securities may cause our stock price to decline as a result of the dilution which will occur to existing stockholders.
- The trading price of our common stock has been volatile and is likely to be volatile in the future.
- We have, in the past, failed to satisfy certain continued listing requirements on Nasdaq and could fail to satisfy those requirements again in the future which could affect the market price of our common stock and liquidity and reduce our ability to raise capital.
- Anti-takeover provisions in our organizational documents and Delaware law, and the shareholder rights plan that we adopted in 2007 and updated in 2021, may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.
- We do not intend to pay cash dividends.

Risks Related to Our Business

We have incurred significant operating losses since inception and cannot assure you that we will achieve profitability.

We have incurred recurring losses from operations and negative cash flows from operating activities. At December 31, 2022, we had an accumulated deficit of $203.6 million. The extent of our future operating income or losses is highly uncertain, and we cannot assure you that we will be able to achieve or maintain profitability.

Our future capital needs are uncertain. Our operations could be curtailed if we are unable to obtain the required additional funding when needed. The terms of any financings may not be advantageous to us.

We held cash, cash equivalents and investment grade securities of $21.2 million as of December 31, 2022. We believe that these resources, and the cash to be generated from future product sales will be sufficient to meet our projected operating requirements for at least the next twelve months from the day of issuance of the financial statements. However, we may still need to raise additional funds to support our future operating and capital needs.

We expect to incur further losses as we grow sales of DPNCheck and Quell. We continue to face significant challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected due to (a) decreases in sales of our products and the uncertainty of future revenues from new products; (b) the effect of supply chain issues on our ability to obtain parts and materials from our suppliers; (c) changes we may make to the business that affect ongoing operating expenses; (d) changes we may make in our business strategy; (e) regulatory developments and inquiries affecting our existing products; (f) changes in our research and development spending plans; and (g) other items affecting our forecasted level of expenditures and use of cash resources. We may attempt to obtain additional funding through public or private financing, collaborative arrangements with strategic partners, asset divestitures, or through additional credit lines or other debt financing sources to increase the funds available to fund operations. However, we may not be able to secure such financing in a timely manner or on favorable terms, if at all. Furthermore, if we issue equity or debt securities to raise additional funds, 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 to grant licenses on terms that are not favorable to us. Without additional funds, we may be forced to delay, scale back or eliminate some of our sales and marketing efforts, research and development activities, or other operations and potentially delay product development in an effort to provide sufficient funds to continue our operations. If any of these events occurs, our ability to achieve our development and commercialization goals would be adversely affected.

We hold an investment portfolio of securities that could experience losses.

We invest our cash resources not required for near-term operations in a portfolio of debt securities which we intend to hold to maturity. These securities are evaluated by independent rating agencies and meet the criteria of “investment grade” securities at the time of purchase. Changes in domestic or world-wide economic conditions, or in the operations of the issuing entities could result in a rating downgrade of the securities or an inability of the issuer to meet its obligation to the Company upon maturity. In this event, the Company would be exposed to loss in value of the security. If the change in economic conditions was so severe as to affect the overall securities market and therefore a significant part of the Company’s portfolio, the loss in value could jeopardize the Company’s ability to adequately fund its operations, its strategic initiatives and achieve its development and commercialization goals.

Our financial condition and results of operations may be adversely affected by a resurgence of the coronavirus.

The resurgence of the COVID-19 coronavirus pandemic, and any future outbreak of contagious diseases, or other adverse public health developments, could have a material and adverse effect on our business operations. Such adverse effects could include disruptions or restrictions on the ability of our customers, distributors and suppliers to maintain normal business activities. It could also affect the ability of our personnel to perform their normal responsibilities and could result in temporary closures of our facilities.

COVID-19 continues to affect individuals and businesses around the globe. We may experience disruptions that could severely impact our business, including:

- restrictions on the conduct of our business imposed by governmental regulators;
- diversion or prioritization of healthcare resources away from clinical trials and diagnostic testing using our medical devices by physician clinics, hospitals, home testing services and other healthcare providers;
- supply chain disruption, including delays in fulfillment or cancellations of purchase orders by our parts and services suppliers which would hamper our manufacturing capabilities;
- limitations on employee resources that would otherwise be focused on our business activities, including because of sickness of employees or their families or requirements imposed on employees to avoid contact with large groups of people;
- disruption in our distribution channels, including shipping providers and distributors.

Our future results of operations could be adversely affected to the extent that COVID-19 or any other epidemic harms our business or the economy in general either domestically or in any other region in which we do business. The extent to which our operations and financial condition could be harmed will depend on future developments which are uncertain and cannot be predicted with confidence. These future developments could include duration of the pandemic or other epidemic, new information concerning severity, efforts for widespread vaccination, treatment of those adversely affected, and other unanticipated developments.

We are focused on growing sales of DPNCheck, our test for peripheral neuropathy, and Quell, our wearable device for chronic pain. We cannot assure you that we will be successful with these products or future product candidates or product enhancements in our development pipeline.

DPNCheck was launched in 2011 and is a nerve conduction test for peripheral neuropathies such as diabetic peripheral neuropathy. Our sales strategy for DPNCheck targets the U.S. Medicare Advantage (MA) sector through our own commercial team and physician offices and hospitals in Japan and China through distribution partners.

The MA market is currently experiencing uncertainty due to changes in several aspects of the program recently proposed by the CMS. On January 30, 2023, CMS issued a final rule regarding the MA Risk Adjustment Data Validation (RADV) program that is used to recover improper risk adjustment payments made to MA plans. Also on February 1, 2023, CMS issued its 2024 Medicare Advantage Advance Notice, which proposed substantial changes to the Hierarchical Condition Categories (HCC) risk adjustment model for calendar year 2024. The proposal includes changes that limit HCC codes for some types of peripheral neuropathies.

The eventual impact of these factors and related uncertainty is unclear; however, there could be a material effect on future DPNCheck revenues and margins. We have been advised that some of our customers may elect to pause or reduce, potentially substantially, the amount of DPNCheck tests they perform. We are unable at this time to predict with specificity the impact this may have on our revenues in future periods.

Quell was launched in June 2015 and is a wearable neuromodulation device for the symptomatic relief and management of chronic pain indications. We are leveraging our core Quell technology into a portfolio of prescription wearable neurotherapeutics. Quell Fibromyalgia, the first product in this emerging portfolio, was launched in late 2022 as an aid for reducing the symptoms of fibromyalgia in adults with high pain sensitivity.

Our future prospects are closely tied to our success with DPNCheck and Quell, which, in turn, depend upon market acceptance and growth in future revenues and margins. We cannot assure you that our commercialization strategy will be successful. If our strategy is not successful, it could materially affect our revenues and results of operations.

Our future success could be adversely affected by a number of factors, including:
- inability to increase adoption of DPNCheck within the MA market and outside the United States;
- regulatory inquiries or issues affecting our products;
- unfavorable changes to current Medicare, Medicare Advantage and commercial payer payment policies;
- changes to payor policies under the Patient Protection and Affordable Care Act;
- inability to efficiently create market demand for prescription wearable neurotherapeutics based on Quell technology at profitable pricing and with efficient marketing;
- manufacturing issues with Quell or our other products;
- unfavorable experiences by patients and physicians using DPNCheck, Quell and our other products; and,

- physicians’ or patients' reluctance to alter their existing practices and adopt the use of our devices.

If we are unable to expand exposure and market demand for DPNCheck and Quell, our ability to increase our revenues will be limited and our business prospects will be adversely affected.

Our current and future revenue is dependent upon commercial acceptance of our products in the marketplace. If our products are not accepted by prescribers and customers, our operations will be materially and adversely affected.

We will continue to incur operating losses until such time as sales of DPNCheck, Quell and other products or product candidates reach a mature level and we are able to generate sufficient revenue from their sale to meet our operating expenses. There can be no assurance that customers will adopt our technology and products, or that prospective customers will agree to pay for our products. In the event that we are not able to significantly increase the number of customers that purchase our products, or if we are unable to charge the necessary prices, our financial condition and results of operations will be materially and adversely affected.

If health care providers are unable to obtain sufficient reimbursement or other financial incentives from third-party health care payers related to the use of our products other than Quell, their adoption and our future product sales will be materially adversely affected.

Widespread adoption of our diagnostic products by the medical community is unlikely to occur without a financial incentive from third-party payers for the use of these products. If health care providers are unable to obtain adequate reimbursement for procedures performed using these products, and if managed care organizations do not receive improved capitated payments due to more accurate patient risk assessment using our products, we may be unable to sell our products at levels that are sufficient to allow us to achieve and maintain profitability, and our business would suffer significantly. Additionally, even if these products and procedures are adequately reimbursed by third-party payers today, adverse changes in payers future policies toward payment would harm our ability to market and sell our products. Third-party payers include governmental programs such as Medicare and Medicaid, private health insurers, workers’ compensation programs and other organizations.

Future regulatory action by CMS or other governmental agencies or negative clinical results may diminish reimbursement payments to physicians for performing procedures using our products. Medicaid reimbursement differs from state to state, and some state Medicaid programs may not cover the procedures performed with our products or pay physicians an adequate amount for performing those procedures, if at all. Additionally, some private payers do not follow the Medicare guidelines and may reimburse for only a portion of these procedures or not at all. We are unable to predict what changes will be made in the reimbursement methods used by private or governmental third-party payers.

The clinical study process is lengthy and expensive with uncertain outcomes. Results of earlier studies may not be predictive of future clinical study results, or the safety profile for such products or products under development.

Clinical testing is difficult to design and implement, can take many years, can be expensive, and carries uncertain outcomes. The results of clinical studies of our products conducted to date and ongoing or future studies of our current, planned, or future products and product candidates may not be predictive of the results of later clinical studies, and interim results of a clinical study do not necessarily predict final results. Our interpretation of data and results from our clinical studies do not ensure that we will achieve similar results in future clinical studies. In addition, clinical data is often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in clinical studies have nonetheless failed to replicate results in later clinical studies. Products in later stages of clinical studies may fail to show the desired safety and efficacy despite having progressed through nonclinical studies. Failure can occur at any stage of clinical testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned.

We rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing our product candidates.

We rely on contract research organizations, medical institutions, clinical investigators, and contract laboratories to perform data collection and analysis and other aspects of our clinical trials. Our clinical trials may be delayed, suspended, or terminated if: the quality or accuracy of the data obtained by the third parties on whom we rely is compromised due to their failure to

adhere to our clinical protocols or regulatory requirements or if for other reasons, these third parties do not successfully carry out their contractual duties or fail to meet regulatory obligations or expected deadlines, or these third parties need to be replaced.

If the third parties on whom we rely fail to perform, our development costs may increase, our ability to obtain regulatory approval, and consequently, to commercialize our product candidates may be delayed or prevented altogether. We currently support medical institutions who are conducting clinical trials related to our products. While we believe that there are alternative approaches to theses medical institutions, in the event that we seek such alternative sources we may not be able to enter into replacement arrangements without delays or incurring additional expenses.

We depend on several single source manufacturers to produce components of our products. Any material adverse changes in our relationships with these manufacturers, or material supply chain delays, could prevent us from delivering products to our customers in a timely manner and may adversely impact our future revenues or costs.

We rely on third-party manufacturers to manufacture components of our Quell, DPNCheck and ADVANCE systems. In the event that our manufacturers cease to manufacture sufficient quantities of our products or components in a timely manner and on terms acceptable to us, we would be forced to locate alternate manufacturers. Additionally, if our manufacturers experience a failure in their production process, are unable to obtain sufficient quantities of the components necessary to manufacture our products, experience extraordinary price increases on parts essential to our products or otherwise fail to meet our quality requirements, we may be forced to delay the manufacture and sale of our products or to locate an alternative manufacturer. We may be unable to locate suitable alternative manufacturers for our products or components for which the manufacturing process is relatively specialized, on terms acceptable to us, or at all. While we have long-standing relationships with our primary suppliers for device components, electrodes and biosensors, these suppliers are, in turn, dependent on other manufacturers of electronic parts and components, and are therefore subject to supply/demand risks of the electronic parts and components marketplace, and the potential for parts obsolescence. As a result, there is a risk that certain parts and components could be in short supply at a time when required by us or they could be discontinued and no longer available to us. Supply of electronic parts and components is presently constrained on a worldwide basis. Situations of long lead times, stock-out, order repricing and cancellations are increasingly common.

We are experiencing transient inventory shortages on our products and essential parts. If any materially adverse changes in our relationships with manufacturers or parts suppliers occur, our ability to supply our customers will be severely limited until we are able to engage an alternate manufacturer or parts supplier or, if applicable, resolve any quality issues with our existing manufacturer. This situation could prevent us from delivering products to our customers in a timely manner, lead to decreased sales or increased costs, or harm our reputation with our customers.

If our manufacturers are unable to supply us with an adequate supply of product components, we could lose customers, our potential future growth could be limited and our business could be harmed.

In order for us to successfully expand our business, our contract manufacturers must be able to provide us with substantial quantities of components of our products in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable cost and on a timely basis. Our potential future growth, coupled with the global supply chain constraints and disruptions caused by the COVID-19 pandemic, could strain the ability of our manufacturers to deliver products and obtain materials and components in sufficient quantities. Manufacturers often experience difficulties in scaling up production, including problems with production yields and quality control and assurance. If we are unable to obtain sufficient quantities of high quality products to meet customer demand on a timely basis, we could lose customers, our growth may be limited and our business could be harmed.

The success of our business depends upon our ability to advance our pipeline products to commercialization.

We commenced commercialization of Quell in June 2015 and we completed a DPNCheck product upgrade during 2022. We have additional product candidates and enhancements of our existing products in our R&D pipeline. We expect that advancing our pipeline products will require significant time and resources. We may not be successful in our commercialization efforts for any of the product candidates or product enhancements currently in our pipeline and we may not be successful in developing, acquiring, or in licensing additional product candidates, to the extent we decide to do so. If we are not successful in advancing new products through our development pipeline, the regulatory process and commercial launch, our business, financial condition, and results of operations will be adversely affected.

Our ability to achieve profitability depends in part on maintaining or increasing our gross margins on product sales which we may not be able to achieve.

A number of factors may adversely impact our gross margins on product sales and services, including:

- shortages of electric components resulting in higher prices or an inability to supply key parts;
- low production volume which will result in high levels of overhead cost per unit of production;
- increased material or labor costs;
- increased service or warranty costs or the failure to reduce service or warranty costs;
- increased price competition;
- variation in the margins across products in a particular period; and
- how well we execute on our strategic and operating plans.

If we are unable to maintain or increase our gross margins on product sales, our results of operations could be adversely impacted, we may not achieve profitability and our stock price could decline.

If we lose any of our officers or key employees, our management and technical expertise could be weakened significantly.

Our success largely depends on the skills, experience, and efforts of our executive officers, Shai N. Gozani, M.D., Ph.D., our founder, Chairman, President and Chief Executive Officer, and Thomas T. Higgins, our Senior Vice President and Chief Financial Officer. We do not maintain key person life insurance policies covering any of our employees. The loss of either of our executive officers could weaken our management and technical expertise significantly and harm our business.

If we are unable to recruit, hire and retain skilled and experienced personnel, our ability to manage and expand our business will be harmed, which would impair our future revenues and profitability.

We are a small company with 27 employees as of December 31, 2022, and our ability to retain our skilled labor force and our success in attracting and hiring new skilled employees will be a critical factor in determining our future performance. We may not be able to meet our future hiring needs or retain existing personnel, particularly given the challenges faced by our business. We will face challenges and risks in hiring, training, managing and retaining engineering and sales and marketing employees. Failure to attract and retain personnel, particularly technical and sales and marketing personnel would materially harm our ability to compete effectively and grow our business.

Failure to develop or enter into relationships to sell products other than our existing products or enhance our existing products could have an adverse effect on our business prospects.

Our future business and financial success will depend, in part, on our ability to effectively market our products, including DPNCheck and Quell, and to enhance these products in response to customer demand. Developing new products and upgrades to existing and future products imposes burdens on our research and development department and our management. This process is costly, and we cannot assure you that we will be able to successfully develop new products or enhance our current products. We also may not be able to enter into relationships with other companies to sell additional products. In addition, as we develop the market for our products, future competitors may develop desirable product features earlier than we do which could make our competitors' products less expensive or more effective than our products and could render our products obsolete or unmarketable. If our product development efforts are unsuccessful, we will have incurred significant costs without recognizing the expected benefits and our business prospects may suffer.

If we are unable to develop new products or enhance existing products, we may be unable to attract or retain customers.

Our success depends on the successful development, regulatory clearance or approval (if required), introduction and commercialization of new generations of products, treatment systems, and enhancements to and/or simplification of existing products. DPNCheck and Quell must keep pace with, among other things, the products of our competitors. We are making significant investments in long-term growth initiatives. Such initiatives require significant capital commitments, involvement of senior management and other investments on our part, which we may be unable to recover. Our timeline for the development of new products or enhancements may not be achieved and price and profitability targets may not prove feasible. Commercialization of new products may prove challenging, and we may be required to invest more time and money than

expected to successfully introduce them. Once introduced, new products may adversely impact orders and sales of our existing products, or make them less desirable or even obsolete. Compliance with regulations, competitive alternatives, and shifting market preferences may also impact the successful implementation of new products or enhancements.

Our ability to successfully develop and introduce new products and product enhancements, and the revenues and costs associated with these efforts, may be affected by our ability to:

- properly identify customer needs;
- prove feasibility of new products in a timely manner;
- educate physicians about the use of new products and procedures;
- comply with internal quality assurance systems and processes timely and efficiently;
- comply with regulatory requirements relating to our products, and limit the timing and cost of obtaining required regulatory approvals or clearances;
- accurately predict and control costs associated with inventory overruns caused by phase-in of new products and phase-out of old products;
- price new products competitively;
- manufacture and deliver our products in sufficient volumes on time, and accurately predict and control costs associated with manufacture of the products; and
- meet our product development plan and launch timelines.

Even if customers accept new products or product enhancements, the revenues from these products may not be sufficient to offset the significant costs associated with making them available to customers. Failure to successfully develop, obtain regulatory approval or clearance for, manufacture or introduce new products or to complete these processes in a timely and efficient manner could result in delays that could affect our ability to attract and retain customers, or could cause customers to delay or cancel orders, causing our backlog, revenues and operating results to suffer.

We currently compete, and may in the future need to compete, against other medical device and consumer companies with greater resources, more established distribution channels and other competitive advantages, and the success of these competitors may harm our ability to generate revenues.

We currently do, and in the future may need to, compete directly and indirectly with a number of other companies that may have competitive advantages over us. Our diagnostic devices for nerve testing compete with companies that sell traditional nerve conduction study and electromyography equipment including Cadwell Laboratories, Inc. and Natus Medical Incorporated. These companies enjoy significant competitive advantages, including:

- greater resources for product development, sales and marketing;
- more established distribution networks;
- greater name recognition;
- more established relationships with health care professionals, customers and third-party payers; and
- additional lines of products and the ability to offer rebates or bundle products to offer discounts or incentives.

As we develop the market for wearable technology for chronic pain, we will be faced with competition from other companies that decide and are able to enter the market as well as competition from other forms of treatment for chronic pain. Some or all of our future competitors in the diagnostic nerve testing market and the chronic pain market may enjoy competitive advantages such as those described above. If we are unable to compete effectively against existing and future competitors, our sales will decline and our business will be harmed.

Security breaches and other disruptions could compromise our information and expose us to liability, which could cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data in our data centers, on our networks, including intellectual property, our proprietary business information, and that of our customers, suppliers and business partners, and personally identifiable information of our employees. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, disrupt our operations, damage our reputation, and cause a loss of confidence in our products and services, which could have a material adverse effect on our business, financial condition, results of operations or cash flows.

If future clinical studies or other articles are published, or physician associations or other organizations announce positions that are unfavorable to our products, our sales efforts and revenues may be negatively affected.

Future clinical studies or other articles regarding our existing products or any competing products may be published that either support a claim, or are perceived to support a claim, that a competitor's product is more accurate or effective than our products or that our products are not as accurate or effective as we claim or previous clinical studies have concluded. Additionally, physician associations or other organizations that may be viewed as authoritative or have an economic interest in nerve conduction studies and in related electrodiagnostic procedures or other procedures that may be performed using our products or in neurostimulation therapies using our devices could endorse products or methods that compete with our products or otherwise announce positions that are unfavorable to our products. Any of these events may negatively affect our sales efforts and result in decreased revenues.

If we expand in foreign markets, we will be affected by new business risks that may adversely impact our financial condition or results of operations.

Foreign markets represented approximately 14% of our revenues in 2022 and 2021. We are evaluating future expansion, particularly in Asia. Any such expansion will subject us to the possibility of new business risks, including:

- failure to fulfill foreign regulatory requirements, if applicable, to market our products;
- availability of, and changes in, reimbursement within prevailing foreign health care payment systems;
- adapting to the differing business practices and laws in foreign countries;
- difficulties in managing foreign relationships and operations, including any relationships that we establish with foreign distributors or sales or marketing agents;
- limited protection for intellectual property rights in some countries;
- difficulty in collecting accounts receivable and longer collection periods;
- costs of enforcing contractual obligations in foreign jurisdictions;
- recessions in economies outside of the United States;
- political instability and unexpected changes in diplomatic and trade relationships;
- currency exchange rate fluctuations; and
- potentially adverse tax consequences.

If we are successful in introducing our products into foreign markets, we will be affected by these additional business risks, which may adversely impact our financial condition or results of operations. In addition, expansion into foreign markets imposes additional burdens on our executive and administrative personnel, research and sales departments, and general managerial resources. Any efforts to introduce our products into foreign markets may not be successful, in which case we may have expended significant resources without realizing the expected benefit.

Risks Related to Government Regulation and Other Legal Compliance Matters

We are subject to extensive regulation by the FDA and other federal and state regulators which could restrict the sales and marketing of Quell, DPNCheck and ADVANCE, as well as other products for which we may seek FDA clearance or approval, and could cause us to incur significant costs.

We sell medical devices that are subject to extensive regulation in the United States by the FDA with regard to manufacturing, labeling, sale, promotion, distribution, shipping and ongoing monitoring and follow-up. Before a new medical device, or a new use of or claim for an existing product, can be marketed in the United States, it must first be cleared or approved by the FDA. Medical devices may be marketed only for the indications for which they are approved or cleared. The regulatory review process can be expensive and lengthy. The FDA's process for granting 510(k) clearance typically takes approximately three to six months, and for De Novo clearance approximately five months to one year. However, in both cases it can be significantly longer. The process for obtaining a pre-market approval (PMA) is much more costly and onerous. By law, the time period designated for the FDA's review of a PMA is 180 days; however, this time is often extended and it is not uncommon for the PMA review process to take three years or longer from the time the application is filed with the FDA.

The FDA may remove our devices from the market or enjoin them from commercial distribution if safety or effectiveness problems develop. Further, we may not be able to obtain additional 510(k) clearances, De Novo clearances or pre-market approvals for new products or for modifications to, or additional indications for, our existing products in a timely fashion, or at

all. Delays in obtaining future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and future profitability. We have made modifications to our devices in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices. If any of these events occurs or if the FDA takes other enforcement actions, we may not be able to provide our customers with the products they require on a timely basis, our reputation could be harmed, and we could lose customers and suffer reduced revenues and increased costs.

We also are subject to numerous post-marketing regulatory requirements, including the FDA's quality system regulations, which relate to the design, manufacture, packaging, labeling, storage, installation and servicing of our products, labeling regulations, medical device reporting regulations and correction and removal reporting regulations. Third-party pharmacies, including online pharmacies, and other distributors of our products may also be subject to federal, state and local licensing, accreditation and other regulatory requirements. Our failure or the failure by any manufacturer, pharmacy or distributor of our products to comply with applicable regulatory requirements could result in enforcement action by the FDA or other regulators or it could result in delays in the distribution of our products. FDA enforcement actions relating to post-marketing regulatory requirements or other issues may include any of the following:

•warning letters, untitled letters, fines, injunctions, product seizures, consent decrees and civil penalties;
•requiring repair, replacement, refunds, customer notifications or recall of our products;
•imposing operating restrictions, suspension or shutdown of production;
•refusing our requests for 510(k) clearance or PMA approval of new products, new intended uses, or modifications to existing products;
•requesting voluntary rescission of 510(k) clearances or withdrawing PMA approvals that have already been granted; and
•criminal prosecution.

If any of these events were to occur, they could harm our reputation, our ability to generate revenues and our profitability.

Also, from time to time, legislation is introduced into Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of medical devices. FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be. The FDA has publicly stated that it is reevaluating its longstanding 510(k) review program. It is not clear when, or if, the program will be modified and what effect the modified review process will have on our ability to bring our product candidates to market.

If we or our manufacturers fail to comply with the FDA's quality system regulation, the manufacturing and distribution of our products could be interrupted, and our product sales and operating results could suffer.

We and our contract manufacturers are required to comply with the FDA's quality system regulation, or QSR, which is a complex regulation that governs the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our devices. The FDA enforces the QSR through periodic inspections. We cannot assure you that our facilities or the facilities of the manufacturers of our products would pass any future inspection. If our facilities or any of the facilities of the manufacturers of our products fail an inspection, the manufacturing or distribution of our products could be interrupted and our operations disrupted. Failure to take adequate and timely corrective action in response to an adverse inspection could result in a suspension or shutdown of our packaging and labeling operations and the operations of the manufacturers of our products or a recall of our products, or other administrative or judicial sanctions. If any of these events occurs, we may not be able to provide our customers with the quantity of products they require on a timely basis, our reputation could be harmed, and we could lose customers and suffer reduced revenues and increased costs.

We are subject to Federal Trade Commission regulatory oversight. Exercise of this regulatory oversight could lead to an outcome which would constrain our marketing of Quell, cause us to incur significant costs and penalties, and adversely affect our financial results.

Under the Federal Trade Commission Act (FTC Act), the FTC is empowered, among other things, to (a) prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce; (b) seek monetary redress and other relief for conduct injurious to consumers; and (c) gather and compile information and conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce. The FTC has very broad enforcement authority, and failure to abide by the substantive requirements of the FTC Act and other consumer protection laws can result in administrative or judicial penalties, including civil penalties, or injunctions affecting the manner in which we would be able to market Quell in the future.

Our products may be subject to recalls, even after receiving FDA clearance or approval, which would harm our reputation, business and financial results.

We are subject to the medical device reporting regulations, which require us to report to the FDA if our products may have caused or contributed to a death or serious injury, or have malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to occur. We are also subject to the correction and removal reporting regulations, which require us to report to the FDA any field corrections and device recalls or removals that we undertake to reduce a risk to health posed by the device or to remedy a violation of the Federal Food, Drug and Cosmetic Act, or FDCA, caused by the device which may present a risk to health. In addition, the FDA and similar governmental agencies in other countries have the authority to require the recall of our products if there is a reasonable probability that the products would cause serious adverse health consequences or death. A government-mandated or voluntary recall by us could occur as a result of manufacturing defects, labeling deficiencies, packaging defects or other failures to comply with applicable regulations. Any recall would divert management attention and financial resources and harm our reputation with customers and could have a material adverse effect on our financial condition and results of operations.

We are subject to federal and state laws prohibiting "kickbacks" and false or fraudulent claims, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

A federal law commonly known as the federal anti-kickback law, and several similar state laws, prohibit the payment of any remuneration that is intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of health care products or services. These laws constrain a medical device company's sales, marketing and other promotional activities by limiting the kinds of business relationships and financial arrangements, including sales programs we may have with hospitals, pharmacies (including online pharmacies), physicians or other potential purchasers of medical devices. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment to Medicare, Medicaid or other third-party payers that are false or fraudulent, or for items or services that were not provided as claimed. We rely on third party health care organizations, pharmacies (including online pharmacies) and distributors to fulfill orders of our products. In addition, from time to time, we may provide coding and billing information as product support to purchasers of our products. Our relationships with health care organizations, pharmacies and other third parties could be scrutinized under federal and state health care laws such as the anti-kickback laws. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance, which can be quite substantial including exclusion from participation in federal health care programs. A number of states have enacted laws that require pharmaceutical and medical device companies to monitor and report payments, gifts and other remuneration made to physicians and other health care professionals and health care organizations. Some state statutes, such as the one in Massachusetts, impose an outright ban on gifts to physicians. These laws are often referred to as "gift ban" or "aggregate spend" laws and carry substantial fines if they are violated. Similar legislation, known as the Physician Payments Sunshine Act, was enacted by Congress during 2014. In the event that we are found to have violated these laws or determine to settle a claim that we have done so, our business may be materially adversely affected as a result of any payments required to be made, restrictions on our future operations or actions required to be taken, damage to our business reputation or adverse publicity in connection with such a finding or settlement or other adverse effects relating thereto. Additionally, even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could harm our business and results of operations.

If we are found to have violated laws protecting the confidentiality of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities, damage our reputation and harm our business.

There are a number of federal and state laws protecting the confidentiality of individually identifiable patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services promulgated patient privacy rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. These privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. Any failure or perceived failure by us or any third-party distributors, pharmacies, service providers, contractors or consultants to comply with privacy, confidentiality, data security or similar obligations, or any data security incidents or other security breaches that result in the accidental, unlawful or unauthorized access to, use of, release of, or transfer of sensitive information, may result in negative publicity, harm to our reputation, governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us, could cause third parties to lose trust in us or

could result in claims by third parties, including class action lawsuits, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations.

The use of our products could result in product liability claims that could be expensive, damage our reputation and harm our business.

Our business exposes us to an inherent risk of potential product liability claims related to the manufacturing, marketing and sale of medical devices. The medical device industry historically has been litigious, and we face financial exposure to product liability claims if the use of our products were to cause or contribute to injury or death. Our products may be susceptible to claims of injury because their use involves the electric stimulation of a patient's nerves. Although we maintain product liability insurance for our products and other commercial insurance, the coverage limits of these policies may not be adequate to cover future claims. We may be unable to maintain sufficient product liability or other commercial insurance on acceptable terms or at reasonable costs, and this insurance may not provide us with adequate coverage against potential liabilities. A successful claim brought against us in excess of, or outside of, our insurance coverage could have a material adverse effect on our financial condition and results of operations. A product liability claim, regardless of its merit or eventual outcome, could result in substantial costs to us, a substantial diversion of management attention and adverse publicity. A product liability claim could also harm our reputation and result in a decline in revenues and an increase in expenses.

Our products are complex in design, and defects may not be discovered prior to shipment to customers, which could result in warranty obligations or product liability or other claims, reducing our revenues and increasing our costs and liabilities.

We depend upon third parties for the manufacture of our products or components. Our products, particularly our electrodes, require a significant degree of technical expertise to produce. If these manufacturers fail to produce our products to specification, or if the manufacturers use defective materials or workmanship in the manufacturing process, the reliability and performance of our products will be compromised.
If our products contain defects that cannot be repaired quickly, easily and inexpensively, we may experience:

- loss of customer orders and delay in order fulfillment;
- damage to our brand reputation;
- increased cost of our warranty program due to product repair or replacement;
- inability to attract new customers;
- diversion of resources from our manufacturing and research and development departments into our service department; and
- legal action.

The occurrence of any one or more of the foregoing could harm our reputation and materially reduce our revenues and increase our costs and liabilities.

Risks Related to Our Intellectual Property

The patent rights we rely upon to protect the intellectual property underlying our products may not be adequate, which could enable third parties to use our technology and would harm our ability to compete in the market.

Our success will depend in part on our ability to develop or acquire commercially valuable patent rights and to protect these rights adequately. The risks and uncertainties that we face with respect to our patents and other related rights include the following:

- the pending patent applications we have filed or to which we have exclusive rights may not result in issued patents or may take longer than we expect to result in issued patents;
- the claims of any patents that are issued may not provide meaningful protection;
- we may not be able to develop additional proprietary technologies that are patentable;
- other parties may challenge patents, patent claims or patent applications licensed or issued to us; and
- other companies may design around technologies we have patented, licensed or developed.

Our issued and filed patents for our wearable therapeutic products are recent. With regard to our legacy neurodiagnostic products, our issued design patents began to expire in 2015, and our issued utility patents began to expire in 2017. In particular, seven of our issued U.S. utility patents covering various aspects of the legacy neurodiagnostic business expired on the same day in 2017. Although the patent protection for material aspects of these products covered by the claims of the patents were lost at

that time, we have additional patents and patent applications directed to other novel inventions that have patent terms extending beyond 2023.

In addition, the laws of other countries may not protect our patent rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Many companies have encountered significant difficulties in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, including certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to medical devices, which could make it difficult for us to stop the infringement of our patent rights or the marketing of competing products in violation of our intellectual property and proprietary rights generally. For this or other reasons, we may not pursue or obtain patent protection in all major markets or may not obtain protection that enables us to prevent the entry of third parties onto the market.

Additionally, proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Further, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

In addition, our patent rights underlying our products may not be adequate, and our competitors or customers may design around our proprietary technologies or independently develop similar or alternative technologies or products that are equal or superior to our technology and products without infringing on any of our patent rights. In addition, the patents licensed or issued to us may not provide a competitive advantage. If any of these events were to occur, our ability to compete in the market would be harmed.

Other rights and measures we have taken to protect our intellectual property may not be adequate, which would harm our ability to compete in the market.

In addition to patents, we rely on a combination of trade secrets, copyright and trademark laws, confidentiality, nondisclosure and assignment of invention agreements and other contractual provisions and technical measures to protect our intellectual property rights. We rely on trade secrets to protect the technology and algorithms we use in our customer data processing and warehousing information system. While we currently require employees, consultants and other third parties to enter into confidentiality, non-disclosure or assignment of invention agreements or a combination thereof where appropriate, any of the following could still occur:

- the agreements may be breached or not enforced in a particular jurisdiction;
- we may have inadequate remedies for any breach;
- trade secrets and other proprietary information could be disclosed to our competitors; or
- others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technologies.

If, for any of the above reasons, our intellectual property is disclosed or misappropriated, it would harm our ability to protect our rights and our competitive position.

We may need to initiate lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive and, if we lose, could cause us to lose some of our intellectual property rights, which would harm our ability to compete in the market.

We rely on patents to protect a portion of our intellectual property and our competitive position. Patent law relating to the scope of claims in the technology fields in which we operate is still evolving and, consequently, patent positions in the medical

device industry are generally uncertain. In order to protect or enforce our patent rights, we may initiate patent litigation against third parties, such as infringement suits or interference proceedings. Litigation may be necessary to:

- assert claims of infringement;
- enforce our patents;
- protect our trade secrets or know-how; or
- determine the enforceability, scope and validity of the proprietary rights of others.

Any lawsuits that we initiate could be expensive, take significant time and divert management's attention from other business concerns. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially valuable. The occurrence of any of these events could harm our business, our ability to compete in the market or our reputation.

Claims that our products infringe on the proprietary rights of others could adversely affect our ability to sell our products and increase our costs.

Substantial litigation over intellectual property rights exists in the medical device industry. We expect that our products could be increasingly subject to third-party infringement claims as the number of competitors grows and the functionality of products and technology in different industry segments overlap. Third parties may currently have, or may eventually be issued, patents on which our products or technologies may infringe. Any of these third parties might make a claim of infringement against us. Any litigation regardless of its impact would likely result in the expenditure of significant financial resources and the diversion of management's time and resources. In addition, litigation in which we are accused of infringement may cause negative publicity, adversely impact prospective customers, cause product shipment delays or require us to develop non-infringing technology, make substantial payments to third parties, or enter into royalty or license agreements, which may not be available on acceptable terms, or at all. If a successful claim of infringement were made against us and we could not develop non-infringing technology or license the infringed or similar technology on a timely and cost-effective basis, our revenues may decrease substantially and we could be exposed to significant liability.

Risks Related to Our Common Stock

We identified a material weakness in our internal control over financial reporting. If our remediation measures are ineffective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to report our financial condition or results of operations accurately or in a timely manner and we may be unable to maintain compliance with applicable stock exchange listing requirements, which may adversely affect investor confidence in us and, as a result, materially and adversely affect our business and the value of our common stock.

In connection with our financial statement close process for the year ended December 31, 2022, we identified a material weakness in our internal control over financial reporting. A "material weakness" is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented, or detected and corrected on a timely basis.

The material weakness identified during the audit of our financial statements for the year ended December 31, 2022 relates to inventory accounting. Specifically, we have concluded that our internal controls were not able to ensure the proper review and determination of inventory costing, and the valuation of our net realizable inventory.

To address this material weakness, our management has taken, and continues to take, remedial actions. We have reviewed and are updating our internal control framework. We expanded our period-end closing process to require that the Corporate Controller perform and document a review of inventory costing and also prepare an analysis of inventory net realizable value, which analysis is required to be reviewed and approved by the Chief Financial Officer.

Our remediation plan is underway; however, the elements of our remediation plan can only be fully accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects or that other material weaknesses and control deficiencies will not be discovered in the future.

If our efforts are not successful or other material weaknesses or control deficiencies occur in the future, we may be unable to report our financial results accurately on a timely basis or help prevent fraud, which could cause our reported financial results to be materially misstated and result in the loss of investor confidence or delisting and cause the market price of our shares to decline. We cannot assure you that the initiatives we have taken to date, or any initiatives we may take in the future, will be sufficient to avoid potential future material weaknesses.

Future sales of securities may cause our stock price to decline as a result of the dilution which will occur to existing stockholders.

Until such time as we are profitable, as to which we can make no assurance, we may need additional funds to develop our business and sustain our operations. We have sold shares of common stock, convertible preferred stock and warrants on several occasions in the past, and any additional sales of shares of our common stock or other securities exercisable into our common stock are likely to have a dilutive effect on some or all of our then existing stockholders. Resales of newly issued shares in the open market could also have the effect of lowering our stock price, thereby increasing the number of shares we may need to issue in the future to raise the same dollar amount and consequently further diluting our outstanding shares.

The perceived risk associated with the possible sale of a large number of shares could cause some of our stockholders to sell their stock, thus causing the price of our stock to decline. In addition, actual or anticipated downward pressure on our stock price due to actual or anticipated issuances or sales of stock could cause some institutions or individuals to engage in short sales of our common stock, which may itself cause the price of our stock to decline.

If our stock price declines, it may be difficult to raise additional capital and it could impair our ability to attract and retain qualified employees, reduce the liquidity of our common stock, and result in the delisting of our common stock from The Nasdaq Stock Market LLC, or Nasdaq.

The trading price of our common stock has been volatile and is likely to be volatile in the future.

The trading price of our common stock has been highly volatile. For the two-year period ended December 31, 2022, our stock price has fluctuated from a low of $1.33 to a high of $38.75. The market price for our common stock will be affected by a number of factors, including:

- the denial or delay of regulatory clearances or approvals for our products under development or receipt of regulatory approval of competing products;
- our ability to accomplish clinical, regulatory and other product development and commercialization milestones and to do so in accordance with our timing estimates;
- changes in policies affecting third-party coverage and reimbursement in the United States and other countries;
- changes in government regulations and standards affecting the medical device industry and our products;
- ability of our products to achieve market success;
- the performance of third-party contract manufacturers and component suppliers;
- actual or anticipated variations in our results of operations or those of our competitors;
- announcements of new products, technological innovations or product advancements by us or our competitors;
- developments with respect to patents and other intellectual property rights;
- sales of common stock or other securities by us or our stockholders in the future;
- additions or departures of key scientific or management personnel;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- trading volume of our common stock;
- regulatory inquiries or developments affecting our products;
- changes in earnings estimates or recommendations by securities analysts, failure to obtain or maintain analyst coverage of our common stock or our failure to achieve analyst earnings estimates;
- public statements by analysts or clinicians regarding their perceptions of our clinical results or the effectiveness of our products;
- decreases in market valuations of medical device companies; and
- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors.

The stock prices of many companies in the medical device industry have experienced wide fluctuations that have often been unrelated to the operating performance of these companies. Periods of volatility in the market price of a company's securities can result in securities class action litigation against a company. If class action litigation is initiated against us, we may incur substantial costs and our management's attention may be diverted from our operations, which could significantly harm our business.

We have, in the past, failed to satisfy certain continued listing requirements on Nasdaq and could fail to satisfy those requirements again in the future which could affect the market price of our common stock and liquidity and reduce our ability to raise capital.

Currently, our common stock trades on the Nasdaq Capital Market. If we fail to maintain compliance with any Nasdaq listing requirements, including minimum bid price for our common stock, we could be delisted and our stock would be considered a penny stock under regulations of the Securities and Exchange Commission, or SEC, and would therefore be subject to rules that impose additional sales practice requirements on broker-dealers who sell our securities. The additional burdens imposed upon broker-dealers by these requirements could discourage broker-dealers from effecting transactions in our common stock, which could severely limit the market liquidity of our common stock and your ability to sell our securities in the secondary market.

Anti-takeover provisions in our organizational documents and Delaware law, and the shareholder rights plan that we adopted in 2007 and updated in 2021, may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Our certificate of incorporation and bylaws contain provisions that could delay or prevent a change of control of our Company or changes in our Board of Directors that our stockholders might consider favorable. Some of these provisions:

- authorize the issuance of preferred stock which can be created and issued by the Board of Directors without prior stockholder approval, with rights senior to those of our common stock;
- provide for a classified Board of Directors, with each director serving a staggered three-year term;
- prohibit our stockholders from filling board vacancies, calling special stockholder meetings, or taking action by written consent;
- provide for the removal of a director only with cause and by the affirmative vote of the holders of 75% or more of the shares then entitled to vote at an election of our directors; and
- require advance written notice of stockholder proposals and director nominations.

We have also adopted a shareholder rights plan that could make it more difficult for a third party to acquire, or could discourage a third party from acquiring, us or a large block of our common stock. A third party that acquires 15% or more of our common stock could suffer substantial dilution of its ownership interest under the terms of the shareholder rights plan through the issuance of common stock to all stockholders other than the acquiring person.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our certificate of incorporation, bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our Board of Directors or initiate actions that are opposed by our then-current Board of Directors, including a merger, tender offer, or proxy contest involving our Company. Any delay or prevention of a change of control transaction or changes in our Board of Directors could cause the market price of our common stock to decline.

We do not intend to pay cash dividends.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of potential gain for the foreseeable future.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our headquarters, engineering activities, and manufacturing and fulfillment activities are located in an approximately 10,000 square foot leased facility in Woburn, Massachusetts. We believe this facility will be adequate for our needs during the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

The Company is not party to any legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is traded on the Nasdaq Capital Market under the symbol "NURO".

Stockholders

On March 21, 2023, there were approximately 45 stockholders of record of our common stock. This number does not include stockholders for whom shares were held in a "nominee" or "street" name. On March 21, 2023, the last reported sale price per share of our common stock on the Nasdaq Capital Market was $1.48.

Unregistered Sales of Securities

Not applicable

Issuer Purchases of Equity Securities

Not applicable

ITEM 6. [RESERVED]

ITEM 7. 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 selected financial data, our financial statements, and the accompanying notes to those financial statements included elsewhere in this Annual Report on Form 10-K. 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 section titled "Risk Factors", contained in Item 1A of this Annual Report on Form 10-K.

Our Business

NeuroMetrix is a commercial stage neurotechnology company based in Woburn, MA. The Company's mission is to improve individual and population health through innovative medical devices and technology solutions for neurological disorders and pain syndromes. We are fully integrated with in-house capabilities spanning research and development, manufacturing, regulatory affairs and compliance, sales and marketing, product fulfillment and customer support. We hold extensive, proprietary intellectual property.

NeuroMetrix created the market for point-of-care nerve testing and introduced sophisticated wearable technology for chronic pain syndromes. Over five million patients have been served with our products. Revenue is derived from the sale of medical devices and after-market consumable products and accessories in the United States and select overseas markets. Products are authorized by the FDA and regulators in foreign jurisdictions where appropriate. We have two principal product categories:

- Diagnostic technology - point-of-care peripheral neuropathy assessment
- Therapeutic technology – wearable neuromodulation for chronic pain syndromes

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 unmet medical need and is particularly effective in screening large populations including the value-based care models such as Medicare Advantage. DPNCheck has been evaluated in numerous clinical studies. It contributes attractive gross margins and has posted average revenue growth of 15% to 20% over the past five years. We believe there is significant, accessible opportunity to expand DPNCheck usage. Towards that goal, we have expanded our dedicated DPNCheck commercial resources and recently launched our next generation technology which enhances the user experience and improves testing efficiency while continuing to deliver quantitative test results and high overall sensitivity and specificity. It also addresses obsolescence issues in the predecessor device.

Our DPNCheck product development efforts in 2023 will focus on the software ecosystem connecting user testing at the clinic level to the overall business enterprise via a DPNCheck data cloud, and also facilitating linkages between clinic testing and patient EMR. This integration project is complex and costly; however, it is essential to expanding usage of DPNCheck, particularly in large organizations.

Chronic pain is a significant public health problem. 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 contributing 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. 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 TENS have achieved limited efficacy in practice due to power limitations, inadequate dosing and low patient adherence.

Quell is our wearable neuromodulation technology for chronic pain. We believe it is designed to address many of the limitations of traditional TENS. It has been refined over the past seven years with over 200,000 chronic pain patients and is protected by over 20 U.S. utility patents. 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. The degree of technological sophistication, combined with our extensive consumer experience and the compelling results of clinical studies gives us the opportunity to leverage this technology base into a portfolio of Quell-based prescription (Rx) wearable neurotherapeutics.

In 2021 Quell received Breakthrough Device Designation from the FDA for a fibromyalgia indication. A pivotal double-blind, randomized, sham-controlled clinical study of Quell - Fibromyalgia has since been completed, and a De Novo submission for marketing authorization was obtained from the FDA in 2022. Quell – Fibromyalgia is indicated for use as an aid for reducing the symptoms of fibromyalgia in adults with high pain sensitivity. This prescription product was introduced at the American College of Rheumatology 2022 Annual Meeting followed by a strategic commercial launch initiated in December 2022 to broaden market awareness and further our understanding of market dynamics.

Quell also received FDA Breakthrough Device Designation in early 2022 for treatment of chronic Chemotherapy Induced Peripheral Neuropathy (CIPN). A CIPN double-blind, randomized, sham-controlled clinical study employing Quell and funded by the National Cancer Institute and the National Institute of Health recently completed enrollment. Study results are expected to be published in the first half of 2023. Positive results from that study would position us for a DeNovo filing with FDA similar to our approach with Quell – Fibromyalgia and, if successful, to an early 2024 launch of our second product in the portfolio of Quell-based prescription wearable therapeutics. We plan a similar approach with other disease indications involving chronic pain. These potentially include Chronic Low Back Pain, Post-Acute Sequelae of COVID 19, Chronic Overlapping Pain Conditions (COPC), Restless Leg Syndrome (RLS) and others.

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.

Results of Operations

Comparison of Years Ended December 31, 2022 and December 31, 2021

	Fiscal Year		Increase (Decrease)	
	2022	2021	Amount	Percent
Revenues	$ 8,256,073	$ 8,253,493	$ 2,580	— %
Gross profit	$ 5,750,240	$ 5,921,660	$ (171,420)	(2.9)%
– % of revenues	69.6 %	71.7 %		
Operating expenses	$ 10,492,006	$ 8,206,267	$ 2,285,739	27.9 %
Other income	$ 325,157	$ 3,150	$ 322,007	10,222.4 %
Net loss	$ (4,416,609)	$ (2,281,457)	$ 2,135,152	93.6 %
Net loss per common share	$ (0.62)	$ (0.45)	$ 0.17	37.8 %

Revenues

Revenues for 2022 increased by $3 thousand, a slight gain from 2021. DPNCheck contributed the majority of revenues in both years. It posted revenue growth of 9.7% in 2022, primarily attributable to Medicare Advantage sales which increased by 13.2% from 2021. This was partially offset by a decline in Asia sales where the healthcare markets continued to be adversely impacted during 2022 by COVID-19 restrictions. Quell revenue declined in 2022 with reduced promotion efforts and the termination of direct-to-consumer sales at the end of the third quarter in 2022. The legacy ADVANCE revenues also declined with the continuing erosion of the customer base.

Gross Profit

Gross profit for 2022 decreased slightly by $171 thousand or 2.9% from 2021 reflecting a continued positive shift in mix to higher margin DPNCheck products offset by increased production costs primarily related to electronic components.

Operating Expenses

Operating expenses increased in 2022 by $2,286 thousand or 27.9% from 2021. The increase reflects investment in our DPNCheck initiatives to drive future growth, including the expansion of our commercial capabilities and completion of our next generation DPNCheck testing technology. It also includes product development costs, and commercialization expenditures related to the emerging Quell Rx portfolio for disease specific indications including Quell - fibromyalgia. Investments were also made in governance and infrastructure including expansion of the Board of Directors and implementation of a new enterprise resource planning (ERP) system. Expansion in commercialization capabilities, governance and infrastructure will increase future operating costs.

Research and development spending in 2022 of $3,240 thousand increased by $643 thousand from 2021, primarily due to a $450 thousand reversal of previously accrued technology costs during 2021. Excluding this 2021 credit, R&D increased by $193 thousand or 6.2% primarily attributable to outside engineering support. Sales and marketing spending of $2,866 thousand increased by $1,246 thousand. The primary contributors to the increase were personnel costs related to fielding a senior-level DPNCheck commercial team for the Medicare Advantage market, and to recruiting a National Director of Sales, Neuromodulation for the emerging Quell Rx portfolio. Promotional costs related to the strategic launch of Quell – fibromyalgia in the fourth quarter of 2022 were also incurred. General and administrative costs of $4,387 thousand increased by $397 thousand or 9.9% primarily due to increased personnel costs.

Other Income

Other income primarily reflects interest income from the Company's securities portfolio as well as its commercial bank accounts. The securities portfolio was established during 2022. Increasing interest rates during 2022 enhanced portfolio performance.

Net loss

Net loss in 2022 was $4,417 thousand or $0.62 per common share versus a net loss in 2021 of $2,281 thousand or $0.45 per common share. Common shares outstanding increased to 7,785,754 at December 31, 2022 from 6,680,480 at the prior year-end.

Liquidity and Capital Resources

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

	Years Ended December 31,	
	2022	2021
Cash, cash equivalents and held-to-maturity securities	$ 21,199,727	$ 22,572,104
Working capital	$ 23,000,575	$ 22,822,162
Current ratio	21.8	17.7
Net debt position	$ (19,885,799)	$ (20,899,698)
Days sales outstanding	20.9	14.1
Inventory turnover	1.8	2.2

Our primary sources of liquidity are cash, cash equivalents and held-to-maturity securities, collections on sales of our products, and net proceeds from equity sales. 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 December 31, 2022, we had $21,200 thousand in cash, cash equivalents and held-to-maturity securities, working capital of $2,300 thousand, and a current ratio of 21.8. We had no term debt or borrowings at the end of 2022 and 2021, which contributed to a negative net debt position at each year end. A net debt position is defined as short-term and long-term financial obligations, less cash, cash equivalents and marketable securities. These measures are generally consistent with 2021 and indicate adequate liquidity and capitalization of the company.

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 in 2022 in comparison with the prior year reflects a greater weighting during 2022 of DPNCheck sales with terms of 30 to 60 days, close to the long end of the Company's customer payments horizon. Inventory turnover rate declined during 2022 as the Company increased its stocking levels to reduce exposure to supply chain delays.

Cash Flows

	Years Ended December 31,		
	2022	2021	Change
Net cash provided by (used in):			
– Operating activities	$ (5,289,416)	$ (2,073,694)	(3,215,722)
– Investing activities	$ (16,893,451)	$ (131,710)	(16,761,741)
– Financing activities	$ 3,864,031	$ 19,551,295	(15,687,264)
Net (decrease) increase in cash and cash equivalents	$ (18,318,836)	$ 17,345,891	

Operating activities
Operations cash usage between 2022 and 2021 increased by $3,216 thousand, primarily due to increased operating expenses of $2,286 thousand and a decline in gross profit of $171 thousand. Working capital increased by $178 thousand in 2022 versus 2021.

Investing activities

Investing activities in 2022 include deployment of cash reserves into held-to-maturity investment grade securities valued at $16,946 thousand at December 31, 2022. Also, purchases of fixed assets for use in production and in research and development totaled $23 thousand in 2022 versus $132 thousand in 2021.

Financing activities

During 2022 we raised net proceeds of $3,834 thousand from the sale of shares of common stock, registered under a shelf registration statement, to investors utilizing an At-The-Market (ATM) facility and administered by an investment bank. This amount compared with $19,430 thousand raised under the ATM in 2021. The 2022 activity allowed us to offset a significant portion of our net cash usage in operations and to close the year with cash, cash equivalents and securities in excess of our goal of $20 million.

We continue to maintain an effective shelf registration statement covering the sales of shares of our common stock and other securities, 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

Our financial statements are based on the selection and application of generally accepted accounting principles, which require us to make estimates and assumptions about future events that affect the amounts reported in our financial statements and the accompanying notes. Future events and their effects cannot be determined with certainty. Therefore, the determination of estimates requires the exercise of judgment. Actual results could differ significantly from those estimates, and any such differences may be material to our financial statements. We believe that the policies set forth below may involve a higher degree of judgment and complexity in their application than our other accounting policies and represents the critical accounting policies used in the preparation of our financial statements. If different assumptions or conditions were to prevail, the results could be materially different from our reported results. Our significant accounting policies are presented within Note 2 to our Financial Statements.

Inventories

Inventories, consisting primarily of finished goods and purchased components, are stated at the lower of cost or net realizable value. Cost is determined using the first-in, first-out inventory valuation method. The realizable value of inventories is based upon the types and levels of inventories held, forecasted demand, anticipated new product launch and commercialization success, pricing, competition, and changes in technology. Our consumable electrodes and biosensors all have an 18 to 36 months shelf life and represent 18% of inventory at December 31, 2022. Should market conditions deteriorate, our inventory realization could be lower than estimated net realizable value.

Recently Issued or Adopted Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (“FASB") and are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently adopted and recently issued accounting pronouncements will not have a material impact on our balance sheets, results of operations and cash flows.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses: Measurement of Credit Losses on Financial Instruments.* The guidance in Accounting Standards Update (“ASU”) 2016-13 replaces the incurred loss impairment methodology under current GAAP. The new impairment model requires immediate recognition of estimated credit losses expected to occur for most financial assets and certain other instruments. It will apply to all entities. For trade receivables, loans and held-to-maturity debt securities, entities will be required to estimate lifetime expected credit losses. This may result in earlier recognition of credit losses. In November 2019 the FASB issued ASU No. 2019-10, which delays this standard’s effective date for SEC smaller reporting companies to the fiscal years beginning on or after December 15, 2022. The Company determined that this update will not have a material impact on the financial statements upon adoption on January 1, 2023.

ITEM 8. Financial Statements and Supplementary Data

The information required by this item may be found on pages F-1 through F-20 of this Annual Report on Form 10-K.

ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

ITEM 9A. 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 the end of the period covered by this Form 10-K, have concluded that, based on such evaluation, solely due to the material weakness in our internal control over financial reporting discussed below, our disclosure controls and procedures were not effective at the reasonable assurance level 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) Management's Report on Internal Control Over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal controls over financial reporting as of December 31, 2022 based on the criteria in *Internal Control — Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). A material weakness is a control deficiency, or combination of control deficiencies, that results in a more than remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. In connection with our evaluation of the Company's internal controls over financial reporting, we identified a control deficiency in inventory accounting which represented a material weakness in our controls over financial reporting as of December 31, 2022. Specifically, our controls were not designed or implemented to ensure the proper review and determination of inventory costing, and the valuation of inventory net realizable value. The Company has taken steps to remediate the deficiency in inventory accounting controls by expanding its period-end closing process to require that the Corporate Controller perform and document a review of inventory costing and also prepare an analysis of inventory net realizable value, which analysis is required to be reviewed and approved by the Chief Financial Officer.

Based on our evaluation under the framework in *Internal Control — Integrated Framework* (2013) issued by the COSO, our management concluded that our internal controls over financial reporting were not effective as of December 31, 2022 based on the material weakness described above.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to rules of the SEC that permit us to provide only management's report in this Annual Report on Form 10-K.

(c) Changes in internal control over financial reporting.

There have been no changes to our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fourth quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. During 2022 we replaced the enterprise resource planning software which we use in accounting for our business activities. The change was necessitated by increasing functional obsolescence of the predecessor system and inadequate provider support. The new system was implemented in the fourth quarter of 2022 without significant issues. Our established internal control system has been modified as necessary to accommodate the new system and to ensure the continuity of reasonable internal controls over financial reporting.

ITEM 9B. Other Information

Not applicable.

ITEM 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

ITEM 10. Directors, Executive Officers and Corporate Governance

Information Regarding the Directors and Executive Officers

Name	Age	Position
Shai N. Gozani, M.D., Ph.D.	58	Chairman of the Board, Chief Executive Officer, President and Secretary
Thomas T. Higgins	71	Senior Vice President, Chief Financial Officer and Treasurer
Bradley M. Fluegel	61	Director
David E. Goodman, M.D.	66	Director
Nancy E. Katz	63	Director
David Van Avermaete	71	Director

Shai N. Gozani, M.D., Ph.D. founded our company in 1996 and currently serves as Chairman of our Board of Directors and as our President, Chief Executive Officer and Secretary. Since founding our company in 1996, Dr. Gozani has served in a number of positions at our company including Chairman since 1996, President from 1996 to 1998 and from 2002 to the present, Chief Executive Officer since 1997 and Secretary since July 2008. Dr. Gozani holds a B.A. in computer science, an M.S. in Biomedical Engineering and a Ph.D. in Neurobiology, from the University of California, Berkeley. He also received an M.D. from Harvard Medical School and the Harvard-M.I.T. Division of Health Sciences at M.I.T. Prior to forming our company, Dr. Gozani completed a neurophysiology research fellowship in the laboratory of Dr. Gerald Fischbach at Harvard Medical School. Dr. Gozani has published articles in the areas of basic and clinical neurophysiology, biomedical engineering and computational chemistry. Since 2019 Dr. Gozani has served on the Board of Directors of Madorra, Inc. The Board has concluded that Dr. Gozani should serve as a director because Dr. Gozani's extensive knowledge of engineering and neurophysiology, combined with the unique understanding of our technology and business he has gained as our founder and as a key executive, provides invaluable insight to our Board and to the entire organization.

Bradley M. Fluegel has served as a member of our Board of Directors since June 2022. Since January 2018, Mr. Fluegel has been a principal of BMF Advisors, where he advises healthcare companies. He previously served as Senior Vice President, Chief Healthcare Commercial Market Development Officer of Walgreens from August 2015 to January 2018 and prior to that Chief Strategy Officer of Walgreens from September 2012 to August 2015. From April 2011 to September 2012, Mr. Fluegel served as Executive in Residence at Health Evolution Partners, a healthcare private equity firm. Mr. Fluegel served as Executive Vice President and Chief Strategy and External Affairs Officer of WellPoint, Inc. (now Elevance Health) from September 2007 to December 2010. Prior to that, Mr. Fluegel served as Senior Vice President of National Accounts and Vice President, Enterprise Strategy at Aetna, Inc. Mr. Fluegel currently serves on the board of directors of Performant Financial Corporation (Nasdaq: PFMT) and Digital Transformation Opportunities Corp. (Nasdaq: DTOC) and formerly served on the board of directors of Itamar Medical Ltd. prior to Zoll Medical's acquisition of the company and Fitbit, Inc. prior to Google's acquisition of the company. Mr. Fluegel received a Master's Degree in Public Policy from Harvard University's Kennedy School of Government and a Bachelor of Arts in Business Administration from the University of Washington. He also serves as a lecturer at the University of Pennsylvania's Wharton School of Business. Mr. Fluegel's qualifications to serve on the Board include his extensive executive experience and his background in the healthcare industry.

David E. Goodman, M.D., M.S.E. has served as a member of our Board of Directors since June 2004. Since 2013, Dr. Goodman has been running his own independent primary care medical practice where he also manages the care of first responders (police, fire, EMS) injured in the line of duty. From 2013 to 2016, Dr. Goodman served as CEO of Feet First, a technology-focused healthcare services company he co-founded that is committed to preventing the devastating and expensive microvascular complications of diabetes. From 2014 to 2016, Dr. Goodman served as a director of Xtant Medical (OTC QX: BONE), a comprehensive supplier of orthopedic and spine surgery products. From 2012 to 2015, Dr. Goodman served as CMO of FirstVitals, a healthcare services company focused on wellness and prevention. Since 2011, Dr. Goodman has also served as an independent consultant. During 2010, Dr. Goodman served as President and Chief Executive Officer of SEDline, Inc., a research-focused company with the mission to expand the scope and applications for neuromonitoring. From 2008 to 2009, Dr. Goodman served as Executive Vice President of Business Development for Masimo Corporation, a manufacturer of non-invasive patient monitors. From 2006 to 2008, Dr. Goodman served as an independent consultant providing product design, regulatory and analytical consulting services to medical device and biopharmaceutical companies and also served in this

capacity from 2003 to 2004 and from 2001 to 2002. From 2005 to 2006, Dr. Goodman served as President and Chief Executive Officer of BaroSense, Inc., a medical device company focused on developing minimally invasive devices for the long-term treatment of obesity. From 2004 to 2005, Dr. Goodman served as President and Chief Executive Officer of Interventional Therapeutic Solutions, Inc., an implantable drug delivery systems company. From 2002 to 2003, Dr. Goodman served as Chairman, President and Chief Executive Officer of Pherin Pharmaceuticals, a pharmaceutical discovery and development company. From 1994 to 2001, Dr. Goodman held various positions, including Chief Executive Officer, Chief Medical Officer and director, for LifeMasters Supported SelfCare, Inc., a disease management services company that Dr. Goodman founded. Dr. Goodman also served as a director of Sound Surgical Technologies LLC, a private manufacturer of aesthetic surgical tools from 2011 until its acquisition by Solta Medical (Nasdaq:SLTM) in 2013. Dr. Goodman holds a B.A.S. in applied science and bioengineering and a M.S.E. in bioengineering from the University of Pennsylvania. He also received an M.D. from Harvard Medical School and the Harvard-M.I.T. Division of Health Sciences and Technology. Dr. Goodman holds 22 issued and pending patents and is a practicing physician with licenses in California and Hawaii. The Board has concluded that Dr. Goodman should serve as a director because Dr. Goodman's medical and engineering background and his many years of executive experience in the medical device industry provide important experience and expertise to the Board.

Nancy E. Katz has served as a member of our Board of Directors since December 2010. From May 2011 to August 2014, Ms. Katz served as Vice President, Consumer Marketing at Medtronic, Inc., a medical technology company. From July 2005 to July 2010, Ms. Katz was Senior Vice President, Bayer Diabetes Care — North America. Prior to this position, she was President and Chief Executive Officer of Calypte Biomedical Corporation, a manufacturer of HIV diagnostics, President of Zila Pharmaceutical, Inc., a manufacturer of oral care products, and held senior marketing positions with the Lifescan division of Johnson & Johnson (blood glucose diabetes products), Schering-Plough Healthcare Products, and with American Home Products. Since October 2016, Ms. Katz has served on the Board of Directors of Cyanotech Corporation (Nasdaq: CYAN). She has previously served on the Boards of Directors of Neoprobe Corporation (AMEX: NEOP), Calypte Biomedical Corporation, LXN Corporation and Pepgen Corporation. She received a B.S. in business from the University of South Florida. The Board has concluded that Ms. Katz should serve as a director because of her executive level experience in the healthcare industry, as well as consumer marketing expertise which provides the Board with valuable insight in business strategy and execution.

David Van Avermaete has served as a member of our Board of Directors since September 2013. Since January 2015, Mr. Van Avermaete has served as President of Inject Safe Technologies, a privately held company that has developed a bandage specifically designed to support injections. From April 2004 to February 2013, Mr. Van Avermaete served as Chief Executive Officer of VeraLight, Inc., a medical device company he founded, that focuses on non-invasive screening for type 2 diabetes. From 2000 to 2004, Mr. Van Avermaete served as Senior Vice President Non-Invasive Technology of InLight Solutions, a Johnson & Johnson company focused on transformational technology in the diabetes field. From 1998 to 2000, Mr. Van Avermaete served as U.S. President of the LifeScan division of Johnson & Johnson and, from 1990 to 1998, in various senior level positions at LifeScan concentrating in sales and marketing. Previously, Mr. Van Avermaete served as Vice President Sales and Marketing at Biotope, Director of Marketing at Roche Diagnostics, and Director of Marketing and Sales at Syntex Medical Diagnostics. Mr. Van Avermaete received a Master of Business Administration and a Master of Science Degree in Microbiology from the University of Arizona and a Bachelor of Science Degree in medical technology and chemistry from Ball State University. The Board has concluded that Mr. Van Avermaete should serve as a director because his executive level experience in the medical device and diabetes field, as well as in entrepreneurial ventures, provides the Board with a valuable perspective in commercializing medical device products.

Thomas T. Higgins has served as our Senior Vice President, Chief Financial Officer and Treasurer since September 2009. Prior to joining NeuroMetrix, from January 2005 to March 2008, Mr. Higgins was Executive Vice President and Chief Financial Officer at Caliper Life Sciences, Inc., a provider of technology and services for life sciences research. Before Caliper, Mr. Higgins was Executive Vice President, Operations and Chief Financial Officer at V.I. Technologies, Inc. (Vitex), a biotechnology company addressing blood safety. Before Vitex, Mr. Higgins served at Cabot Corporation in various senior finance and operations roles. His last position at Cabot was President of Distrigas of Massachusetts Corporation, a subsidiary involved in the liquefied natural gas business, and prior to that he was Vice President and General Manager of Cabot's Asia Pacific carbon black operations. Before joining Cabot, Mr. Higgins was with PricewaterhouseCoopers where he started his career. Mr. Higgins holds a BBA with honors from Boston University.

Other information required by this item is incorporated by reference from the discussion responsive thereto under the captions "Board Matters and Corporate Governance," "Information Regarding the Directors and Executive Officers," "Code of

Business Conduct and Ethics" and "Delinquent Section 16(a) Reports" in our proxy statement for the 2023 annual meeting of stockholders (the "2023 Proxy Statement").

ITEM 11. Executive Compensation

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Directors' Compensation" and "Compensation of Executive Officers" in our 2023 Proxy Statement.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" in our 2023 Proxy Statement.

ITEM 13. Certain Relationships and Related Transactions, and Director Independence

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Certain Relationships and Related Person Transactions" and "Board Matters and Corporate Governance" in our 2023 Proxy Statement.

ITEM 14. Principal Accounting Fees and Services

The response to this item is incorporated by reference from the discussion responsive thereto under the caption "Accounting Fees" in our 2023 Proxy Statement.

PART IV

ITEM 15. Exhibits and Financial Statement Schedule

(a) 1. *Financial Statements*

The financial statements are listed in the accompanying index to financial statements on page F-1.

2. *Financial Statement Schedule*

The financial statement schedule is listed in the accompanying index to financial statements on page F-1. Other financial statement schedules required under this Item and Item 8 are omitted because they are not applicable or the required information is shown in the financial statements or the footnotes thereto.

3. *Exhibit Index*

The following is a list of exhibits filed as part of this Annual Report on Form 10-K:

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
3.1.1	Third Amended and Restated Certificate of Incorporation of NeuroMetrix, Inc. dated July 27, 2004		S-8 (Exhibit 4.1)	8/9/2004	333-118059
3.1.2	Certificate of Designations for Series A Junior Cumulative Preferred Stock, par value $0.001 per share, dated March 7, 2007		8-A12(b) (Exhibit 3.1)	3/8/2007	001-33351
3.1.3	Certificate of Amendment to Restated Certificate of Incorporation of NeuroMetrix, Inc. dated September 1, 2011		8-K (Exhibit 3.1)	9/1/2011	001-33351
3.1.4	Certificate of Amendment to Restated Certificate of Incorporation of NeuroMetrix, Inc. dated February 15, 2013		8-K (Exhibit 3.1)	2/15/2013	001-33351
3.1.5	Certificate of Amendment to Restated Certificate of Incorporation of NeuroMetrix, Inc. dated December 1, 2015		8-K (Exhibit 3.1)	12/1/2015	001-33351
3.1.6	Certificate of Amendment of Restated Certificate of Incorporation of NeuroMetrix, Inc. dated May 11, 2017		8-K (Exhibit 3.1)	5/12/2017	001-33351
3.1.7	Certificate of Amendment to Restated Certificate of Incorporation of NeuroMetrix, Inc. dated November 18, 2019		8-K (Exhibit 3.1)	11/18/2019	001-33351
3.1.8	Certificate of Designation of Preferences, Rights and Limitations of Series A-1 Convertible Preferred Stock, par value $0.001 per share, dated June 5, 2013		8-K (Exhibit 3.1)	6/6/2013	001-33351
3.1.9	Certificate of Designation of Preferences, Rights and Limitations of Series A-2 Convertible Preferred Stock, par value $0.001 per share, dated June 5, 2013		8-K (Exhibit 3.2)	6/6/2013	001-33351
3.1.10	Certificate of Designation of Preferences, Rights and Limitations of Series A-3 Convertible Preferred Stock, par value $0.001 per share, dated June 24, 2014		8-K (Exhibit 3.1)	6/25/2014	001-33351
3.1.11	Certificate of Designation of Preferences, Rights and Limitations of Series A-4 Convertible Preferred Stock, par value $0.001 per share, dated June 24, 2014		8-K (Exhibit 3.2)	6/25/2014	001-33351
3.1.12	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock, par value $0.001 per share, dated May 26, 2015		8-K (Exhibit 3.1)	5/29/2015	001-33351

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
3.1.13	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock, par value $0.001 per share, dated December 30, 2015		8-K (Exhibit 3.1)	12/30/2015	001-33351
3.1.14	Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock, par value $0.001 per share, dated June 3, 2016		8-K (Exhibit 3.1)	6/3/2016	001-33351
3.1.15	Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock, par value $0.001 per share, dated December 28, 2016		8-K (Exhibit 3.1)	12/29/2016	001-33351
3.1.16	Certificate of Designation of Preferences, Rights and Limitations of Series F Convertible Preferred Stock, par value $0.001 per share, dated July 10, 2017		8-K (Exhibit 3.1)	7/11/2017	001-33351
3.2.1	Amended and Restated Bylaws of NeuroMetrix, Inc.		8-K (Exhibit 3.1)	12/10/2021	001-33351
4.1	Description of Securities of the Registrant		10-K (Exhibit 4.1)	1/28/2022	001-33351
4.2	Specimen Certificate for Shares of Common Stock		S-1/A (Exhibit 4.1)	7/19/2004	333-115440
4.3.1	Shareholder Rights Agreement, dated as of March 7, 2007, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent		8-A12(b) (Exhibit 4.1)	3/8/2007	001-33351
4.3.2	Amendment to Shareholder Rights Agreement, dated September 8, 2009, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent		8-K (Exhibit 4.1)	9/14/2009	001-33351
4.3.3	Amendment No. 2 to Shareholder Rights Agreement, dated June 5, 2013, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent		8-K (Exhibit 4.2)	6/6/2013	001-33351
4.3.4	Amendment No. 3 to Shareholder Rights Agreement, dated June 25, 2014, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent		8-K (Exhibit 4.2)	6/25/2014	001-33351
4.3.5	Amendment No. 4 to Shareholder Rights Agreement, dated May 28, 2015, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent		10-Q (Exhibit 4.1)	7/23/2015	001-33351
4.3.6	Amendment No. 5 to Shareholder Rights Agreement, dated December 29, 2015, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent		8-K (Exhibit 4.3)	12/30/2015	001-33351
4.3.7	Amendment No. 6 to Shareholder Rights Agreement, dated June 3, 2016, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent		8-K (Exhibit 4.2)	6/3/2016	001-33351

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
4.3.8	Amendment No. 7 to Shareholder Rights Agreement, dated December 28, 2016, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent		8-K (Exhibit 4.2)	12/29/2016	001-33351
4.3.9	Amendment No. 8 to Shareholder Rights Agreement, dated February 8, 2017, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent		10-K (Exhibit 4.2.9)	2/8/2017	001-33351
4.3.10	Amendment No. 9 to Shareholder Rights Agreement, dated July 10, 2017, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent		8-K (Exhibit 4.2)	7/11/2017	001-33351
4.3.11	Amendment No. 10 to Shareholder Rights Agreement, dated February 5, 2018, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent		10-K (Exhibit 4.2.11)	2/8/2018	001-33351
4.3.12	Amendment No. 11 to Shareholder Rights Agreement, dated January 21, 2019, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent		10-K (Exhibit 4.2.11)	1/24/2019	001-33351
4.3.13	Amendment No. 12 to Shareholder Rights Agreement, dated January 27, 2020, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent		10-K (Exhibit 4.3.13)	1/28/2020	001-33351
4.3.14	Amendment No. 13 to Shareholder Rights Agreement, dated January 25, 2021, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent		10-K (Exhibit 4.3.14)	1/29/2021	001-33351
4.3.15	Amendment No. 14 to Shareholder Rights Agreement, dated July 20, 2021, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent		10-Q (Exhibit 4.1)	7/22/2021	001-33351
4.3.16	Amendment No. 15 to Shareholder Rights Agreement, dated March 6, 2023, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent		8-K (Exhibit 4.1)	3/10/2023	001-33351
4.4.1	Form of Unit Warrant to purchase Common Stock (February 2012)		S-1/A (Exhibit 4.5)	1/31/2012	333-178165
4.4.2	Form of Placement Agent Warrant (February 2012)		S-1/A (Exhibit 4.6)	1/31/2012	333-178165
4.5	Form of Common Stock Purchase Warrant (June 2013)		8-K/A (Exhibit 4.1)	6/7/2013	001-33351
4.6	Form of Common Stock Purchase Warrant (June 2014)		8-K (Exhibit 4.1)	6/25/2014	001-33351
4.7.1	Form of Warrant (2015) issued as part of a Unit on May 29, 2015		S-1/A (Exhibit 4.3)	5/4/2015	333-188133
4.7.2	Form of Underwriter's Warrant (2015) issued on May 29, 2015		S-1/A (Exhibit 4.5)	4/13/2015	333-188133
4.8	Form of Series A Common Stock Purchase Warrant (December 2015)		8-K (Exhibit 4.1)	12/30/2015	001-33351
4.9	Form of Series B Common Stock Purchase Warrant (December 2015)		8-K (Exhibit 4.2)	12/30/2015	001-33351
4.10	Form of Common Stock Purchase Warrant (June 2016)		8-K (Exhibit 4.1)	6/3/2016	001-33351
4.11	Form of Common Stock Purchase Warrant (December 2016)		8-K (Exhibit 4.1)	12/29/2016	001-33351

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
Lease Agreements					
10.1.1	Lease Agreement, dated August 27, 2014, between Cummings Properties, LLC and NeuroMetrix, Inc.		10-Q (Exhibit 10.1)	10/28/2014	011-33351
10.1.2	Lease Extension #1, dated June 14, 2018, between Cummings Properties, LLC and NeuroMetrix, Inc.		10-Q (Exhibit 10.2)	7/19/2018	011-33351
Credit Facilities, Loan and Equity Agreements					
10.2	Repurchase and Forfeiture Agreement by and between NeuroMetrix, Inc. and the parties named therein		10-Q (Exhibit 10.1)	7/23/2015	001-33351
10.3.1	Securities Purchase Agreement by and between NeuroMetrix, Inc. and the purchasers named therein, dated December 29, 2015		8-K (Exhibit 10.1)	12/30/2015	001-33351
10.3.2	Registration Rights Agreement by and between NeuroMetrix, Inc. and the purchasers named therein, dated December 29, 2015		8-K (Exhibit 10.2)	12/30/2015	001-33351
10.4.1	Securities Purchase Agreement by and between NeuroMetrix, Inc. and the purchasers named therein, dated June 2, 2016		8-K (Exhibit 10.1)	6/3/2016	001-33351
10.4.2	Registration Rights Agreement by and between NeuroMetrix, Inc. and the purchasers named therein, dated June 2, 2016		8-K (Exhibit 10.2)	6/3/2016	001-33351
10.5.1	Securities Purchase Agreement by and between NeuroMetrix, Inc. and the purchasers named therein, dated December 28, 2016		8-K (Exhibit 10.1)	12/29/2016	001-33351
10.5.2	Registration Rights Agreement by and between NeuroMetrix, Inc. and the purchasers named therein, dated December 28, 2016		8-K (Exhibit 10.2)	12/29/2016	001-33351
10.5.3	Promissory Note with Comerica Bank dated April 27, 2020		8-K (Exhibit 10.1)	4/30/2020	001-33351
10.5.4	Loan Agreement by and between NeuroMetrix, Inc. and Comerica Bank, dated April 27, 2020		8-K (Exhibit 10.2)	4/30/2020	001-33351
10.5.5	At Market Issuance Sales Agreement by and between NeuroMetrix, Inc. and Ladenburg Thalmann & Co. Inc., dated October 22, 2021		S-3 (Exhibit 1.2)	10/22/2021	333-260438
Equity Compensation Plans					
10.6+	Twelfth Amended and Restated 2004 Stock Option and Incentive Plan		14A (Appendix A)	3/16/2021	001-33351
10.7+	2009 Non-Qualified Inducement Stock Plan		S-8 (Exhibit 99.1)	6/3/2009	333-159712
10.8+	Employee Stock Purchase Plan, as amended		S-8 (Exhibit 99.1)	5/19/2022	333-265080
10.9.1+	2022 Equity Incentive Plan		S-8 (Exhibit 99.2)	5/19/2022	333-265080
10.9.2+	Form of Stock Option Agreement under 2022 Equity Incentive Plan		S-8 (Exhibit 99.3)	5/19/2022	333-265080

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
10.9.3+	Form of Restricted Stock Unit Agreement under 2022 Equity Incentive Plan		S-8 (Exhibit 99.4)	5/19/2022	333-265080
Agreements with Executive Officers and Directors					
10.10+	Form of Indemnification Agreement between NeuroMetrix, Inc. and each of its directors		S-1/A (Exhibit 10.8)	6/22/2004	333-115440
10.11.1+	Indemnification Agreement dated June 21, 2004, by and between Shai N. Gozani, M.D., Ph.D., and NeuroMetrix, Inc.		S-1/A (Exhibit 10.20)	6/22/2004	333-115440
10.11.2+	Employment Agreement dated December 30, 2020, by and between NeuroMetrix, Inc. and Shai N. Gozani, M.D., Ph.D., and NeuroMetrix, as amended		10-K (Exhibit 10.12.2)	1/28/2022	001-33351
10.12.1+	Indemnification Agreement, dated September 10, 2009, by and between NeuroMetrix, Inc. and Thomas T. Higgins		8-K (Exhibit 10.2)	9/15/2009	001-33351
10.12.2+	Employment Agreement, dated December 30, 2020 by and between NeuroMetrix, Inc. and Thomas T. Higgins, as amended		10-K (Exhibit 10.13.2)	1/28/2022	001-33351
10.13+	Amended and Restated Management Retention and Incentive Plan, as modified, dated February 3, 2017		10-K (Exhibit 10.17)	2/9/2017	001-33351
10.14+	Amended and Restated Management Retention and Incentive Plan, as modified, dated January 20, 2020		10-K (Exhibit 10.16.2)	1/28/2020	001-33351
Agreements with Respect to Collaborations, Licenses, Research and Development					
10.15†	Manufacturing and Supply Agreement, dated as of August 2, 2006, by and between Parlex Polymer Flexible Circuits, Inc. and NeuroMetrix, Inc.		8-K (Exhibit 99.1)	8/2/2006	000-50856
Other					
16.1	Letter from Moody, Famiglietti and Andronico, LLP		8-K (Exhibit 16.1)	12/3/2021	001-33351
23.1	Consent of Baker Tilly US, LLP, an independent registered public accounting firm.	X			
31.1	Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of Principal Accounting and Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32	Certification of the Principal Executive Officer and the Principal Accounting and Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002.	X			

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
101.1	The following materials from NeuroMetrix, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2022, formatted in XBRL (Extensible Business Reporting Language): (i) Balance Sheets as of December 31, 2022 and 2021, (ii) Statements of Operations for the years ended December 31, 2022 and 2021, (iii) Statements of Changes in Stockholders' Equity for the years ended December 31, 2022 and 2021, (iv) Statements of Cash Flows for the years ended December 31, 2022 and 2021, and (v) Notes to Financial Statements.	X			
101.INS	XBRL Instance Document	X			
101.SCH	XBRL Taxonomy Extension Schema	X			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase	X			
101.DEF	XBRL Taxonomy Extension Definition Linkbase	X			
101.LAB	XBRL Taxonomy Extension Label Linkbase	X			
101.PRE	XBRL Taxonomy Extension Presentation Linkbase	X			

+ Indicates management contract or any compensatory plan, contract or arrangement.

† Confidential treatment has been granted with respect to certain portions of this Exhibit, which portions have been omitted and filed separately with the Securities and Exchange Commission as part of an application for confidential treatment pursuant to the Securities Exchange Act of 1934, as amended.

ITEM 16. Form 10-K Summary

We may voluntarily include a summary of information required by Form 10-K under this Item 16. We have elected not to include such summary information.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

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

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

Date: March 22, 2023

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant on March 22, 2023 in the capacities indicated below.

Name	Title
/s/ SHAI N. GOZANI, M.D., PH.D. Shai N. Gozani, M.D., Ph.D.	Chairman, President and Chief Executive Officer (Principal Executive Officer)
/s/ THOMAS T. HIGGINS Thomas T. Higgins	Senior Vice President, Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)
/s/ BRADLEY M. FLUEGEL Bradley M. Fluegel	Director
/s/ DAVID E. GOODMAN, M.D. David E. Goodman, M.D.	Director
/s/ NANCY E. KATZ Nancy E. Katz	Director
/s/ DAVID VAN AVERMAETE David Van Avermaete	Director

INDEX TO FINANCIAL STATEMENTS

NeuroMetrix, Inc.

Years ended December 31, 2022 and 2021

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of NeuroMetrix, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of NeuroMetrix, Inc. (the "Company") as of December 31, 2022 and 2021, and the related statements of operations, changes in stockholders' equity, and cash flows for each of the years in the two year period ended December 31, 2022, and the related notes and schedule (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the years in the two year period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Inventory Valuation

Critical Audit Matter Description

As described in Note 2 to the financial statements, inventories are stated at the lower of cost or net realizable value. Cost is determined using the first-in, first-out method. Management estimates the net realizable value of inventory by considering the types and levels of inventories held, forecasted demand, pricing, economic and market conditions, and changes to technology.

The Company continually evaluates quantities on hand and the carrying value of inventories to determine the need for net realizable value adjustments for inventories, based on prior experience as well as forecasts of product sales. We identified the valuation of net realizable value adjustments to inventories as a critical audit matter. The evaluation of management's assumptions of estimated sales price and reasonably predictable costs of completion, result in the application of a high degree of auditor judgment. These significant assumptions are forward-looking and could be affected by future economic and market conditions.

How We Addressed the Matter in Our Audit

The primary procedures we performed to address this critical audit matter included:

- obtaining an understanding and evaluating the design of controls over the Company's determination of lower of cost or net realizable value adjustments for inventory.
- testing the accuracy, completeness, and relevance of the underlying data used in management's analysis
- evaluating the appropriateness of management's methods and assumptions used in developing their estimate, which included consideration of recent changes in the Company's selling strategy, projected selling prices, and predictable costs of completion, as well as reviewing such assumptions for management bias
- inquiring with senior financial and operational management to corroborate relevance and reliability of assumptions used in management's analysis, related to current strategic changes in the business impacting projected selling prices and expected demand.

/s/ Baker Tilly US, LLP

We have served as the Company's auditor since 2017

Tewksbury, Massachusetts
March 22, 2023

NeuroMetrix, Inc.

Balance Sheets

	December 31,	
	2022	**2021**
Assets		
Current assets:		
Cash and cash equivalents	$ 4,253,268	$ 22,572,104
Held-to-maturity securities	16,946,459	—
Accounts receivable, net of allowances of $25,000 at December 31, 2022 and 2021	646,771	310,818
Inventories	1,614,987	706,553
Prepaid expenses and other current assets	645,502	598,384
Total current assets	24,106,987	24,187,859
Fixed assets, net	165,619	198,703
Right to use asset	370,609	475,230
Other long-term assets	26,400	26,400
Total assets	$ 24,669,615	$ 24,888,192
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 368,082	$ 284,036
Accrued expenses and compensation	589,939	853,155
Lease obligation, current portion	148,391	228,506
Total current liabilities	1,106,412	1,365,697
Lease obligation, net of current portion	207,516	306,709
Total liabilities	1,313,928	1,672,406
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock	—	—
Convertible preferred stock	1	1
Common stock, $0.0001 par value; 25,000,000 authorized at December 31, 2022 and 2021; 7,785,754 and 6,680,480 shares issued and outstanding at December 31, 2022 and 2021, respectively	778	669
Additional paid-in capital	226,934,774	222,378,373
Accumulated deficit	(203,579,866)	(199,163,257)
Total stockholders' equity	23,355,687	23,215,786
Total liabilities and stockholders' equity	$ 24,669,615	$ 24,888,192

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

NeuroMetrix, Inc.

Statements of Operations

	Years Ended December 31,	
	2022	**2021**
Revenues	$ 8,256,073	$ 8,253,493
Cost of revenues	2,505,833	2,331,833
Gross profit	5,750,240	5,921,660
Operating expenses:		
Research and development	3,239,725	2,596,415
Sales and marketing	2,865,615	1,619,711
General and administrative	4,386,666	3,990,141
Total operating expenses	10,492,006	8,206,267
Loss from operations	(4,741,766)	(2,284,607)
Interest income	325,157	3,150
Net loss:	$ (4,416,609)	$ (2,281,457)
Net loss per common share:		
Basic and diluted	$ (0.62)	$ (0.45)

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

NeuroMetrix, Inc.

Statements of Changes in Stockholders' Equity

	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	$ 381	$ 202,129,195	$ (196,881,800)	$ 5,247,775
Stock-based compensation expense	—	—	—	—	698,173	—	698,173
Issuance of common stock under at the market offering	—	—	2,756,705	275	19,429,346	—	19,429,621
Issuance of common stock upon exercise of stock options	—	—	50,000	5	78,495		78,500
Issuance of common stock under employee stock purchase plan	—	—	16,371	3	43,171	—	43,174
Vesting of restricted stock under option plan	—	—	33,665	6	(6)	—	—
Net loss	—	—	—	—	—	(2,281,457)	(2,281,457)
Balance at December 31, 2021	200	$ 1	6,664,296	$ 669	$ 222,378,373	$ (199,163,257)	$ 23,215,786
Stock-based compensation expense	—	—	—	—	477,062	—	477,062
Issuance of common stock under at the market offering	—	—	916,334	91	3,833,681	—	3,833,772
Issuance of common stock to settle compensation obligation	—	—	50,213	5	215,412	—	215,417
Issuance of common stock under employee stock purchase plan	—	—	20,206	2	30,257	—	30,259
Vesting of restricted stock under option plan	—	—	38,449	11	(11)	—	—
Net loss	—	—	—	—	—	(4,416,609)	(4,416,609)
Balance at December 31, 2022	200	$ 1	7,689,498	$ 778	$ 226,934,774	$ (203,579,866)	$ 23,355,687

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

NeuroMetrix, Inc.

Statements of Cash Flows

	Years Ended December 31,	
	2022	**2021**
Cash flows for operating activities:		
Net loss	$ (4,416,609)	$ (2,281,457)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	49,391	76,378
Stock-based compensation	477,062	698,173
Inventory provision charged to research and development	—	400,000
Inventory provision charged to cost of revenue	356,700	99,141
Loss on disposal of fixed assets	6,875	40,123
Accretion of interest income on held-to-maturity securities	(76,190)	—
Settlement of compensation obligation	26,019	—
Impairment charge against right of use asset	—	126,748
Changes in operating assets and liabilities:		
Accounts receivable	(335,953)	23,479
Inventories	(1,265,134)	(154,412)
Prepaid expenses and other current and long-term assets	(181,805)	(613,300)
Accounts payable	84,046	141,720
Accrued expenses and compensation	(13,818)	(630,287)
Net cash used in operating activities	(5,289,416)	(2,073,694)
Cash flows for investing activities:		
Purchases of held-to-maturity securities	(40,933,126)	—
Proceeds from maturities of held-to-maturity securities	24,062,857	—
Purchases of fixed assets	(23,182)	(131,710)
Net cash used in investing activities	(16,893,451)	(131,710)
Cash flows from financing activities:		
Net proceeds from issuance of stock	3,864,031	19,551,295
Net cash provided by financing activities	3,864,031	19,551,295
Net (decrease) increase in cash and cash equivalents	(18,318,836)	17,345,891
Cash and cash equivalents, beginning of year	22,572,104	5,226,213
Cash and cash equivalents, end of year	$ 4,253,268	$ 22,572,104
Supplemental disclosure of non-cash financing activity:		
Common stock issued to settle employee incentive compensation obligations	$ 189,398	$ —

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

1. Description of Business and Basis of Presentation

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 point-of-care test for diabetic peripheral neuropathy which is the most common long-term complication of Type 2 diabetes. Quell is an app-enabled, wearable device for lower extremity chronic pain and for the symptoms of fibromyalgia.

On June 30, 2021, the Company entered into a Termination Agreement with GSK Consumer Healthcare S.A. ("GSK") pursuant to which the parties terminated the 2018 Development and Services Agreement which provided GSK with license and intellectual property rights for the commercialization of the Quell technology for markets outside the United States. Under the terms of the Termination Agreement, GSK transferred back to NeuroMetrix all of GSK's rights in the Quell technology related to markets outside the United States, including technology improvements and intellectual property. NeuroMetrix agreed to make royalty payments to GSK ranging between 5% and 8% for a ten-year period based on net sales of Quell devices that are available to consumers for purchase without a prescription from a licensed medical professional outside the United States. There were no sales qualifying for royalty payments in 2022 or 2021.

The Company held cash, cash equivalents and investment grade securities totaling $21.2 million on December 31, 2022. The Company has a history of operating losses and has financed its operations primarily from sales of equity, from collaboration milestone payments, and from sales of its products. The Company believes that its present balance of cash resources and held-to-maturity securities 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 could include the effects of an existing or emerging 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.

2. Summary of Significant Accounting Policies

Use of Estimates and Assumptions

The preparation of financial statements in conformity with United States generally accepted accounting principles 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.

The Company bases its estimates on historical experience and various other assumptions that it believes to be reasonable under the circumstances and regularly assesses these estimates, but actual results could differ materially from these estimates. Effects of changes in estimates are recorded in the period in which they occur.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of ninety days or less to be cash equivalents. Cash equivalents are recorded at cost which approximates fair value. The Company invests cash primarily in a money market account and other investments.

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 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 December 31, 2022 was $16,877,403**.**

Concentrations of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash equivalents, trade receivables, and held-to-maturity securities. The Company invests its cash equivalents in highly rated institutions.

At December 31, 2022 and 2021, two customers accounted for 31% and 35% of accounts receivable, respectively. One customer accounted for 32% of revenues for the year ended December 31, 2022 and one customer accounted for 27% of revenues, for the year ended December 31, 2021.

Inventories

Inventories, consisting primarily of finished goods and purchased components, are stated at the lower of cost or net realizable value. Cost is determined using the first-in, first-out method. The net realizable value of inventories is based upon the types and levels of inventories held, forecasted demand, pricing, competition, and changes in technology. Deterioration in market and economic conditions could adversely affect the recovery of inventory value.

Leases

The Company presents the lease obligations on the balance sheet, by recording a right-of-use asset and a lease liability for all leases other than those that, at lease commencement, have a lease term of 12 months or less. On the lease commencement date, the Company measures and records a lease liability equal to the present value of the remaining lease payments, discounted using the rate implicit in the lease or if that cannot be readily determined, the Company's incremental borrowing rate.

Fair Value

The Company follows the provisions of Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("ASC") Topic 820-10, Fair Value Measurements and Disclosures ("ASC 820-10"), which defines fair value, establishes a framework for measuring fair value in GAAP and requires certain disclosures about fair value measurements. Fair Value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability.

As a basis for considering such assumptions, ASC 820-10 established a three-tier fair value hierarchy which prioritizes the inputs used in measuring fair value as follows: Level 1 observable inputs such as quoted prices in active markets; Level 2 inputs, other than quoted prices in active markets, that are observable either directly or indirectly; and Level 3 unobservable inputs for which there are little or no market data, which require the Company to develop its own assumptions. The hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

As of December 31, 2022 and 2021, the Company had no financial assets or liabilities measured at fair value on a recurring basis. The carrying amounts of the Company’s cash equivalents, accounts receivable, accounts payable, and accrued expenses approximate their fair value at December 31, 2022 and 2021 due to their short-term nature.

Revenue Recognition

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 at the point in time when contractual performance obligations have been satisfied and control of the product has been transferred to the customer. The Company has a single product delivery performance obligation. Accrued product returns using the most likely amount method are estimated based on historical data and evaluation of current information and variable consideration is not constrained.

Accounts Receivable

Accounts receivable are recorded in 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. The Company does not have any off-balance sheet credit exposure related to its customers. Allowance for doubtful accounts was $25,000 as of December 31, 2022 and December 31, 2021.

Income Taxes

The Company records income taxes using the asset and liability method. Deferred income tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases, and operating loss and tax credit carryforwards. The Company’s financial statements contain certain deferred tax assets, which have arisen primarily as a result of operating losses, as well as other temporary differences between financial and tax accounting. In accordance with the provisions of the Income Taxes topic of the Codification, the Company is required to establish a valuation allowance if the likelihood of realization of the deferred tax assets is reduced based on an evaluation of objective verifiable evidence. Management judgment is required in determining the Company’s provision for income taxes, the Company’s deferred tax assets and liabilities and any valuation allowance recorded against those net deferred tax assets. The Company evaluates the weight of all available evidence to determine whether it is more likely than not that some portion or all of the net deferred income tax assets will not be realized.

Utilization of the net operating loss carryforwards (“NOL”) and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future, as provided by Section 382 of the Internal Revenue Code of 1986, as well as similar state provisions. Ownership changes may limit the amount of NOL and tax credit carryforwards that can be utilized to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of

certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. If the Company has experienced a change of control, utilization of its NOL or tax credits carryforwards would be subject to an annual limitation under Section 382. Any limitation may result in expiration of a portion of the NOL or research and development credit carryforwards before utilization. Subsequent ownership changes could further impact the limitation in future years. Further, until a study is completed and any limitation known, no amounts are being presented due to an uncertain tax position. A full valuation allowance has been provided against the Company's NOL carryforwards and research and development credit carryforwards and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the balance sheet or statement of operations if an adjustment were required.

A two-step evaluation of all tax positions was performed, ensuring that these tax return positions meet the "more likely than not" recognition threshold and can be measured with sufficient precision to determine the benefit recognized in the financial statements. These evaluations provide the Company with a comprehensive model for how it should recognize, measure, present, and disclose in its financial statements certain tax positions that it has taken or expects to take on income tax returns.

Research and Development

Costs incurred in research and development are expensed as incurred. Included in research and development costs are wages, benefits, product design consulting, and other operating costs such as facilities, supplies, electronic components and overhead directly related to research and development efforts.

Product Warranty Costs

Product warranty costs are estimated based on historical experience, product failure rates, repair volume and labor costs. Warranty costs are accrued at the time of sale within cost of revenue and periodically reviewed in the aggregate. The liabilities for product warranty costs of $16,700 and $28,400 at December 31, 2022 and 2021, respectively, are included in accrued expenses and compensation in the accompanying balance sheets.

Fixed Assets and Long-Lived Assets

Fixed assets are recorded at cost and depreciated using the straight-line method over the estimated useful life of each asset. Expenditures for repairs and maintenance are charged to expense as incurred. On disposal, the related assets and accumulated depreciation are eliminated from the accounts and any resulting gain or loss is included in the Company's statement of operations. Leasehold improvements are amortized over the shorter of the estimated useful life of the improvement or the remaining term of the lease.

The Company periodically evaluates the recoverability of its fixed assets and other long-lived assets which may result in an adjustment of estimated depreciable lives or asset impairment. When indicators of impairment are present, the carrying values of the asset are evaluated in relation to the assets operating performance and future undiscounted cash flows of the underlying assets. If an impairment is indicated, the asset carrying value is reduced to fair value based on market value estimates and assumptions concerning the amount and timing of future cash flows and discount rates.

Accounting for Stock-Based Compensation

Stock-based compensation cost is recognized ratably over the service period. The Company uses the Black-Scholes option pricing model for determining the fair value of stock options and amortizes stock-based compensation expense using the straight-line method. The Black-Scholes model requires assumptions regarding expected share price volatility, expected life of options, expected annual dividend yield, and risk-free interest rate (See Note 3 — Stock-Based Compensation).

Net Loss per Common Share

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

	Years Ended December 31,	
	2022	2021
Net loss applicable to common stockholders	$ (4,416,609)	$ (2,281,457)
Weighted average number of common shares outstanding, basic and dilutive	7,130,139	5,111,045
Net loss per common share applicable to common stockholders, basic and diluted	$ (0.62)	$ (0.45)

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:

	Years Ended December 31,	
	2022	2021
Options	525,462	504,045
Unvested restricted stock awards	96,250	30,000
Unvested restricted stock units	194,731	—
Convertible preferred stock	62	62
Total	816,505	534,107

Advertising and Promotional Costs

Advertising and promotional costs are expensed as incurred. Advertising and promotion expense were $268,703 and $276,263, in 2022 and 2021, respectively.

Accumulated Other Comprehensive Items

For 2022 and 2021, the Company had no components of other comprehensive income or loss other than net loss.

Segments

The Company operates in a single segment covering the sale of medical equipment and consumables. The majority of the Company’s assets, revenues, and expenses for 2022 and 2021 were located in or derived from operations in the United States. Revenues from sales outside the United States accounted for approximately 14% of total revenues in 2022 and 2021.

Risks and Uncertainties

The Company is subject to risks common to companies in the medical device industry, including, but not limited to, environmental risk such as the COVID-19 pandemic, development by the Company or its competitors of new technological innovations, dependence on key personnel, customers’ reimbursement from third-party payers, protection of proprietary technology, and compliance with regulations of the U.S Food and Drug Administration, Federal Trade Commission and other governmental agencies.

The Company relies on in-house assembly and third-party manufacturers to manufacture the major portion of its current products and product components. The disruption or termination of the supply of these products or a significant increase in the cost of these products from these sources could have an adverse effect on the Company's business, financial position, and result of operations.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") and are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently adopted and recently issued accounting pronouncements will not have a material impact on our balance sheets, results of operations and cash flows.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses: Measurement of Credit Losses on Financial Instruments.* The guidance in Accounting Standards Update ("ASU") 2016-13 replaces the incurred loss impairment methodology under current GAAP. The new impairment model requires immediate recognition of estimated credit losses expected to occur for most financial assets and certain other instruments. It will apply to all entities. For trade receivables, loans and held-to-maturity debt securities, entities will be required to estimate lifetime expected credit losses. This may result in earlier recognition of credit losses. In November 2019 the FASB issued ASU No. 2019-10, which delays this standard's effective date for SEC smaller reporting companies to the fiscal years beginning on or after December 15, 2022. The Company determined that this update will not have a material impact on the financial statements upon adoption on January 1, 2023.

3. Stock-Based Compensation

The Company's 2022 Equity Incentive Plan (the "Stock Plan") provides for granting of incentive and nonqualified stock option and stock bonus awards to officers, employees and outside consultants. Outstanding options under the Stock Plan generally vest over four years and terminate 10 years after the grant date, or earlier if the option holder is no longer an executive officer, employee, consultant, advisor or director of the Company. As of December 31, 2022, 1,239,890 shares of common stock were authorized for issuance under the Stock Plan, of which 209,131 shares had been issued, 96,250 restricted stock awards and 194,731 restricted stock units remain unvested, 525,462 shares were subject to outstanding options at a weighted average exercise price of $3.34 per share and 214,316 shares were available for future grant.

The Company's 2009 Non-Qualified Inducement Stock Plan (the "Inducement Plan") is intended to encourage employees, including prospective employees, upon whose efforts the Company depends for the successful conduct of its business, to acquire an equity interest in the Company. The Inducement Plan provides for the granting of awards, including non-qualified stock options, restricted stock, and unrestricted stock. As of December 31, 2022, 1,250 shares of common stock were authorized for issuance and were available for future grant under the Inducement Plan.

The exercise price of stock options awarded under the Stock Plan and the Inducement Plan may not be less than the fair value of the common stock on the date of the option grant. For holders of more than 10% of the Company's total combined voting power of all classes of stock, incentive stock options may not be granted at less than 110% of the fair value of the Company's common stock and for a term not to exceed five years.

The Company's 2010 Employee Stock Purchase Plan (the "ESPP"), amended and restated in 2021 to increase stock purchase capacity, authorizes an annual increase on the first day of each of the Company's fiscal years equal to the lesser of (i) 50,000 shares, (ii) 1 percent of the shares of common stock outstanding on the last day of the immediately preceding fiscal year, or (iii) such lesser number of shares as is determined by the Board. All full-time employees and certain part-time employees are eligible to participate in the ESPP. For part-time employees to be eligible, they must have customary employment of more than five months in any calendar year and more than 20 hours per week. Employees who, after exercising their rights to purchase shares under the ESPP, would own shares representing 5% or more of the voting power of the Company's common stock, are ineligible to participate.

Under the ESPP, participating employees can authorize the Company to withhold up to 10% of their earnings during consecutive six-month payment periods for the purchase of the shares. At the conclusion of each period, participating employees can purchase shares at 85% of the lower of their fair value at the beginning or end of the period. The ESPP is regarded as a compensatory plan. For the years ended December 31, 2022 and 2021, the Company issued 20,206 and 16,371

3. Stock-Based Compensation - (continued)

shares of its common stock, respectively, under the ESPP. As of December 31, 2022, there were 165,923 remaining shares to be issued under the ESPP.

The Company uses the Black-Scholes option pricing model for determining the fair value of shares of common stock issued or to be issued under the ESPP. The following assumptions were used in determining fair value: The risk-free interest rate assumption is based on the United States Treasury's constant maturity rate for a six month term (corresponding to the expected option term) on the date the option was granted. The expected dividend yield is zero as the Company does not currently pay dividends nor expects to do so during the expected option term. An expected term of six months is used based on the duration of each plan offering period. The volatility assumption is based on daily historical volatility during the time period that corresponds to the expected option term and expected future stock price volatility.

The assumptions that the Company used in the Black-Scholes pricing model to determine the fair value of the stock options used in the calculation of stock-based compensation expense for the years ended December 31, 2022 and 2021 were as follows:

	Years Ended December 31,	
	2022	2021
Risk-free interest rate	1.8% — % 3.7%	1.2% — % 1.6%
Expected dividend yield	—	—
Expected option term	5 years	10 years
Volatility	70.0 %	70.0%

A summary of option activity for the year ended December 31, 2022 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2021	504,045	$ 3.34		
Granted	21,500	3.84		
Exercised	—	—		
Forfeited	(83)	165.98		
Expired	—	—		
Outstanding at December 31, 2022	525,462	$ 3.34	7.8	$ —
Vested or expected to vest at December 31, 2022	481,462	$ 3.33	7.8	$ —
Exercisable at December 31, 2022	481,462	$ 3.33	7.8	$ —

Expected to vest options are determined by applying the estimated forfeiture rate to the total outstanding options. Aggregate intrinsic value represents the total pre-tax intrinsic value (the aggregate difference between the closing stock price of the Company's common stock as of December 31, 2022, as applicable, and the exercise price for the in-the-money options) that would have been received by the option holders if all the in-the-money options had been exercised on December 31, 2022.

The weighted average per share grant-date fair values of options granted during 2022 and 2021 was $3.84 and $2.93, respectively.

The aggregate intrinsic value of options issued or exercised during 2022 was $0 and 2021 was $449,500.

Total unrecognized stock-based compensation costs related to non-vested stock options was $76,194, which related to 44,000 shares with a per share weighted fair value of $3.41 as of December 31, 2022. This unrecognized cost is expected to be recognized over a weighted average period of approximately 2.7 years.

3. Stock-Based Compensation - (continued)

Cash received from option exercises and purchases under the Stock Plan and ESPP for 2022 and 2021, was $30,259 and $121,674, respectively. The Company issues new shares upon option exercises and purchases under the Company's ESPP.

During 2022 and 2021, certain employees and directors have been granted restricted stock awards and restricted stock units that are service based. The fair value of the restricted stock awards and units are calculated based on the closing price of common stock on the date of issuance.

During 2022, 96,000 restricted stock awards and 221,236 restricted stock units were granted to employees and members of the Board of Directors that vest at different times during the years 2022 through 2025. Included therein were grants to the members of the Board of Directors, 52,941 restricted stock units in May 2022, that cliff vest in one year from issuance, 27,472 restricted stock units in July 2022 to a new member of the Board of Directors that vest quarterly over a two year period and 96,000 restricted stock awards and 140,823 restricted stock units to employees that vest quarterly at different times during the years 2022 through 2025. During 2021, 30,000 restricted stock awards were granted to an employee that vest quarterly during the years 2022 through 2024.

A summary of restricted stock activity for the year ended December 31, 2022 is presented below:

	Restricted Stock Awards	Weighted Average Grant Date Fair Value	Restricted Stock Units	Weighted Average Grant Date Fair Value
Unvested at December 31, 2021	30,000	$ 9.10	—	
Granted	96,000	$ 4.48	221,236	$ 3.41
Vested	(19,684)	$ 6.36	(18,722)	$ 3.47
Forfeited	(10,066)	$ 5.47	(7,733)	$ 3.44
Unvested at December 31, 2022	96,250	$ 5.43	194,731	$ 3.40

The Company recorded stock-based compensation expense of $477,062 and $698,173 for 2022 and 2021, respectively.

Total compensation cost related to non-vested awards not yet recognized at December 31, 2022 was $1,057,845. These unrecognized costs are expected to be recognized over a weighted-average period of 2.1 years.

4. Inventories

Inventories consist of the following:

	December 31,	
	2022	2021
Purchased components	$ 982,129	$ 422,093
Finished goods	632,858	284,460
	$ 1,614,987	$ 706,553

The Company recorded a charge of $356,700 to cost of goods sold in the fourth quarter of 2022 for Quell inventory to reduce the carrying value to net realizable value. During 2021, inventory was reduced by $400,000 upon the transfer to research and development of Quell electronic components intended for use in development of new products for disease specific pain indications.

5. Fixed Assets

Fixed assets consist of the following:

	Estimated Useful Life (Years)	December 31, 2022	December 31, 2021
Computer and laboratory equipment	3	$ 459,218	$ 913,966
Furniture and equipment	3	33,104	241,413
Production equipment	7	296,180	284,069
Leasehold improvements	*	58,128	65,395
		846,630	1,504,843
Less – accumulated depreciation		(681,011)	(1,306,140)
		$ 165,619	$ 198,703

* Lesser of life of lease or estimated useful life.

Depreciation expense was $49,391 and $76,378 for 2022 and 2021, respectively. During 2022, the Company wrote off fully depreciated fixed assets no longer in service with a cost basis and accumulated depreciation of $674,520. It also disposed of assets with a cost basis of $6,875 and recognized a loss in this amount. During 2021, the Company disposed of property and equipment with a cost basis of $131,731 resulting in a loss of $40,123.

6. Accrued Expenses and Compensation

Accrued expenses and compensation consist of the following for the years ended December 31, 2022 and 2021:

	December 31, 2022	December 31, 2021
Professional services	$ 155,000	$ 109,000
Compensation	249,224	440,474
Warranty	16,700	28,400
Leasehold	—	60,000
Sales tax	131,621	108,788
Other	37,394	106,493
	$ 589,939	$ 853,155

7. Income Taxes

Current income tax expense (benefit) attributable to continuing operations was zero for the years ended December 31, 2022 and 2021.

The Company's effective income tax rate differs from the statutory federal income tax rate as follows for the years ended December 31, 2022 and 2021.

	Years Ended December 31,	
	2022	2021
Federal statutory rate	(21.0)%	(21.0)%
State tax provision, net of federal provision	(4.9)	(4.6)
Permanent items	0.1	(2.0)
Federal research and development credits	(3.3)	(2.0)
382 Limitation - NOL and tax credits	(17.4)	—
Valuation allowance	46.5	29.6
Effective income tax rate	—	—

The Company's deferred tax assets consist of the following:

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 3,369,688	$ 2,247,647
Research and development credit carryforwards	310,000	92,465
Accrued expenses	74,459	117,795
Inventory reserve	88,983	23,396
Stock-based compensation	323,337	325,695
Right of use asset	87,872	134,950
Capitalized R&D	719,888	—
Other	—	5,637
Total gross deferred tax assets	4,974,227	2,947,585
Valuation allowance	(4,868,469)	(2,827,759)
Deferred tax liabilities:		
Lease liability	$ (91,502)	$ (119,826)
Other	$ (14,256)	$ —
Net deferred tax assets	$ —	$ —

At December 31, 2022, the Company had federal NOL of approximately $134.4 million, of which $124.2 began to expire in 2022 and $10.2 million have an indefinite carryforward. At December 31, 2022, the Company had state NOLs of $55.2 million, some of which have an indefinite carryforward, and others that begin to expire in 2025. At December 31, 2022, the Company has federal and state tax credits of approximately $1.9 million and $0.9 million, respectively, which may be available to reduce future taxable income and related taxes thereon. These amounts include tax benefits of approximately $2.5 million and $75,000 attributable to NOL and tax credit carryforwards, respectively, that result from the exercise of employee stock options. The Company experienced an ownership change in 2019 as defined under Internal Revenue Service Regulations, which significantly reduced the tax benefits associated with these carryforwards under Internal Revenue Code Sections 382 and 383. The federal and state research and development credits each began to expire in 2022.

In accordance with the provisions of the Income Taxes topic of the Codification, the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating losses. Management has determined that it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets and, as a result, a valuation allowance of approximately $4.9 million and $2.8 million has been established at December 31, 2022 and 2021, respectively. The Company experienced a change in control during 2019. Accordingly, utilization of their respective consolidated and/ or separately computed NOL's and/ or tax credit carryforwards is subject to an annual limitation for federal tax purposes under Internal Revenue Code Sections 382 and 383. Due to this change

in control, the Company estimates that approximately $123,800,000 of federal NOL's and/or tax credit carryforwards are effectively eliminated according to the Internal Revenue Code Sections 382 and 383 limitations. A large portion of state NOLs and/ or tax credit carry forwards are also eliminated. The Company has not recorded any amounts for unrecognized tax benefits as of December 31, 2022 or 2021. The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending income tax examinations. The Company's tax years are still open under statute from December 31, 2019 to the present. Earlier years may be examined to the extent that tax credit or net operating loss carryforwards are used in future periods. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision.

8. Commitments and Contingencies

Operating Leases

The Company's lease on its Woburn, Massachusetts corporate office and manufacturing facilities (the "Woburn Lease") extends through September 2025 at a monthly base rent of $13,846 and with a 5-year extension option. The Company's lease on its former corporate office in Waltham, Massachusetts (the "Waltham lease") ended in February 2022. During the years ended December 31, 2022 and 2021 the Company recorded sublet income on the Waltham lease totaling $22,795 and $125,739, respectively within operating expenses on the Company's Statement of Operations.

Impairment charges related to the Waltham lease recorded within the Company's Statement of Operations for the year ended December 31, 2022 and 2021 were zero and $126,748, respectively.

The following is a maturity analysis of the annual cash flows of the operating lease liabilities as of December 31, 2022:

2023	$	165,785
2024		165,785
2025		117,431
Total minimum lease payments	$	449,001
Discount rate, 15.0%	$	93,094
Lease obligation, current portion		148,391
Lease obligation, net of current portion		207,516
	$	449,001

Total recorded rent expense net of sublet income was $163,061 and $201,496, for 2022 and 2021, respectively. The Company records rent expense on its facility leases on a straight-line basis over the lease term. The remaining operating lease term was 3.2 years as of December 31, 2022.

Contingencies

The Company is not party to any legal proceedings

9. Retirement Plan

The Company maintains a 401(k) defined contribution savings plan for its employees who meet certain service period and age requirements. Contributions are permitted up to the maximum allowed under the Internal Revenue Code of each covered employee's salary. The savings plan permits the Company to contribute at its discretion. In 2022 and 2021 the Company made no contributions to the plan.

10. Stockholders' Equity

Preferred stock and convertible preferred stock consist of the following:

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

Preferred stock activity

As of December 31, 2022, 200 shares of Series B convertible preferred stock remained outstanding. There were no preferred stock conversions in 2022. The shares of Series B convertible preferred stock are convertible into the equivalent of 62 common shares.

Other equity activity

During 2022, the Company issued in settlement of management incentive compensation 50,213 shares of fully vested common stock with a value of $215,417.

During 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 2022 Equity Incentive Plan.

During 2022 and 2021, respectively, the Company issued pursuant to its ATM Agreement 916,334 shares of common stock for net proceeds of $3,833,772 and 2,756,705 shares of its common stock for net proceeds of $19,429,621.

During 2022 and 2021, respectively, the Company issued 20,206 shares of fully vested common stock with a value of $30,259 and 16,371 shares of fully vested common stock with a value of $43,174 pursuant to the Company's 2010 Employee Stock Purchase Plan, respectively.

As of December 31, 2022 and 2021, the Company had 25,000,000 shares of common stock authorized and 7,785,754, and 6,680,480 shares issued and outstanding, respectively. Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are not entitled to receive dividends unless declared by the Board of Directors.

At December 31, 2022, the Company has reserved authorized shares of common stock for future issuance as follows:

Outstanding stock options	525,462
Convertible preferred stock	62
Unvested restricted stock units	194,731
Possible future issuance under inducement plan	1,250
Possible future issuance under stock option plans	214,316
Possible future issuance under employee stock purchase plan	165,923
Total	1,101,744

11. Management Retention and Incentive Plan

Under the Company's Management Retention and Incentive Plan (the "Plan"), a portion of the consideration payable upon a change in control transaction, as defined in the Plan and its amendments, would be paid in cash to certain executive officers and key employees and recorded as compensation expense within the Statement of Operations during the period in which the change of control transaction occurs.

Schedule II — Valuation and Qualifying Accounts

Description	Balance at Beginning of Period	Charged to costs and expenses	Charged to other accounts	Recoveries/ (Deductions)	Balance at End of Period
December 31, 2022					
Allowance for Doubtful Accounts	$ 25,000	$ —	$ —	$ —	$ 25,000
Deferred Tax Asset Valuation Allowance	2,827,759	2,187,921	—	(147,211) (1)	4,868,469
Accrued Product Returns	39,000		—	(38,000)	1,000
Warranty Reserve	28,400	—	—	(11,700)	16,700
December 31, 2021					
Allowance for Doubtful Accounts	$ 25,000	$ —	$ —	$ —	$ 25,000
Deferred Tax Asset Valuation Allowance	3,012,513	2,467,804	—	(2,652,558) (1)	2,827,759
Accrued Product Returns	545,000	—	—	(506,000)	39,000
Warranty Reserve	49,600	—	—	(21,200)	28,400

(1) Expiration of Federal and State Net Operating Loss Carryforwards and other reductions.

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-118059, 333-135242, 333-151195, 333-159712, 333-159713, 333-167180, 333-173769, 333-183071, 333-186827, 333-189393, 333-190177, 333-197407, 333-205827, 333-211379, 333-218431, 333-226245, 333-236105, 333-256489 and 333-265080) and on Form S-3 (Nos. 333-150087, 333-162303, 333-189392, 333-197405, 333-199359, 333-208923, 333-211919, 333-215792, 333-219783 and 333-260438) of our report dated March 22, 2023 relating to the financial statements and schedule of NeuroMetrix, Inc. (the "Company"), as of and for the years ended December 31, 2022 and 2021, which appears in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

/s/ Baker Tilly US, LLP
Tewksbury, Massachusetts
March 22, 2023

Exhibit 31.1

CERTIFICATION

I, Shai N. Gozani, certify that:

1. I have reviewed this Annual Report on Form 10-K 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: March 22, 2023

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

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

Exhibit 31.2

CERTIFICATION

I, Thomas T. Higgins, certify that:

1. I have reviewed this Annual Report on Form 10-K 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: March 22, 2023

/s/ THOMAS T. HIGGINS

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

Exhibit 32

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 Annual Report for the year ended December 31, 2022 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 22, 2023

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

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

Date: March 22, 2023

/s/ THOMAS T. HIGGINS

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