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, 2020
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 (check one):

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. ☐

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, 2020, 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 $7,690,938 based on the closing sale price of the common stock as reported on the Nasdaq Capital Market on June 30, 2020.

As of January 27, 2021, there were 3,796,147 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 April 27, 2021, or the 2021 Annual Meeting of Stockholders.

NEUROMETRIX, INC.

ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2020

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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, or the Exchange Act, including, without limitation, statements regarding our or our management's expectations, hopes, beliefs, intentions or strategies regarding the future, such as our estimates regarding anticipated operating losses, future revenues and projected expenses, our future liquidity and our expectations regarding our needs for and ability to raise additional capital; our ability to manage our expenses effectively and raise the funds needed to continue our business; our belief that there are unmet needs for the management of chronic pain and in the diagnosis and treatment of diabetic neuropathy; our expectations surrounding 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; our estimate of our customer returns of our products; the rate and degree of market acceptance of any future products; our reliance on key scientific management or personnel; the payment and reimbursement methods used by private or government third party payers; and other factors discussed elsewhere in this 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 develops and commercializes health care products that utilize non-invasive neurostimulation. Our core expertise in biomedical engineering has been refined over two decades of designing, building and marketing medical devices that stimulate nerves and analyze nerve response for diagnostic and therapeutic purposes. We created the market for point-of-care nerve testing and were first to market with sophisticated wearable technology for symptomatic relief of chronic pain. Our business is fully integrated with in-house capabilities spanning research and development, manufacturing, regulatory affairs and compliance, sales and marketing, product fulfillment and customer support. We derive revenues from the sale of medical devices and after-market consumable products and accessories. Our products are sold in the United States and select overseas markets. They are cleared by the U.S. Food and Drug Administration (FDA) and regulators in foreign jurisdictions where appropriate. We have two principal product categories:

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

Peripheral neuropathies, also called polyneuropathies, are diseases of the peripheral nerves. They affect about 10% of adults in the United States, with the prevalence rising to 25-50% among individuals 65 years and older. Peripheral neuropathies are associated with loss of sensation, pain, increased risk of falling, weakness, and other complications. People with peripheral neuropathies 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 numerous clinical studies.

Chronic pain is a significant public health problem. It is defined by the National Institutes of Health (NIH) as pain lasting more than 12 weeks. This contrasts with acute pain which is a normal bodily response to injury or trauma. Chronic pain conditions include low back pain, arthritis, fibromyalgia, neuropathic pain, cancer pain and many others. Chronic pain may be triggered by an injury or there may be an ongoing cause such as disease or illness. There may also be no clear cause. Chronic pain can also lead to other health problems. These can include fatigue, sleep disturbance and mood changes, which cause difficulty in carrying out important activities and 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. Increasingly, restrictions are being imposed on access to prescription opioids. Reflecting the complexity of chronic pain and the difficulty in treating it, we believe that inadequate relief leads 25% to 50% of pain sufferers to seek alternatives to prescription pain medications. These alternatives include nutraceuticals, acupuncture, chiropractic care, non-prescription analgesics, electrical stimulators, braces, sleeves, pads and other items. In total these pain relief products and services account for approximately $20 billion in annual out-of-pocket spending in the United States.

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

Goals and 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. DPNCheck has been evaluated in multiple clinical trials. It contributes attractive gross margins and has posted average growth rates exceeding 25% over the five years through 2018. Growth during 2019-2020 was below trend due to a downturn in demand in Mexico, followed by the effects of the COVID-19 pandemic. We believe that growth may rebound in 2021 as the pandemic situation eases. We are prepared to support renewed growth with product supply and user training resources. Also, we are developing the next generation DPNCheck technology which will enhance the user experience, improve manufacturing, and restrict inappropriate re-use and the potential use of non-compliant biosensors. Release of the new DPNCheck technology, planned for late 2021, may also provide an opportunity for customer upgrades, and pricing and margin-expansion.

Quell is our wearable technology for chronic pain. Over the past year we restructured the Quell commercial model to the point where it now delivers a positive net operating contribution after direct costs. Most of our sales are direct-to-consumer via our e-commerce platform, www.QuellRelief.com. Having refined the core commercial model, including efficient ad spending, our objective has now turned to profitable growth. During 2021, this could encompass greater ad promotion in order to more rapidly expand the Quell user population, and it could include additional applications for the technology and, potentially, other markets.

Both DPNCheck and Quell are sophisticated neurotechnology products that are unique in their markets. Our goal for both products is the same: to optimize market positioning and financial performance for the benefit of our shareholders.

Research and Development Innovation for Competitive Advantage

Our products are proprietary and were developed in-house by our R&D team. We believe that continual product innovation, focusing on our unique competency of precision neurostimulation, is essential to profitable growth and competitive advantage. Our 2021 R&D efforts include completion leading to launch of the DPNCheck Generation 2 product. We will also continue to innovate the Quell platform.

Our Business Model

Our products typically consist of a medical device used in conjunction with a consumable electrode or biosensor. Other accessories and consumables are also available to customers. Our commercial objective is to build an installed base of active customer accounts that regularly order high-margin aftermarket products. We successfully implemented this model with our original NC-stat system and have applied it to subsequent product generations including ADVANCE. Our more recent products, DPNCheck and Quell, conform to this 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 electronic medical records.

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. The modified device costs less than the original device but has the same functionality with respect to sural nerve testing. More than 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 studies, including over 20 studies specifically addressing the accuracy and clinical utility of the DPNCheck device in assessment of DPN. Cumulatively through 2020 approximately 6,900 DPNCheck devices have been shipped to customers.

Quell

Quell is a wearable device for symptomatic relief and management of chronic pain. 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 neoprene 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. We also recently launched an Apple Watch® app that 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 cleared by the FDA for symptomatic relief and management of chronic pain and is available OTC via e-commerce. The device was made commercially available in June 2015. Cumulatively through 2020 over 198,000 Quell devices have been shipped to customers.

ADVANCE System

Our legacy neurodiagnostics business is primarily the ADVANCE System which 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. We do not actively market the ADVANCE device.

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 carpal tunnel syndrome, or 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, 2020, we had an installed base of approximately 150 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 chronic pain (OTC)	> 198,000
SENSUS	Q1 2013 – Q4 2020	Transcutaneous Electrical Nerve Stimulation	Symptomatic relief and management of chronic pain (prescription)	> 11,000
DPNCheck	Q4 2011 – present	Nerve Conduction	Evaluation of peripheral neuropathies	> 1,600,000
ADVANCE	Q2 2008 – present	Nerve Conduction	Evaluation of entrapment and systemic neuropathies	> 1,900,000 (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, the Middle East and Mexico. Cumulatively through December 31, 2020, over 6,900 DPNCheck devices have been shipped to customers. Quell customers are primarily consumers in the United States. Cumulatively through December 31, 2020, over 198,000 Quell devices have been shipped. Our legacy ADVANCE System customers include approximately 150 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, 2020, two customers accounted for 50% of accounts receivable and two customers accounted for 35% of revenue.

Sales, Marketing, and Distribution

Our U.S. sales efforts for DPNCheck focus on Medicare Advantage organizations and associated 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 early 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, in Japan DPNCheck is sold by our distribution partner Fukuda Denshi Co., Ltd.; in China DPNCheck is sold by Omron Medical (Beijing) Ltd.; and in Mexico DPNCheck is sold by Scienta Farma, S.A. De C.V..

Quell is distributed in the United States primarily via the Company's e-commerce website *www.quellrelief.com*, and via the Amazon e-commerce platform. Digital advertising is used to expand product awareness.

Our installed base of ADVANCE accounts is supported by our customer service department. We are not actively pursuing new ADVANCE customers. Internationally, ADVANCE account support is handled by a small network of independent distributors.

Sales and marketing efforts for DPNCheck and ADVANCE are led by our Senior Vice President, General Manager, Diagnostics. We provide technical, clinical, and business practices training for our customer service employees.

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, or 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 help control costs.

A New England based 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 frequent 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 cleared 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 seven engineers includes one who holds an M.D. degree. Our founder and Chief Executive Officer directs our R&D efforts and coordinates our clinical program. He holds both M.D. and Ph.D. degrees.

R&D efforts planned for 2021 will address our two commercial products:

- *DPNCheck Generation 2.* DPNCheck, our nerve conduction test for peripheral neuropathies including DPN, has been on the market since 2011 without any significant engineering changes. While the product has performed well and we believe that demand is growing, some features need to be added to improve the user experience, improve the manufacturing process, and restrict the potential use of non-compliant biosensors. Completion of this technology upgrade will be a primary R&D activity during 2021:

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- *Quell R&D.* During 2021 we intend to continue to enhance and innovate the Quell platform.

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

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 our clinical study results in leading peer-reviewed journals while also encouraging our clinical collaborators and clinical study grant recipients to do the same.

Competition

Quell is promoted 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 (TENS) have achieved limited success in practice due to device limitations, ineffective dosing and low patient adherence. We believe that the personalization features of our wearable technology for chronic pain and sleep, including app control, the high power and automation, and the digital health integration characteristics place Quell in a unique neurostimulation category. There are numerous manufacturers of transcutaneous electrical nerve stimulation devices including widely marketed over-the-counter TENS.

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 a number of 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 established reputations as having effective worldwide distribution channels for 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, 2020, we had 47 issued U.S. patents, 15 issued foreign patents, and 19 patent applications. Our wearable therapeutic products have 16 issued U.S. utility patents and nine issued U.S. design patents plus 12 utility and design patent applications. The foreign patents for wearable therapeutics were assigned to GSK under the terms of our 2018 collaboration agreement. For our DPNCheck diagnostic device, 18 utility patents (three U.S. and 15 foreign) were issued that cover the core technology and there is one additional utility patent application.

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 2022 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, OptiTherapy, 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, NC-stat, and SENSUS.

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 2021 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 are receiving their medical care through managed care programs which monitor and often require pre-approval of the services that a member will receive. Some managed care programs are paying their providers on a per capita basis a predetermined annual payment per member which puts the providers at financial risk for the services provided to their members. This is generally the case under Medicare Advantage where contracting insurers receive a capitated fee from CMS to provide all necessary medical care to participating members. These capitated fees 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 insurer fully absorbs the risk of patient health care costs. Insurers 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 insurers receive capitation fees consistent with the cost of treating 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. We believe that the clinical and economic proposition for DPNCheck is attractive to Medicare Advantage insurers and risk bearing provider organizations. We are focusing our United States sales effort for DPNCheck on the Medicare Advantage managed care market segment.

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

U.S. Food and Drug Administration (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, or 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*), or 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 the Quell and DPNCheck devices and the ADVANCE System, 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, or 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. Although this Guidance does not impact our marketed products, 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, or 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 including 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 we have transitioned many 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.

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.

The previously reported investigation by the Federal Trade Commission (the "Commission") regarding Quell® advertising was settled in March 2020. The Company did not admit to any of the Commission's allegations, agreed to certain modifications of Quell advertising claims, and pledged to pay to the Commission future commercial milestone payments, if and when received, pursuant to a collaboration agreement with a third party.

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 April 2019, NeuroMetrix underwent a successful MDSAP audit by the registrar TÜV SÜD. There were no observations noted during the MDSAP audit. The FDA accepts MDSAP audit reports as a substitute for routine Agency inspections.

Human Capital Resources

As of December 31, 2020, we had 20 full time employees. Of these employees, seven were in research and development, four in sales and marketing, four in production/distribution, and five 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 cultural fit and energy are important considerations. 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 to which all employees are required to annually confirm compliance. During 2020, 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

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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 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.

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, 2020, we had an accumulated deficit of $196.9 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 ability to continue as a going concern is dependent on our ability to raise additional capital. 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 and cash equivalents of $5.2 million as of December 31, 2020. We believe that these resources, and the cash to be generated from future product sales will be sufficient to meet our projected operating requirements through the fourth quarter of 2021. Accordingly, we will need to raise additional funds to support our future operating and capital needs in the first quarter of 2022 and beyond.

Our financial statements have been prepared assuming that we will continue as a going concern which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. We expect to incur further losses as we grow sales of DPNCheck and Quell. We will be dependent on funding our operations through additional public or private financing, asset divestitures, collaborative arrangements with strategic partners, or through additional credit lines or other debt financing sources. These circumstances raise substantial doubt about our ability to continue as a going concern for the one-year period from the date of issuance of these financial statements. As a result of this uncertainty and the substantial doubt about our ability to continue as a going concern as of December 31, 2020, the report of our independent registered public accounting firm in this Annual Report on Form 10-K for the years ended December 31, 2020 and 2019 includes a going concern emphasis of matter explanatory paragraph. Our financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

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 related to the COVID-19 pandemic and other factors including the uncertainty of future revenues from new products; (b) the effect of the COVID-19 pandemic on our ability to obtain parts and materials from our suppliers while continuing to staff critical production and fulfillment functions; (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.

Our financial condition and results of operations may continue to be adversely affected by the ongoing coronavirus outbreak.

The ongoing COVID-19 coronavirus pandemic, 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.

As 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 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.

While we were able to maintain our business operations during 2020, albeit at a level below our plans for the year, our future results of operations could be adversely affected to the extent that this pandemic 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 COVID-19 affects our operations will depend on future developments, which continue to be uncertain and cannot be predicted with confidence, including the duration of the pandemic, new information that may emerge concerning pandemic severity, efforts for widespread vaccination of the public, and treatment of those who have contracted COVID-19, among others, could have an adverse effect on our business and financial condition.

We are focused on growing sales of DPNCheck, our test for diabetic 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.

We are focused on growing sales of DPNCheck primarily in the United States, Asia and Mexico, and sales of Quell within the United States. DPNCheck was launched in 2011 and is a quantitative nerve conduction test for systemic neuropathies such as DPN. Quell has been on the market since June 2015 and is an over-the-counter wearable device for chronic pain. 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 Medicare Advantage market and Outside the United States (OUS) markets;
- 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 Quell at profitable pricing and efficient digital 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. The failure of such acceptance will materially and adversely affect our operations.

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. Importantly, we cannot predict the effects that implementation of the Patient Protection and Affordable Care Act will have on CMS, commercial insurers, health care providers, and ultimately on our business.

We are subject to extensive regulation by the FDA which could restrict the sales and marketing of the Quell and DPNCheck devices and the ADVANCE System, 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, but it can be significantly longer. The process for obtaining a pre-market approval, or 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 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. Our failure or the failure by any manufacturer of our products to comply with applicable regulatory requirements could result in enforcement action by the FDA. 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.

We depend on several single source manufacturers to produce components of our products. Any material adverse changes in our relationships with these manufacturers 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.

We have experienced transient inventory shortages on our products and essential parts. If any materially adverse changes in our relationships with these 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 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.

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.

The previously reported investigation by the Federal Trade Commission (the "Commission") regarding Quell® advertising was settled in March 2020. The Company did not admit to any of the Commission's allegations, agreed to certain modifications of Quell advertising claims, and pledged to pay to the Commission future commercial milestone payments, if and when received, pursuant to a collaboration agreement with a third party.

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.

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 initiated a DPNCheck product upgrade during 2019. We have additional product candidates and enhancements of our existing products in our R&D pipeline, including the planned DPNCheck Generation 2 product. 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 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:

- lower than expected manufacturing yields of high cost components leading to increased manufacturing costs;
- 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;
- the timing of revenue recognition and revenue deferrals;
- 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.

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 2020.

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.

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, 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. From time to time, we may provide coding and billing information as product support to purchasers of our products. 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. We do not believe that we are subject to the HIPAA rules. However, if we are found to be in violation of the privacy rules under HIPAA, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or 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 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.

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 20 employees as of December 31, 2020, 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 consumer market for pain relief 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.

As we expand into 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 15% and 13% of our revenues in 2020 and 2019, respectively. We are working to expand market penetration, 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. Our 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.

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 will need significant 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, we may be unable to raise additional capital. A sustained inability to raise capital could force us to go out of business. Significant declines in the price of our common stock could also 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, 2020, our stock price has fluctuated from a low of $0.81 to a high of $13.80, as adjusted for stock splits during that time. 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. During 2019 we received notification from Nasdaq informing us of certain listing deficiencies related to the minimum bid price listing requirements. Although we have since cured the deficiency, it is possible that we could fall out of compliance again in the future. If we fail to maintain compliance with any Nasdaq listing requirements, 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, 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. In addition, the terms of our credit facility preclude us from paying any dividends. 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

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

ITEM 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 January 27, 2021, there were approximately 25 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 January 27, 2021, the last reported sale price per share of our common stock on the Nasdaq Capital Market was $4.40.

EQUITY COMPENSATION PLAN INFORMATION

The following table sets forth information as of December 31, 2020 regarding the number of securities to be issued upon exercise, and the weighted average exercise price of outstanding options, warrants, and rights under our equity compensation plans and the number of securities available for future issuance under our equity compensation plans.

Equity Compensation Plan Information as of December 31, 2020

	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column a)	
	(a)	(b)	(c)	
Equity compensation plans approved by security holders(1)	361,956	$ 3.68	53,356	(2)
Equity compensation plans not approved by security holders(3)	—	—	1,250	
Totals	361,956	$ 3.68	54,606	

(1) Includes information related to our Amended and Restated 1996 Stock Option/Restricted Stock Plan, Amended and Restated 1998 Equity Incentive Plan, Eleventh Amended and Restated 2004 Stock Option and Incentive Plan, and Fourth Amended and Restated 2010 Employee Stock Purchase Plan.

(2) As of December 31, 2020, there were 53,356 shares available for future grant under the Eleventh Amended and Restated 2004 Stock Option and Incentive Plan and no shares available under the Fourth Amended and Restated 2010 Employee Stock Purchase Plan.

(3) Includes information related to our Amended and Restated 2009 Non-Qualified Inducement Stock Plan, which is designed to provide equity grants to new employees. Pursuant to this plan, we were authorized to issue Non-Qualified Stock Options, Restricted Stock Awards and Unrestricted Stock Awards.

ITEM 6. SELECTED FINANCIAL DATA

The information required by this item may be found on pages F-1 through F-21 of this Annual Report on Form 10-K.

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.

Overview

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

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

Peripheral neuropathies, also called polyneuropathies, are diseases of the peripheral nerves. They affect about 10% of adults in the United States, with the prevalence rising to 25-50% among individuals 65 years and older. Peripheral neuropathies are associated with loss of sensation, pain, increased risk of falling, weakness, and other complications. People with peripheral neuropathies 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 numerous clinical studies.

Chronic pain is a significant public health problem. It is defined by the National Institutes of Health (NIH) as pain lasting more than 12 weeks. This contrasts with acute pain which is a normal bodily response to injury or trauma. Chronic pain conditions include low back pain, arthritis, fibromyalgia, neuropathic pain, cancer pain and many others. Chronic pain may be triggered by an injury or there may be an ongoing cause such as disease or illness. There may also be no clear cause. Chronic pain can also lead to other health problems. These can include fatigue, sleep disturbance and mood changes which cause difficulty in carrying out important activities and 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. Increasingly, restrictions are being imposed on access to prescription opioids. Reflecting the complexity of chronic pain and the difficulty in treating it, we believe that inadequate relief leads 25% to 50% of pain sufferers to seek alternatives to prescription pain medications. These alternatives include nutraceuticals, acupuncture, chiropractic care, non-prescription analgesics, electrical stimulators, braces, sleeves, pads and other items. In total these pain relief products and services account for approximately $20 billion in annual out-of-pocket spending in the United States.

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

Results of Operations

Comparison of Years Ended December 31, 2020 and December 31, 2019

Revenues

	Years Ended December 31,			
	2020	2019	Change	% Change
	(in thousands)			
Revenues	$ 7,378.0	$ 9,272.5	$ (1,894.5)	(20.4)%

Revenues include sales of Quell, DPNCheck and ADVANCE to physician offices, clinics, hospitals, other healthcare providers and insurers, domestic and international distributors and retail consumers. Revenues comprise sales of medical devices as well as aftermarket electrodes and other supplies. Revenues were $7.4 million and $9.3 million during the years ended December 31, 2020 and 2019, respectively. Revenues during the year ended December 31, 2020 were adversely affected by the economic effects of the COVID-19 pandemic. A recovery trend in customer orders and shipment volume was observed beginning late in the second quarter which continued during the second half of 2020. This trend particularly benefited DPNCheck sales in U.S. Medicare Advantage accounts.

Cost of Revenues and Gross Profit

	Years Ended December 31,			
	2020	2019	Change	% Change
	(in thousands)			
Cost of revenues	$ 2,128.4	$ 7,026.9	$ (4,898.5)	(69.7)%
Gross profit	$ 5,249.6	$ 2,245.6	$ 3,004.0	133.8 %

Our gross profit margin was 71.2% in 2020 versus 24.2% in the prior year. The unusually low gross margin in 2019 reflected an inventory charge of $2.6 million as part of restructuring the Quell business. Excluding this charge, the gross margin rate in 2019 was 54.0%. The margin improvement in 2020 was due to improved profitability of Quell sales and higher weighting of DPNCheck business within total revenue.

Operating Expenses

	Years Ended December 31,			
	2020	2019	Change	% Change
	(in thousands)			
Operating expenses:				
Research and development	$ 2,391.3	$ 3,102.0	$ (710.7)	(22.9)%
Sales and marketing	1,436.8	4,755.2	(3,318.4)	(69.8)%
General and administrative	3,516.3	5,923.2	(2,406.9)	(40.6)%
Total operating expenses	$ 7,344.4	$ 13,780.4	$ (6,436.0)	(46.7)%

Research and Development

Research and development expenses for 2020 decreased by 22.9% from 2019. GSK co-funded specific Quell development projects in the amounts of $0.4 million and $1.5 million in 2020 and 2019, respectively. The co-funding arrangement with GSK was not extended beyond 2020. In addition, personnel costs decreased by $0.6 million due to business restructuring.

Sales and Marketing

Sales and marketing expense for 2020 decreased by 69.8% from 2019 primarily attributable to reduced Quell advertising and trade show spending of $1.6 million. In addition, personnel costs decreased by $0.7 million due to business restructuring and professional services costs decreased by $0.8 million.

General and Administrative

General and administrative expense for 2020 decreased by 40.6% from 2019 due to lower professional service costs of $2.0 million. In addition, personnel costs decreased by $0.1 million due to business restructuring, which was offset with an increase in insurance costs of $0.2 million.

Collaboration income

	Years Ended December 31,			
	2020	2019	Change	% Change
	(in thousands)			
Collaboration income	$ —	$ 7,716.7	$ (7,716.7)	(100.0) %

Collaboration income in 2019 included development milestones paid by GlaxoSmithKline (GSK) under a 2018 Quell collaboration agreement. The final development milestones were achieved in 2019. Cumulative development milestone payments from GSK during the 2018-2019 period were approximately $20.5 million.

Other Income

	Years Ended December 31,			
	2020	2019	Change	% Change
	(in thousands)			
Other income	$ 2.7	$ 45.0	$ (42.3)	(94.0)%

Other income primarily includes interest income.

Net loss per common share applicable to common stockholders, basic and diluted

Net loss per common share applicable to common stockholders was $(0.69), basic and diluted for 2020. Net loss per common share applicable to common stockholders was $(3.90), basic and diluted for 2019. Weighted average shares outstanding used in computing per share amounts are included in Note 2 to the Financial Statements.

Liquidity and Capital Resources

Our principal source of liquidity is cash of $5.2 million at December 31, 2020. Funding for our operations largely depends on revenues from the sales of our commercial products. A low level of market interest in our products, a decline in our consumables sales, or unanticipated increases in our operating costs, and the adverse effects of the COVID-19 pandemic could have an adverse effect on our liquidity and cash.

	December 31, 2020	December 31, 2019	Change	% Change
		(in thousands)		
Cash and cash equivalents	$ 5,226.2	$ 3,126.2	$ 2,100.0	67.2 %

During 2020 our cash and cash equivalents increased by $2.1 million from 2019 reflecting net proceeds of $4.1 million from common stock sales under our ATM program partially offset by $2.1 million in cash used in operating activities. During 2020 the Company terminated its loan facility with a commercial bank.

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

	Years Ended December 31,	
	2020	2019
Days sales outstanding (days)	15.4	26.8
Inventory turnover rate (times per year)	1.9	3.5

Days sales outstanding (DSO) reflect customer payment terms which vary from payment on order to 60 days from invoice date. The decrease in DSO is due to a shift in our sales channel to payment-on-order Quell e-commerce sales. The inventory turnover rate decelerated to 1.9 turns in 2020 versus 3.5 turns in 2019. This reflected lower sales on approximately constant inventory levels in the comparable period.

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

	Years Ended December 31,	
	2020	2019
	(in thousands)	
Net cash used in operating activities (excluding cash provided by collaboration income)	(2,066.9)	(11,338.0)
Net cash provided by collaboration income	—	7,716.7
Net cash used in operating activities	(2,066.9)	(3,621.3)
Net cash used in investing activities	—	(48.1)
Net cash provided by financing activities	4,166.9	15.1

During 2020 our operating activities used approximately $2.1 million.

During the year ended December 31, 2020, our financing activities reflected approximately $4.2 million net proceeds from issuance of stock.

The Company has suffered recurring losses from operations and negative cash flows from operating activities. These factors raise substantial doubt about the Company’s ability to continue as a going concern for the one-year period from the date

of issuance of these financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. We held cash and cash equivalents of $5.2 million as of December 31, 2020. We believe that these resources, and the cash to be generated from future product sales will be sufficient to meet our projected operating requirements through the fourth quarter of 2021. Accordingly, we will need to raise additional funds to support our operating and capital needs in the first quarter of 2022 and beyond.

We continue to face challenges and uncertainties. Among these uncertainties is the future effect on the Company's business of the COVID-19 pandemic which depressed sales of the Company's products during 2020. As a result, our available capital resources may be consumed more rapidly than currently expected due to (a) decreases in sales of our products related to COVID-19 pandemic and other factors including the uncertainty of future revenues from new products; (b) the effect of the COVID-19 pandemic on our ability to obtain parts and materials from our suppliers while continuing to staff critical production and fulfillment functions; (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 affecting our existing products; (f) changes we may make 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, or other debt financing sources. However, we may not be able to secure such financing in a timely manner or on favorable terms, if at all.

We have an effective shelf registration statement on Form S-3 on file with the SEC 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. If we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. 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.

At December 31, 2020, the Company has federal net operating loss carryforwards (“NOL”) of approximately $143.7 million, of which $138.4 million begin to expire in 2021 and $5.3 million have an indefinite carryforward. At December 31, 2020, the Company has state NOLs of $53.1 million, some of which have an indefinite carryforward, and others that begin to expire in 2025. At December 31, 2020, the Company has federal and state tax credits of approximately $1.8 million and $1.1 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 NOLs, the state NOLs, and the federal and state research and development credits each began to expire in 2020. A full valuation allowance has been provided against our NOL carryforwards and research and development credit carryforwards. If an NOL or tax credit adjustment is required, it would be offset by a similar adjustment to the valuation allowance. Thus, NOL or tax credit adjustments would have no impact to the balance sheet or statement of operations.

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 represent 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.

Revenue Recognition and Accounts Receivable

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

Revenue recognition involves judgments, including assessments of expected returns and expected customer relationship periods. We analyze various factors, including a review of specific transactions, historical product returns, average customer relationship periods, customer usage, customer balances, and market and economic conditions. Changes in judgments or estimates on these factors could materially impact the timing and amount of revenues and costs recognized. Should market or economic conditions deteriorate, our actual return or bad debt experience could exceed its estimate. Certain product sales are made with a 30-day or 60-day right of return.

Trade accounts receivable are recorded at the invoiced amount and do not bear interest.

Accounts receivable are recorded net of the allowance for doubtful accounts receivable. The allowance for doubtful accounts is our best estimate of the amount of probable credit losses in our existing accounts receivable. We review our allowance for doubtful accounts and determine the allowance based on an analysis of customer past payment history, product usage activity, and recent communications between us and the customer. Individual customer balances which are past due and over 90 days outstanding are reviewed individually for collectability. Account balances are written-off against the allowance when we feel it is probable the receivable will not be recovered. We do not have any off-balance sheet credit exposure related to our customers.

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. We write down inventory to its net realizable value for excess or obsolete inventory. The realizable value of inventories is based upon the types and levels of inventories held, forecasted demand, pricing, competition, and changes in technology. Our consumable electrodes and biosensors have an eighteen to thirty-six month shelf life. Should current market and economic conditions deteriorate, our actual recoveries could be less than our estimates.

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 is required to measure and record 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.

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. Significant 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 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 IRS 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 as 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.

Management performed a two-step evaluation of all tax positions, 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 management with a comprehensive model for how a company should recognize, measure, present, and disclose in its financial statements certain tax positions that the Company 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, and overhead directly related to the Company's research and development efforts.

Collaboration income

Collaboration income is recognized within Other Income when contractual performance obligations, outside the ordinary activities of the Company, have been satisfied and control has been transferred to a collaboration partner. Collaboration income for each performance obligation is based on relative fair value of the overall transaction price. A deferred collaboration income liability is recorded when payments are received prior to satisfaction of performance obligations.

Product Warranty Costs

The Company accrues estimated product warranty costs at the time of sale which are included in cost of sales in the statements of operations. The amount of the accrued warranty liability is based on historical information such as past experience, product failure rates, number of units repaired, and estimated cost of material and labor. The liabilities for product warranty costs 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 whenever events or changes in circumstances indicate that an event of impairment may have occurred. This periodic review 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 the future undiscounted cash flows are less than their book value, an impairment may exist. The impairment is measured as the difference between the book value and the fair value of the underlying asset. Fair values are based on estimates of the market prices and assumptions concerning the amount and timing of estimated future cash flows and assumed discount rates, reflecting varying degrees of perceived risk.

Accounting for Stock-Based Compensation

Stock-based compensation cost is generally recognized ratably over the requisite service period. The Company uses the Black-Scholes option pricing model for determining the fair value of its stock options and amortizes its stock-based compensation expense using the straight-line method. The Black-Scholes model requires certain assumptions that involve judgment. Such assumptions are the expected share price volatility, expected life of options, expected annual dividend yield, and risk-free interest rate.

Advertising and Promotional Costs

Advertising and promotional costs are expensed as incurred.

Recently Issued or Adopted Accounting Pronouncements

Not Applicable.

ITEM 8. Financial Statements and Supplementary Data

The information required by this item may be found on pages F-1 through F-21 of this Annual Report on Form 10-K.

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

Not Applicable.

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, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

(b) 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 control over financial reporting as of December 31, 2020 based on the criteria in *Internal Control — Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on our evaluation under the framework in *Internal Control — Integrated Framework* (2013) issued by the COSO, our management concluded that our internal control over financial reporting was effective as of December 31, 2020.

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 year ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. Other Information

On January 25, 2021, we entered into Amendment No. 13 to our Shareholder Rights Agreement ("Amendment No. 13") with American Stock Transfer & Trust Company, LLC dated as of March 7, 2007, as amended. Amendment No. 13 extends the term of the Shareholder Rights Agreement by an additional year. The foregoing description of Amendment No. 13 is subject to, and is qualified in its entirety by reference to, the full text of Amendment No. 13, a copy of which is set forth as Exhibit 4.3.14 to this Annual Report on Form 10-K and is incorporated herein by reference.

PART III

ITEM 10. Directors, Executive Officers and Corporate Governance

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Management and Corporate Governance” and “Corporate Code of Conduct and Ethics” in our proxy statement for the 2021 annual meeting of stockholders.

ITEM 11. Executive Compensation

The response to this item is incorporated by reference from the discussion responsive thereto under the caption “Executive Officer and Director Compensation” in our proxy statement for the 2021 annual meeting of stockholders.

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 proxy statement for the 2021 annual meeting of stockholders.

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 “Management and Corporate Governance” in our proxy statement for the 2021 annual meeting of stockholders.

ITEM 14. Principal Accounting Fees and Services

The response to this item is incorporated by reference from the discussion responsive thereto under the caption “Ratification of Appointment of Independent Registered Public Accounting Firm” in our proxy statement for the 2021 annual meeting of stockholders.

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

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
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
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	Second Amended and Restated Bylaws of NeuroMetrix, Inc.		S-8 (Exhibit 4.2)	8/9/2004	333-118059

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
3.2.2	Amendment No. 1 to Second Amended and Restated Bylaws of NeuroMetrix, Inc.		8-K (Exhibit 3.1)	9/17/2007	001-33351
4.1	Description of Securities of the Registrant	X			
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
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

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
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	X			
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
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 Agreement, dated September 10, 2014, between, Boston Properties, Inc. and NeuroMetrix, Inc.		10-Q (Exhibit 10.2)	10/28/2014	011-33351
10.1.3	Lease Extension #1, dated June 14, 2018, between Cummings Properties, LLC and NeuroMetrix, Inc.				
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

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
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	At Market Issuance Sales Agreement by and between NeuroMetrix, Inc. and Ladenburg Thalmann & Co. Inc., dated February 19, 2020		8-K (Exhibit 10.1)	2/19/2020	001-33351
10.5.4	Promissory Note with Comerica Bank dated April 27, 2020		8-K (Exhibit 10.1)	4/30/2020	001-33351
10.5.5	Loan Agreement by and between NeuroMetrix, Inc. and Comerica Bank, dated April 27, 2020		8-K (Exhibit 10.2)	4/30/2020	001-33351
Equity Compensation Plans					
10.6+	Amended and Restated 1996 Stock Option/Restricted Stock Plan		S-1/A (Exhibit 10.2)	6/22/2004	333-115440
10.7.1+	Amended and Restated 1998 Equity Incentive Plan		S-1/A (Exhibit 10.3)	6/22/2004	333-115440
10.7.2+	Second Amendment to Amended and Restated 1998 Equity Incentive Plan		S-1 (Exhibit 10.18)	6/22/2004	333-115440
10.8.1+	Eleventh Amended and Restated 2004 Stock Option and Incentive Plan		14A (Appendix C)	1/18/2019	001-33351
10.8.2+	Form of Restricted Stock Agreement		10-Q (Exhibit 10.4)	5/14/2010	001-33351
10.8.3+	Form of Incentive Stock Option Agreement		10-Q (Exhibit 10.1)	11/15/2004	000-50856
10.8.4+	Form of Non-Qualified Stock Option Agreement For Company Employees		10-Q (Exhibit 10.2)	11/15/2004	000-50856
10.8.5+	Form of Non-Qualified Stock Option Agreement For Non-Employee Directors		10-Q (Exhibit 10.3)	11/15/2004	000-50856
10.9+	2009 Non-Qualified Inducement Stock Plan		S-8 (Exhibit 99.1)	6/3/2009	333-159712
10.10.1+	Fourth Amended and Restated 2010 Employee Stock Purchase Plan		14A (Appendix B)	3/9/2018	001-33351
Agreements with Executive Officers and Directors					
10.11+	Form of Indemnification Agreement between NeuroMetrix, Inc. and each of its directors		S-1/A (Exhibit 10.8)	6/22/2004	333-115440
10.12.1+	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

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
10.12.2+	Employment Agreement dated December 30, 2020, by and between NeuroMetrix, Inc. and Shai N. Gozani, M.D., Ph.D., and NeuroMetrix		8-K (Exhibit 10.13.5)	12/31/2020	001-33351
10.13.1+	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
10.13.2+	Employment Agreement, dated December 30, 2020 by and between NeuroMetrix, Inc. and Thomas T. Higgins		8-K (Exhibit 10.14.4)	12/31/2020	001-33351
10.14+	Amended and Restated Management Retention and Incentive Plan, as modified, dated February 3, 2017		10-K (Exhibit 10.17)	2/9/2017	001-33351
Agreements with Respect to Collaborations, Licenses, Research and Development					
10.15+	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
10.16†	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
10.17†	Asset Purchase Agreement, dated as of January 12, 2018, by and between Novartis Consumer Health S.A. and NeuroMetrix, Inc.		10-K (Exhibit 10.19)	2/8/2018	001-33351
10.18†	Development and Services Agreement, dated as of January 12, 2018, by and between Novartis Consumer Health S.A. and NeuroMetrix, Inc.		10-K (Exhibit 10.20)	2/8/2018	001-33351
10.19†	Contribution Agreement, dated as of December 22, 2017, by and between Quell Intellectual Property Corp., LLC and NeuroMetrix, Inc.		10-K (Exhibit 10.21)	2/8/2018	001-33351
10.20†	Amended and Restated Limited Liability Company Agreement of Quell Intellectual Property Corp., LLC, dated as of January 12, 2018, by and between Novartis Consumer Health S.A. and NeuroMetrix, Inc.		10-K (Exhibit 10.22)	2/8/2018	001-33351
10.21	NeuroMetrix License Agreement, dated as of December 21, 2017, by and between Quell Intellectual Property Corp., LLC and NeuroMetrix, Inc.		10-K (Exhibit 10.23)	2/8/2018	001-33351
10.22	GSK License Agreement, dated as of December 21, 2017, by and between Quell Intellectual Property Corp., LLC and NeuroMetrix, Inc.		10-K (Exhibit 10.24)	2/8/2018	001-33351
10.23	Assignment Agreement, dated as of January 12, 2018, by and between Novartis Consumer Health S.A. and NeuroMetrix, Inc.		10-K (Exhibit 10.25)	2/8/2018	001-33351
10.24*	Amendment No.1 to Development and Services Agreement, dated as of December 6, 2018, by and between GSK Consumer Health S.A. and NeuroMetrix, Inc.		10-K (Exhibit 10.26)	1/24/2019	001-33351

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
23.1	Consent of Moody, Famiglietti & Andronico, 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			
101	The following materials from NeuroMetrix, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2020, formatted in XBRL (Extensible Business Reporting Language): (i) Balance Sheets as of December 31, 2020 and 2019, (ii) Statements of Operations for the years ended December 31, 2020 and 2019, (iii) Statements of Changes in Stockholders' Equity for the years ended December 31, 2020 and 2019, (iv) Statements of Cash Flows for the years ended December 31, 2020 and 2019, and (v) Notes to Financial Statements.	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: January 28, 2021

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 January 28, 2021 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/ 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, 2020 and 2019

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, 2020 and 2019, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the two year period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations, negative cash flows from operating activities and has an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 (i) relates to accounts or disclosures that are material to the financial statements and (ii) 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

As described in Note 2 to the financial statements, inventories are stated at the lower of cost or net realizable value. Management estimates the net realizable value of inventory by considering the types and levels of inventories held, forecasted demand, pricing, competition, and changes in technology.
We identified inventory valuation as a critical audit matter. The principal consideration for our determination that inventory valuation is a critical audit matter is that there was significant judgment by management to estimate the net realizable value of inventory and excess and obsolete inventory reserves, including forecasted customer demand. This in turn led to subjective auditor judgment, and significant effort in performing procedures to assess the reasonableness of management's estimates related to inventory valuation and in evaluating the audit evidence obtained.
Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. These procedures included, among others:

- testing management's process for estimating the net realizable value of inventory and excess and obsolete inventory reserves, including evaluating the appropriateness of the analysis of forecasted demand and testing the completeness, accuracy and relevance of the underlying data used in the analysis

- evaluating management's analysis of forecasted demand involved evaluating the reasonableness of management's assumptions through evaluating performance trends.

/s/ Moody, Famiglietti, & Andronico, LLP

Moody, Famiglietti, & Andronico, LLP

We have served as the Company's auditor since 2017

Tewksbury, Massachusetts
January 28, 2021

NeuroMetrix, Inc.

Balance Sheets

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 5,226,213	$ 3,126,206
Accounts receivable, net of allowances of $25,000 and $70,000 at December 31, 2020 and 2019, respectively	334,297	298,967
Inventories	1,051,282	1,163,714
Collaboration receivable	—	189,008
Prepaid expenses and other current assets	478,074	652,919
Total current assets	7,089,866	5,430,814
Fixed assets, net	183,494	273,448
Right to use asset	692,692	1,159,774
Other long-term assets	28,523	29,650
Total assets	$ 7,994,575	$ 6,893,686
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 142,316	$ 725,658
Accrued expenses and compensation	998,442	1,443,574
Accrued product returns	545,000	689,000
Lease obligation, current portion	599,632	588,546
Total current liabilities	2,285,390	3,446,778
Lease obligation, net of current portion	461,410	916,674
Total liabilities	2,746,800	4,363,452
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, 2020 and 2019; 3,793,739 and 1,400,674 shares issued and outstanding at December 31, 2020 and 2019, respectively	379	140
Additional paid-in capital	202,129,195	197,319,698
Accumulated deficit	(196,881,800)	(194,789,605)
Total stockholders' equity	5,247,775	2,530,234
Total liabilities and stockholders' equity	$ 7,994,575	$ 6,893,686

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

NeuroMetrix, Inc.

Statements of Operations

	Years Ended December 31,	
	2020	**2019**
Revenues	$ 7,377,975	$ 9,272,522
Cost of revenues	2,128,417	7,026,899
Gross profit	5,249,558	2,245,623
Operating expenses:		
Research and development	2,391,316	3,101,976
Sales and marketing	1,436,806	4,755,168
General and administrative	3,516,340	5,923,190
Total operating expenses	7,344,462	13,780,334
Loss from operations	(2,094,904)	(11,534,711)
Other income:		
Collaboration income	—	7,716,667
Other income	2,709	45,030
Total other income	2,709	7,761,697
Net loss applicable to common stockholders:	$ (2,092,195)	$ (3,773,014)
Net loss per common share applicable to common stockholders:		
Basic and diluted	$ (0.69)	$ (3.90)

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

NeuroMetrix, Inc.

Statements of Changes in Stockholders' Equity

	Series B – F Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Number of Shares	Amount	Number of Shares	Amount			
Balance at December 31, 2018	17,513.63	$ 18	738,029	$ 74	$ 197,114,310	$ (191,016,591)	$ 6,097,811
Stock-based compensation expense	—	—	—	—	190,331	—	190,331
Issuance of common stock upon conversion of preferred stock	(17,313.63)	(17)	658,314	65	(48)	—	—
Issuance of common stock under employee stock purchase plan	—	—	4,331	1	15,105	—	15,106
Net loss	—	—	—	—	—	(3,773,014)	(3,773,014)
Balance at December 31, 2019	200.00	1	1,400,674	140	197,319,698	(194,789,605)	2,530,234
Stock-based compensation expense	—	—	—	—	599,117	—	599,117
Issuance of common stock under at the market offering	—	—	2,348,619	234	4,143,197	—	4,143,431
Issuance of common stock to settle compensation obligations	—	—	31,000	3	43,748	—	43,751
Issuance of common stock under employee stock purchase plan	—	—	13,446	2	23,435	—	23,437
Net loss	—	—	—	—	—	(2,092,195)	(2,092,195)
Balance at December 31, 2020	200.00	$ 1	3,793,739	$ 379	$ 202,129,195	$ (196,881,800)	$ 5,247,775

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

NeuroMetrix, Inc.

Statements of Cash Flows

	Years Ended December 31,	
	2020	**2019**
Cash flows for operating activities:		
Net loss	$ (2,092,195)	$ (3,773,014)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	89,954	124,012
Stock-based compensation	599,117	190,331
Settlement of compensation obligation	43,751	—
Allowance for doubtful accounts	—	49,361
Impairment charge against right of use asset	350,000	400,000
Inventory provision	—	2,595,884
Changes in operating assets and liabilities:		
Accounts receivable	(35,330)	734,629
Inventories	112,432	(897,734)
Collaboration receivable	189,008	(189,008)
Prepaid expenses and other current and long-term assets	(151,124)	243,536
Accounts payable	(583,342)	(572,426)
Accrued expenses and compensation	(445,132)	(157,644)
Accrued product returns	(144,000)	(412,658)
Deferred collaboration income	—	(1,956,522)
Net cash used in operating activities	(2,066,861)	(3,621,253)
Cash flows for investing activities:		
Purchases of fixed assets	—	(48,076)
Net cash used in investing activities	—	(48,076)
Cash flows from financing activities:		
Net proceeds from issuance of stock	4,166,868	15,106
Debt proceeds	773,200	—
Repayment of debt proceeds	(773,200)	—
Net cash provided by financing activities	4,166,868	15,106
Net increase (decrease) in cash and cash equivalents	2,100,007	(3,654,223)
Cash and cash equivalents, beginning of year	3,126,206	6,780,429
Cash and cash equivalents, end of year	$ 5,226,213	$ 3,126,206
Supplemental disclosure of cash flow information:		
Common stock issued to settle employee incentive compensation obligations	$ 43,751	$ —

—

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

1. Description of Business and Basis of Presentation

NeuroMetrix, Inc (the Company) 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, over-the-counter wearable device for chronic pain.

The Company entered a collaboration with GlaxoSmithKline ("GSK") to enhance the development of Quell for promotion by GSK outside the United States and by the Company within the United States. GSK made development milestone payments to the Company of approximately $20.5 million through 2019 and co-funded specific development projects through 2020. If GSK commercializes Quell in pre-defined countries, GSK would be obligated to pay approximately $4.5 million in commercialization milestones which the Company has assigned to the Federal Trade Commission (see Note 8 Commitments and Contingencies).

The accompanying financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company has suffered recurring losses from operations and negative cash flows from operating activities. At December 31, 2020, the Company had an accumulated deficit of $196.9 million. These factors raise substantial doubt about the Company's ability to continue as a going concern for the one-year period from the date of issuance of these financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

At December 31, 2020, the Company held cash and cash equivalents of $5.2 million. The Company believes that these resources and the cash to be generated from future product sales will be sufficient to meet its projected operating requirements through 2021. Accordingly, the Company will need to raise additional funds to support its operating and capital needs in the first quarter of 2022 and beyond. The Company continues to face significant challenges and uncertainties and, as a result, the Company's available capital resources may be consumed more rapidly than currently expected due to (a) decreases in sales of the Company's products related to the COVID-19 pandemic and other factors, and the uncertainty of future revenues from new products; (b) the effect of the COVID-19 pandemic on the Company's ability to obtain parts and materials from suppliers while continuing to staff critical production and fulfillment functions; (c) changes the Company may make to the business that affect ongoing operating expenses; (d) changes the Company may make in its business strategy; (e) regulatory developments affecting the Company's existing products; (f) changes the Company may make in its research and development spending plans; and (g) other items affecting the Company's forecasted level of expenditures and use of cash resources. The Company may attempt to obtain additional funding from a public or private financing, collaborative arrangements with strategic partners, divestiture of assets or through additional credit lines or other debt financing sources to increase the funds available to fund operations. However, the Company may not be able to secure such financing in a timely manner or on favorable terms, if at all. Furthermore, if the Company issues equity or debt securities to raise additional funds, its existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of the Company's existing stockholders. If the Company raises additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to its potential products or to proprietary technologies, or grant licenses on terms that are not favorable to the Company. Without additional funds, the Company may be forced to delay, scale back or eliminate some of its 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 its operations. If any of these events occurs, the Company's ability to achieve its development and commercialization goals would be adversely affected.

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.

Concentrations of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash equivalents and trade receivables. The Company invests its cash equivalents in highly rated institutions and limits its investment in any individual account to not exceed FDIC limits.

At December 31, 2020 and 2019, two customers accounted for 50% and 42% of accounts receivable, respectively. Two customers accounted for 35% of revenues for the year ended December 31, 2020 and one customer accounted for 19% of revenues, for the year ended December 31, 2019.

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 is required to measure and record 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 carrying amounts of the Company’s cash equivalents, accounts receivable, accounts payable, and accrued expenses approximate their fair value at December 31, 2020 and 2019 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 when contractual performance obligations have been satisfied and control of the product has been transferred to the customer. In most cases, the Company has a single product delivery performance obligation. Accrued product returns are estimated based on historical data and evaluation of current information.

Accounts Receivable

Accounts receivable are recorded at the amount the Company expects to collect, net of the allowance for doubtful accounts receivable. The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses based on customer past payment history, product usage activity, and recent communications with the customer. Individual customer balances which are over 90 days past due are reviewed individually for collectability and written-off when recovery is not probable. 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, 2020 and $70,000 as of December 31, 2019.

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. Significant 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 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 as 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, and overhead directly related to research and development efforts.

Collaboration income

Collaboration income is recognized within Other Income when contractual performance obligations, outside the ordinary activities of the Company, have been satisfied and control has been transferred to a collaboration partner. Collaboration income for each performance obligation is based on relative fair value of the overall transaction price. A deferred collaboration income liability is recorded when payments are received prior to satisfaction of performance obligations.

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 $49,600 and $75,300 at December 31, 2020 and 2019, 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,	
	2020	2019
Net loss applicable to common stockholders	$ (2,092,195)	$ (3,773,014)
Weighted average number of common shares outstanding, basic and dilutive	3,014,497	968,116
Net loss per common share applicable to common stockholders, basic and diluted	$ (0.69)	$ (3.90)

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,	
	2020	2019
Options	198,484	38,936
Warrants	17,248	44,534
Convertible preferred stock	62	478,184
Total	215,794	561,654

Advertising and Promotional Costs

Advertising and promotional costs are expensed as incurred. Advertising and promotion expense were $210,548 and $1,652,171, in 2020 and 2019, respectively.

Accumulated Other Comprehensive Items

For 2020 and 2019, 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 2020 and 2019 were located in or derived from operations in the United States. Revenues from sales outside the United States accounted for approximately 15% and 13% of total revenues in 2020 and 2019, respectively.

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 FDA, FTC 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.

3. Stock-Based Compensation

The Company's 2004 Stock Option and Incentive Plan (the "Stock Plan") amended and restated in 2019 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, 2020, 439,890 shares of common stock were authorized for issuance under the 2004 Stock Plan, of which 24,578 shares had been issued, 361,956 shares were subject to outstanding options at a weighted average exercise price of $3.68 per share and 53,356 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, 2020, 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 2018 authorizes an annual increase on the first day of each of the Company’s fiscal years equal to the lesser of (i) 2,500 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, 2020 and 2019, the Company issued 13,446 and 4,331 shares of its common stock, respectively, under the ESPP. As of December 31, 2020, there were no 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 three or five year 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. The expected option term of three to five years is estimated based on an analysis of actual option exercises. 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 pre-vesting forfeiture rate is based on the historical and projected average turnover rate of employees.

3. Stock-Based Compensation - (continued)

The weighted average grant-date fair value of stock options used in the calculation of stock-based compensation expense for the years ended December 31, 2020 and 2019 was calculated using the following assumptions:

	Years Ended December 31,	
	2020	2019
Risk-free interest rate	0.8%	1.9%
Expected dividend yield	—	—
Expected option term	10 years	10 years
Volatility	70.0 %	72.4 %

A summary of option activity for the year ended December 31, 2020 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2019	164,980	$ 7.16		
Granted	200,000	1.57		
Exercised	—	—		
Forfeited	(2,996)	31.57		
Expired	(28)	5,875.19		
Outstanding at December 31, 2020	361,956	$ 3.68	9.2	$ —
Vested or expected to vest at December 31, 2020	161,158	$ 6.25	8.5	$ —
Exercisable at December 31, 2020	161,158	$ 6.25	8.5	$ —

Expected to vest options are determined by applying the pre-vesting 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, 2020, 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, 2020.

The weighted average per share grant-date fair values of options granted during 2020 and 2019 was $1.57 and $4.58, respectively.

The aggregate intrinsic value of options issued or exercised during 2020 and 2019 was $0.

Total unrecognized stock-based compensation costs related to non-vested stock options was $197,162, which related to 361,956 shares with a per share weighted fair value of $3.68 as of December 31, 2020. This unrecognized cost is expected to be recognized over a weighted average period of approximately 0.8 years.

Cash received from option exercises and purchases under the Stock Plan and ESPP for 2020 and 2019, was $23,436 and $15,106, respectively. The Company issues new shares upon option exercises and purchases under the Company's ESPP.

The Company recorded stock-based compensation expense of $599,117 and $190,331 for 2020 and 2019, respectively.

4. Inventories

Inventories consist of the following:

	December 31,	
	2020	2019
Purchased components	$ 716,848	$ 720,209
Finished goods	334,434	443,505
	$ 1,051,282	$ 1,163,714

The Company recorded inventory charges of zero and $2,595,884 for the years ended December 31, 2020 and 2019, respectively, to reflect estimated net realizable value.

5. Fixed Assets

Fixed assets consist of the following:

	Estimated Useful Life (Years)	December 31,	
		2020	2019
Computer and laboratory equipment	3	$ 905,966	$ 905,966
Furniture and equipment	3	241,413	241,413
Production equipment	7	216,000	216,000
Leasehold improvements	*	141,485	141,485
		1,504,864	1,504,864
Less – accumulated depreciation		(1,321,370)	(1,231,416)
		$ 183,494	$ 273,448

* Lesser of life of lease or estimated useful life.

Depreciation expense was $89,954 and $124,012 for 2020 and 2019, respectively.

6. Accrued Expenses and Compensation

Accrued expenses and compensation consist of the following for the years ended December 31, 2020 and 2019:

	December 31,	
	2020	2019
Technology fees	$ 450,000	$ 450,000
Professional services	343,000	454,000
Compensation	49,837	62,322
Advertising and promotion	31,000	68,000
Warranty	49,600	75,300
Other	75,005	333,952
	$ 998,442	$ 1,443,574

7. Income Taxes

Current income tax expense (benefit) attributable to continuing operations was zero for the years ended December 31, 2020 and 2019.

The Company's effective income tax rate differs from the statutory federal income tax rate as follows for the years ended December 31, 2020 and 2019.

	Years Ended December 31,	
	2020	2019
Federal tax provision (benefit) rate	(21.0)%	(21.0)%
State tax provision, net of federal provision	(4.6)	19.9
Permanent items	5.9	1.1
Federal research and development credits	—	—
382 Limitation - NOL and tax credits	(1.9)	861.5
Other	(0.3)	—
Change in statutory tax rate	—	—
Valuation allowance	21.9	(861.5)
Effective income tax rate	—	—

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

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 2,211,161	$ 1,592,993
Research and development credit carryforwards	43,667	—
Accrued expenses	112,995	96,030
Inventory reserve	311,639	306,855
Stock-based compensation	245,988	222,420
Right of use asset	290,268	—
Other	—	(9,455)
Total gross deferred tax assets	3,215,718	2,208,843
Valuation allowance	(3,012,513)	(2,208,843)
Deferred tax liabilities:		
Lease liability	$ (189,498)	$ —
Other	$ (13,707)	$ —
Net deferred tax assets	$ —	$ —

At December 31, 2020, the Company has federal net operating loss carryforwards ("NOL") of approximately $143.7 million, of which $138.4 million begin to expire in 2021 and $5.3 million have an indefinite carryforward. At December 31, 2020, the Company has state NOLs of $53.1 million, some of which have an indefinite carryforward, and others that begin to expire in 2025. At December 31, 2020, the Company has federal and state tax credits of approximately $1.8 million and $1.1 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 NOLs, the state NOLs, and the federal and state research and development credits each began to expire in 2020.

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 $3.0 million and $2.2 million has been established at December 31, 2020 and 2019, 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 $143,300,000 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. As a result of these eliminations, the Company's federal net operating loss and credit carryforwards are reduced to approximately $7,300,000 and $0 respectively, before valuation allowance. State credit carryforwards are reduced to zero. 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, 2017 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") extends through February 2022 at a current monthly rent of $41,074, subject to annual increase, and with a 5-year extension option. The Company is actively seeking to sublet the Waltham lease. At December 31, 2020, the Company carried an impairment reserve of $400,000 that reduced the right of use asset for idle facility costs.

The following is a maturity analysis of the annual undiscounted cash flows of the operating lease liabilities as of December 31, 2020:

2021	$	653,164
2022		247,347
2023		165,785
2024		165,785
2025		117,431
Total minimum lease payments	$	1,349,512

Weighted-average discount rate, 14.7%	$	288,470
Lease obligation, current portion		599,632
Lease obligation, net of current portion		461,410
	$	1,349,512

Total recorded rent expense was $667,618 and $664,098, for 2020 and 2019, respectively. The Company records rent expense on its facility leases on a straight-line basis over the lease term. Weighted average remaining operating lease term was 3.0 years as of December 31, 2020.

Other Contingencies

A previously reported investigation by the Federal Trade Commission (the "FTC") regarding Quell® advertising was settled in March 2020. The Company did not admit to any of the FTC allegations, agreed to certain modifications of Quell advertising claims, and pledged to pay to the FTC future commercial milestone payments, if and when received, pursuant to a collaboration agreement with a third party. An officer of the Company, also named in the investigation, paid the FTC four million dollars as part of the settlement.

9. Fair Value Measurements

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

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

		Fair Value Measurements at December 31, 2019 Using		
	December 31, 2019	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 698,807	$ 698,807	$ —	$ —
Total	$ 698,807	$ 698,807	$ —	$ —

10. 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 2020 and 2019 the Company made no contributions to the plan.

11. Credit Facility and Debt

The Company terminated a Loan and Security Agreement (the "Credit Facility") with a bank in 2020. The Credit Facility had previously supported letters of credit in the amount of $226,731 issued in favor of the Company's landlords. These letters of credit are now secured by the Company's cash balances.

In April 2020 the Company received a loan of $773,200 under the Paycheck Protection Program of the Coronavirus Aid, Relief, and Economic Security Act and fully repaid the loan in May 2020.

12. Stockholders' Equity

Preferred stock and convertible preferred stock consist of the following:

	December 31,	
	2020	2019
Preferred stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2020 and 2019; no shares issued and outstanding at December 31, 2020 and 2019	$ —	$ —
Series B convertible preferred stock, $0.001 par value, 147,000 shares designated at December 31, 2020 and 2019, and 200 shares issued and outstanding at December 31, 2020 and 2019, respectively	1	1
Series D convertible preferred stock, $0.001 par value, 21,300 shares designated at December 31, 2020 and 2019, and no shares issued and outstanding at December 31, 2020 and 2019, respectively	—	—
Series F convertible preferred stock, $0.001 par value, 10,621 shares designated at December 31, 2020 and 2019, and no shares issued and outstanding at December 31, 2020 and 2019, respectively	—	—

Preferred stock activity

As of December 31, 2020, 200.00 shares of Series B Preferred Stock remained outstanding. There were no preferred stock conversions in 2020.

In 2019, 14,052.93 shares of Series D Preferred Stock were converted into a total of 534,333 shares of common stock and 3,260.70 shares of the Series F Preferred Stock were converted into a total of 123,981 shares of common stock.

Other equity activity

In February 2020, the Company entered into an At Market Issuance Sales Agreement (the "Agreement") with respect to an at-the-market equity offering program ("ATM program"), under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock, par value $0.0001 per share, having an aggregate offering price of up to $4,482,000 (the "Placement Shares"). The issuance and sale of the Placement Shares by the Company under the Agreement will be made pursuant to the Company's effective "shelf" registration statement on Form S-3. During the year ended December 31, 2020, 2,348,619 shares of common stock were issued pursuant to the Agreement for net proceeds of $4,143,431.

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

In June and December 2020, the Company issued 13,446 shares of fully vested common stock with a value of $23,437 pursuant to the Company's 2010 Employee Stock Purchase Plan.

As of December 31, 2020, the Company had 25,000,000 shares of common stock authorized and 3,793,739 shares issued and outstanding. 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, 2020, the Company has reserved authorized shares of common stock for future issuance as follows:

Outstanding stock options	361,956
Possible future issuance under inducement plan	1,250
Possible future issuance under stock option plans	53,356
Possible future issuance under employee stock purchase plan	—
Total	416,562

13. Business Restructuring

The Company restructured its business activities in the second quarter of 2019 to reduce operating costs and improve efficiency. Operations were consolidated in a single location, headcount was reduced, and excess inventory was written down to net realizable value. The impairment reserve was further adjusted in the third quarter of 2019 to bring the total recorded restructuring charge to $2.6 million in 2019. This charge was increased by $350,000 in 2020 to reflect estimates of idle facility costs. The impairment reserve against the right to use asset was $400,000 at December 31, 2020.

The reserve for business restructuring as of December 31, 2020 is presented below.

Description	Balance at Beginning of Period	Provision	Amounts Paid Out	Balance at End of Period
December 31, 2020				
Severance obligations:	$ —	$ —	$ —	$ —
Relocation costs:	—	—	—	—
Impairment charge for idle facility	400,000	350,000	(350,000)	400,000
December 31, 2019				
Severance obligations:	$ —	$ 224,773	$ (224,773)	$ —
Relocation costs:	—	100,000	(100,000)	—
Impairment charge for idle facility	—	400,000	—	400,000

Within the Company's Statements of Operations for the year ended December 31, 2020, $350,000 of impairment costs were recorded as follows: $154,000 within research and development, $87,500 within sales and marketing, and $108,500 within general and administrative.

Within the Company's Statement of Operations for the year ended December 31, 2019, $1,895,884 of inventory-related write downs were recorded within cost of revenues, and severance and relocation costs were recorded as follows: $311,514 within research and development, $221,387 within sales and marketing, and $191,872 within general and administrative.

14. 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, 2020						
Allowance for Doubtful Accounts	$ 70,000	$ —	$ —	$ (45,000)		$ 25,000
Deferred Tax Asset Valuation Allowance	2,208,843	3,427,540	—	(2,623,870)	(1)	3,012,513
Accrued Product Returns	689,000		—	(144,000)		545,000
Warranty Reserve	75,300	—	—	(25,700)		49,600
December 31, 2019						
Allowance for Doubtful Accounts	$ 25,000	$ 49,361	$ —	$ (4,361)		$ 70,000
Deferred Tax Asset Valuation Allowance	35,041,300	1,535,093	—	(34,367,550)	(1)	2,208,843
Accrued Product Returns	1,101,658	—	—	(412,658)		689,000
Warranty Reserve	129,837	—	—	(54,537)		75,300

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

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2020, NeuroMetrix, Inc. had three classes of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): (i) common stock, $0.0001 par value per share ("Common Stock"); (ii) rights to purchase shares of preferred stock, par value $0.001 per share ("Preferred Stock Purchase Rights"), and (iii) warrants to purchase Common Stock.

Unless the context otherwise requires, all references to "we", "us", the "Company", or "NeuroMetrix" in this Exhibit 4.1 refer to NeuroMetrix, Inc.

DESCRIPTION OF CAPITAL STOCK

The following description of our securities is intended as a summary only and is qualified in its entirety by reference to our amended and restated certificate of incorporation, amended and restated bylaws, and shareholder rights agreement, as amended, which are filed as exhibits to the annual report on Form 10-K of which this Exhibit 4.1 is a part. We refer in this section to our amended and restated certificate of incorporation as our certificate of incorporation, and we refer to our amended and restated bylaws as our bylaws.

Authorized Capitalization

Our authorized capital stock consists of 25,000,000 shares of Common Stock and 5,000,000 shares of preferred stock, $0.001 par value per share ("Preferred Stock") in one or more series. As of December 31, 2020, we had outstanding 3,784,657 shares of our Common Stock and 200 shares of our Series B Convertible Preferred Stock. At that date, we also had an aggregate of 361,956 shares of Common Stock reserved for issuance upon exercise of outstanding stock options granted under our stock incentive plans.

Transfer Agent and Registrar. The transfer agent for our Common Stock and outstanding shares of Preferred Stock is American Stock Transfer & Trust Company.

Listing. Our Common Stock is traded on the Nasdaq Capital Market under the symbol "NURO" and our warrants to purchase shares of Common Stock are listed under the symbol "NUROW" on the Nasdaq Capital Market.

Common Stock

The holders of our Common Stock are generally entitled to one vote for each share held on all matters submitted to a vote of the stockholders and do not have any cumulative voting rights. Except as may be required by law and in connection with some significant actions, such as mergers, consolidations, or amendments to our certificate of incorporation that affect the rights of stockholders, holders of our Common Stock vote together as a single class. There is no cumulative voting in the election of our directors, which means that, subject to any rights to elect directors that are granted to the holders of any class or series of Preferred Stock, a plurality of the votes cast at a meeting of stockholders at which a quorum is present is sufficient to elect a director. Holders of our Common Stock are entitled to receive proportionally any dividends declared by our Board of Directors, subject to any preferential dividend rights of outstanding Preferred Stock.

Subject to the preferential rights of any other class or series of stock, all shares of our Common Stock have equal dividend, distribution, liquidation and other rights, and have no preference, appraisal or exchange rights, except for any appraisal rights provided by Delaware law. Furthermore, holders of our Common Stock have no conversion, sinking fund or redemption rights, or preemptive rights to subscribe for any of our securities. Our certificate of incorporation and bylaws do not restrict the ability of a holder of our Common Stock to transfer his or her shares of our Common Stock.

In the event of our liquidation or dissolution, holders of our Common Stock are entitled to share ratably in all assets remaining after payment of all debts and other liabilities, subject to the prior rights of any outstanding Preferred Stock. Holders of our Common Stock have no preemptive, subscription, sinking fund, redemption, exchange or conversion rights. The Common Stock, when issued, will be duly authorized, fully paid and nonassessable.

Preferred Stock

Pursuant to our certificate of incorporation, we are authorized to issue "blank check" Preferred Stock, which may be issued from time to time in one or more series upon authorization by our Board of Directors. Our Board of Directors, without further approval of the stockholders, is authorized to fix the designations, powers, including voting powers, preferences and the relative, participating, optional or other special rights of the shares of each series and any qualifications, limitations and restrictions thereof. The issuance of Preferred Stock, while providing flexibility in connection with possible acquisitions and other corporate purposes could, among other things, adversely affect the voting power or other rights of the holders of our Common Stock and, under certain circumstances, make it more difficult for a third party to gain control of us, discourage bids for our Common Stock at a premium or otherwise adversely affect the market price of the Common Stock.

The Preferred Stock will have the terms described below unless otherwise provided in the prospectus supplement relating to a particular series of the Preferred Stock. You should read the prospectus supplement relating to the particular series of the Preferred Stock being offered for the specific terms of that series, including:

- the designation and stated value per share of the Preferred Stock and the number of shares offered;
- the amount of liquidation preference per share, if any;
- the price at which the Preferred Stock will be issued;
- the dividend rate, or method of calculation of the dividend rate, if any, the dates on which dividends will be payable, whether dividends will be cumulative or noncumulative and, if cumulative, the dates from which dividends will commence to accumulate;
- any redemption or sinking fund provisions;
- if other than the currency of the United States, the currency or currencies, including composite currencies, in which the Preferred Stock is denominated and/or in which payments will or may be payable;
- any conversion provisions; and
- any other rights, preferences, privileges, limitations and restrictions on the Preferred Stock.

The Preferred Stock will, when issued, be duly authorized, fully paid and nonassessable. Unless otherwise specified in the applicable prospectus supplement, each series of the Preferred Stock will rank equally as to dividends and liquidation rights in all respects with each other series of Preferred Stock. The rights of holders of shares of each series of Preferred Stock will be subordinate to those of our general creditors.

Rank. Unless otherwise specified in the applicable prospectus supplement, the Preferred Stock, with respect to dividend rights and rights upon our liquidation, dissolution or winding up our affairs, ranks:

- senior to all classes or series of our Common Stock and to all equity securities ranking junior to such Preferred Stock with respect to dividend rights or rights upon our liquidation, dissolution or winding up our affairs;

- on a parity with all equity securities issued by us, the terms of which specifically provide that such equity securities rank on a parity with the Preferred Stock with respect to dividend rights or rights upon our liquidation, dissolution or winding up of our affairs; and

- junior to all equity securities issued by us, the terms of which specifically provide that such equity securities rank senior to the Preferred Stock with respect to dividend rights or rights upon our liquidation, dissolution or winding up of our affairs.

The term "equity securities" does not include convertible debt securities.

Dividends. Holders of the Preferred Stock of each series will be entitled to receive, when, as and if declared by our board of directors, cash dividends at such rates and on such dates descripted in the applicable prospectus supplement. Different series of Preferred Stock may be entitled to dividends at different rates or based on different methods of calculation. The dividend rate may be fixed or variable or both. Dividends will be payable to the holders of record as they appear on our stock books on record dates fixed by our board of directors, as specified in the applicable prospectus supplement.

Dividends on any series of the Preferred Stock may be cumulative or noncumulative, as described in the applicable prospectus supplement. If our board of directors does not declare a dividend payable on a dividend payment date on any series of noncumulative Preferred Stock, then the holders of that noncumulative Preferred Stock will have no right to receive a dividend for that dividend payment date, and we will have no obligation to pay the dividend accrued for that period, whether or not dividends on that series are declared payable on any future dividend payment dates. Dividends on any series of cumulative Preferred Stock will accrue from the date we initially issue shares of such series or such other date specified in the applicable prospectus supplement.

No full dividends may be declared or paid or funds set apart for the payment of any dividends on any parity securities unless dividends have been paid or set apart for payment on the Preferred Stock. If full dividends are not paid, the Preferred Stock will share dividends pro rata with the parity securities.

No dividends may be declared or paid or funds set apart for the payment of dividends on any junior securities unless full cumulative dividends for all dividend periods terminating on or prior to the date of the declaration or payment will have been paid or declared and a sum sufficient for the payment set apart for payment on the Preferred Stock.

Liquidation Preference. Upon any voluntary or involuntary liquidation, dissolution or winding up of our affairs, then, before we make any distribution or payment to the holders of any Common Stock or any other class or series of our capital stock ranking junior to the Preferred Stock in the distribution of assets upon any liquidation, dissolution or winding up of our affairs, the holders of each series of Preferred Stock shall be entitled to receive out of assets legally available for distribution to stockholders, liquidating distributions in the amount of the liquidation preference per share set forth in the applicable prospectus supplement, plus any accrued and unpaid dividends thereon. Such dividends will not include any accumulation in respect of unpaid noncumulative dividends for prior dividend periods. Unless otherwise specified in the applicable prospectus supplement, after payment of the full amount of their liquidating distributions, the holders of Preferred Stock will have no right or claim to any of our remaining assets. Upon any such voluntary or involuntary liquidation, dissolution or winding up, if our available assets are insufficient to pay the amount of the liquidating distributions on all outstanding Preferred Stock and the corresponding amounts payable on all other classes or series of our capital stock ranking on parity with the Preferred Stock and all other such classes or series of shares of capital stock ranking on parity with the Preferred Stock in the distribution of assets, then the holders of the Preferred Stock and all other such classes or series of capital stock will share ratably in any such distribution of assets in proportion to the full liquidating distributions to which they would otherwise be entitled.

Upon any liquidation, dissolution or winding up, and if we have made liquidating distributions in full to all holders of Preferred Stock, we will distribute our remaining assets among the holders of any other classes or series of capital stock ranking junior to the Preferred Stock according to their respective rights and preferences and, in each

case, according to their respective number of shares. For such purposes, our consolidation or merger with or into any other corporation, trust or entity, or the sale, lease or conveyance of all or substantially all of our property or business will not be deemed to constitute a liquidation, dissolution or winding up of our affairs.

Redemption. If so provided in the applicable prospectus supplement, the Preferred Stock will be subject to mandatory redemption or redemption at our option, as a whole or in part, in each case upon the terms, at the times and at the redemption prices set forth in such prospectus supplement.

The prospectus supplement relating to a series of Preferred Stock that is subject to mandatory redemption will specify the number of shares of Preferred Stock that shall be redeemed by us in each year commencing after a date to be specified, at a redemption price per share to be specified, together with an amount equal to all accrued and unpaid dividends thereon to the date of redemption. Unless the shares have a cumulative dividend, such accrued dividends will not include any accumulation in respect of unpaid dividends for prior dividend periods. We may pay the redemption price in cash or other property, as specified in the applicable prospectus supplement. If the redemption price for Preferred Stock of any series is payable only from the net proceeds of the issuance of shares of our capital stock, the terms of such Preferred Stock may provide that, if no such shares of our capital stock shall have been issued or to the extent the net proceeds from any issuance are insufficient to pay in full the aggregate redemption price then due, such Preferred Stock shall automatically and mandatorily be converted into the applicable shares of our capital stock pursuant to conversion provisions specified in the applicable prospectus supplement.

Notwithstanding the foregoing, we will not redeem any Preferred Stock of a series unless:

- if that series of Preferred Stock has a cumulative dividend, we have declared and paid or contemporaneously declare and pay or set aside funds to pay full cumulative dividends on the Preferred Stock for the past and current dividend period; or

- if such series of Preferred Stock does not have a cumulative dividend, we have declared and paid or contemporaneously declare and pay or set aside funds to pay full dividends for the current dividend period.

In addition, we will not acquire any Preferred Stock of a series unless:

- if that series of Preferred Stock has a cumulative dividend, we have declared and paid or contemporaneously declare and pay or set aside funds to pay full cumulative dividends on all outstanding shares of such series of Preferred Stock for all past dividend periods and the then current dividend period; or

- if that series of Preferred Stock does not have a cumulative dividend, we have declared and paid or contemporaneously declare and pay or set aside funds to pay full dividends on the Preferred Stock of such series for the then current dividend period.

However, at any time we may purchase or acquire Preferred Stock of that series (1) pursuant to a purchase or exchange offer made on the same terms to holders of all outstanding Preferred Stock of such series or (2) by conversion into or exchange for shares of our capital stock ranking junior to the Preferred Stock of such series as to dividends and upon liquidation.

If fewer than all of the outstanding shares of Preferred Stock of any series are to be redeemed, we will determine the number of shares that may be redeemed pro rata from the holders of record of such shares in proportion to the number of such shares held or for which redemption is requested by such holder or by any other equitable manner that we determine. Such determination will reflect adjustments to avoid redemption of fractional shares.

Unless otherwise specified in the applicable prospectus supplement, we will mail notice of redemption at least 30 days but not more than 60 days before the redemption date to each holder of record of Preferred Stock to be redeemed at the address shown on our stock transfer books. Each notice shall state:

- the redemption date;
- the number of shares and series of the Preferred Stock to be redeemed;
- the redemption price;
- the place or places where certificates for such Preferred Stock are to be surrendered for payment of the redemption price;
- that dividends on the shares to be redeemed will cease to accrue on such redemption date;
- the date upon which the holder's conversion rights, if any, as to such shares shall terminate; and
- the specific number of shares to be redeemed from each such holder if fewer than all the shares of any series are to be redeemed.

If notice of redemption has been given and we have set aside the funds necessary for such redemption in trust for the benefit of the holders of any shares so called for redemption, then from and after the redemption date, dividends will cease to accrue on such shares, and all rights of the holders of such shares will terminate, except the right to receive the redemption price.

Voting Rights. Holders of Preferred Stock will not have any voting rights, except as described in the next paragraph, as otherwise from time to time required by law or as indicated in the applicable prospectus supplement.

Unless otherwise provided for any series of Preferred Stock, so long as any Preferred Stock of a series remains outstanding, we will not, without the affirmative vote or consent of the holders of at least two-thirds of the Preferred Stock of such series outstanding at the time, given in person or by proxy, either in writing or at a meeting with each of such series voting separately as a class:

- authorize, or create, or increase the authorized or issued amount of, any class or series of shares of capital stock ranking senior to such series of Preferred Stock with respect to payment of dividends or the distribution of assets upon liquidation, dissolution or winding up, or reclassify any of our authorized shares of capital stock into such shares, or create, authorize or issue any obligation or security convertible into or evidencing the right to purchase any such shares; or

- amend, alter or repeal the provisions of our restated certificate or the amendment to our certificate of incorporation designating the terms for such series of Preferred Stock, whether by merger, consolidation or otherwise, so as to materially and adversely affect any right, preference, privilege or voting power of such series of Preferred Stock or the holders thereof.

Notwithstanding the preceding bullet point, if the Preferred Stock remains outstanding with the terms thereof materially unchanged, the occurrence of any of the events described above shall not be deemed to materially and adversely affect the rights, preferences, privileges or voting power of holders of Preferred Stock, even if upon the occurrence of such an event we may not be the surviving entity. In addition, any increase in the amount of (1) authorized Preferred Stock or the creation or issuance of any other series of Preferred Stock, or (2) authorized shares of such series or any other series of Preferred Stock, in each case ranking on parity with or junior to the Preferred Stock of such series with respect to payment of dividends or the distribution of assets upon liquidation, dissolution or winding up, shall not be deemed to materially and adversely affect such rights, preferences, privileges or voting powers.

The foregoing voting provisions will not apply if, at or prior to the time when the act with respect to which such vote would otherwise be required will be effected, we have redeemed or called for redemption all outstanding

shares of such series of Preferred Stock and, if called for redemption, have deposited sufficient funds in trust to effect such redemption.

Conversion Rights. The terms and conditions, if any, upon which any series of Preferred Stock is convertible into Common Stock will be set forth in the applicable prospectus supplement relating thereto. Such terms will include the number of shares of Common Stock into which the shares of Preferred Stock are convertible, the conversion price, rate or manner of calculation thereof, the conversion period, provisions as to whether conversion will be at our option or at the option of the holders of the Preferred Stock, the events requiring an adjustment of the conversion price and provisions affecting conversion in the event of the redemption.

Transfer Agent and Registrar. The transfer agent and registrar for the Preferred Stock will be set forth in the applicable prospectus supplement.

Series B Convertible Preferred Stock Outstanding

As of December 31, 2020, we had 200 shares of our Series B Convertible Preferred Stock with a stated value of $100 outstanding. The Series B Convertible Preferred Stock is convertible at the option of the holder into the number of shares of Common Stock determined by dividing the stated value by the adjusted conversion price of $333.30, which is subject to adjustment as provided in the Certificate of Designation for the Series B Preferred Stock, subject to a 9.99% ownership limitation. The Series B Convertible Preferred Stock has no dividend rights, liquidation preference or other preferences over Common Stock and has no voting rights except as provided in the Certificate of Designation, as filed with the Secretary of State of the State of Delaware, or as otherwise required by law. You should refer to the certificate of designation of preferences, rights and limitations of Series B Convertible Preferred Stock, which is included as exhibit to the annual report on Form 10-K.

Shareholder Rights Plan

On March 7, 2007, we entered into a Rights Agreement with American Stock Transfer & Trust Company, as rights agent, and approved the declaration of a dividend distribution of one preferred share purchase right on each outstanding share of our Common Stock to shareholders of record as of the close of business on June 8, 2007. Each right entitles the registered holder to purchase from us 1.152 shares of our Series A Junior Convertible Preferred Stock at a price of $75.00, subject to adjustment.

Initially, the rights are not exercisable and are attached to and trade with all shares of Common Stock outstanding as of, and issued subsequent to March 8, 2007. The rights will separate from the Common Stock and will become exercisable upon the earlier of (i) the close of business on the tenth calendar day following the first public announcement that a person or group of affiliated or associated persons, or an Acquiring Person, has acquired beneficial ownership of 15% or more of the outstanding shares of Common Stock, other than as a result of repurchases of stock by the Company or certain inadvertent actions by a shareholder or (ii) the close of business on the tenth business day (or such later day as our Board of Directors may determine) following the commencement of a tender offer or exchange offer that could result upon its consummation in a person or group becoming the beneficial owner of 15% or more of the outstanding shares of Common Stock.

The rights may be redeemed in whole, but not in part, at a price of $0.01 per right (payable in cash, Common Stock or other consideration deemed appropriate by our board) by the board only until the earlier of (i) the time at which any person becomes an Acquiring Person or (ii) the expiration date of the Rights Agreement. Immediately upon the action of the board ordering redemption of the rights, the rights will terminate and thereafter the only right of the holders of rights will be to receive the redemption price.

The rights will expire on March 8, 2022, unless previously redeemed or exchanged by the Company. The rights distribution was not taxable to stockholders.

The above summary of the Rights Agreement does not purport to be complete. You should refer to the Rights Agreement, as amended, which is included as an exhibit to the annual report on Form 10-K.

Certain Effects of Authorized but Unissued Stock

We have shares of Common Stock and Preferred Stock available for future issuance without stockholder approval. We may issue these additional shares for a variety of corporate purposes, including future public offerings to raise additional capital or facilitate corporate acquisitions or for payment as a dividend on our capital stock. The existence of unissued and unreserved Common Stock and Preferred Stock may enable our board of directors to issue shares to persons friendly to current management or to issue Preferred Stock with terms that could render more difficult or discourage a third-party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, if we issue Preferred Stock, the issuance could adversely affect the voting power of holders of Common Stock and the likelihood that such holders will receive dividend payments and payments upon liquidation.

Delaware Law and Certificate of Incorporation and Bylaws Provisions

Board of Directors. Our certificate of incorporation provides that:

- our Board of Directors is divided into three classes, as nearly equal in number as possible, to serve staggered terms so that approximately one-third of our board will be elected each year;
- subject to the rights of the holders of any class or series of Preferred Stock then outstanding, our directors may be removed (i) only with cause and (ii) only by the affirmative vote of the holders of at least seventy-five percent (75%) of the voting power of all of the then outstanding shares then entitled to vote at an election of directors voting together as a single class, unless otherwise specified by law; and
- any vacancy on our Board of Directors, however occurring, including a vacancy resulting from an enlargement of the board, may only be filled by vote of a majority of the directors then in office, even if less than a quorum, or by a sole remaining director, and not by the stockholders.

These provisions could discourage, delay or prevent a change in control of our company or an acquisition of our company at a price which many stockholders may find attractive. The existence of these provisions could limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions may also have the effect of discouraging a third party from initiating a proxy contest, making a tender offer or attempting to change the composition or policies of our Board of Directors.

Stockholder Action; Special Meeting of Stockholders. Our certificate of incorporation and bylaws also provide that:

- stockholder action may be taken only at a duly called and convened annual or special meeting of stockholders and then only if properly brought before the meeting;
- stockholder action may not be taken by written action in lieu of a meeting;
- special meetings of stockholders may be called only by our Board of Directors pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office; and
- in order for any matter to be considered "properly brought" before a meeting, a stockholder must comply with requirements regarding specified information and advance notice to us.

These provisions could delay, until the next stockholders' meeting, actions which are favored by the holders of a majority of our outstanding voting securities. These provisions may also discourage another person or entity from making a tender offer for our Common Stock, because a person or entity, even if it acquired a majority of our outstanding voting securities, would be able to take action as a stockholder only at a duly called stockholders' meeting, and not by written consent.

Provisions of Delaware Law Governing Business Combinations. We are subject to the "business combination" provisions of Section 203 of the Delaware General Corporation Law. In general, such provisions prohibit a publicly held Delaware corporation from engaging in any "business combination" transactions with any "interested stockholder" for a period of three years after the date on which the person became an "interested stockholder," unless:

- prior to such date, the board of directors approved either the "business combination" or the transaction which resulted in the "interested stockholder" obtaining such status; or

- upon consummation of the transaction which resulted in the stockholder becoming an "interested stockholder," the "interested stockholder" owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the "interested stockholder") those shares owned by (a) persons who are directors and also officers and (b) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- at or subsequent to such time the "business combination" is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the "interested stockholder."

A "business combination" is defined to include mergers, asset sales and other transactions resulting in financial benefit to a stockholder. In general, an "interested stockholder" is a person who, together with affiliates and associates, owns 15% or more of a corporation's voting stock or within three years did own 15% or more of a corporation's voting stock. The statute could prohibit or delay mergers or other takeover or change in control attempts with respect to us and, accordingly, may discourage attempts to acquire us.

Indemnification. Our restated certificate provides that no director of our company shall be personally liable for any monetary damages for any breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the company or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the General Corporation Law of the State of Delaware, or (iv) for any transaction from which the director derived an improper personal benefit. Our restated certificate also provides that if the General Corporation Law of the State of Delaware is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of our company shall be eliminated or limited to the fullest extent permitted by the General Corporation Law of the State of Delaware, as so amended. The restated certificate further provides that no amendment to or repeal of these provisions shall apply to or have any effect on the liability or alleged liability of any director for or with respect to any acts or omissions of such director occurring prior to such amendment or repeal. Our restated certificate further provides for the indemnification of our directors and officers to the fullest extent permitted by Section 145 of the Delaware General Corporation Law, including circumstances in which indemnification is otherwise discretionary.

AMENDMENT NO. 13 TO
SHAREHOLDER RIGHTS AGREEMENT

This Amendment No. 13 to Shareholder Rights Agreement (the "***Amendment***"), dated as of January 28, 2021, by and between NeuroMetrix, Inc., a Delaware corporation (the "**Company**"), and American Stock Transfer & Trust Company, LLC (the "***Rights Agent***"), amends that certain Shareholder Rights Agreement, dated as of March 7, 2007, as previously amended, between the Company and the Rights Agent (as so amended, the "***Rights Agreement***").

WHEREAS, the Company and the Rights Agent are parties to the Rights Agreement; and

WHEREAS, the Company desires to extend the term of the Final Expiration Date (as defined in the Rights Agreement) by an additional year;

WHEREAS, pursuant to Section 27 of the Rights Agreement, the Company and the Rights Agent may from time to time supplement or amend the Rights Agreement subject to the terms of the Rights Agreement; and

WHEREAS, the Board of Directors of the Company has determined that an amendment to the Rights Agreement as set forth herein is necessary and desirable in connection with the foregoing and the Company and the Rights Agent desire to evidence such amendment in writing.

NOW, THEREFORE, in consideration of these premises and mutual agreements set forth herein, the parties agree as follows:

1. Amendment to Section 7. Section 7(a) of the Rights Agreement is amended by striking Section 7(a) thereof in its entirety and replacing it with the following:

"(a) Subject to Section 7(e) hereof, the registered holder of any Right Certificate may exercise the Rights evidenced thereby (except as otherwise provided herein) in whole or in part at any time after the Distribution Date upon surrender of the Right Certificate, with the form of election to purchase and the certificate on the reverse side thereof duly executed, to the Rights Agent at the office or offices of the Rights Agent designated for such purpose, together with payment of the aggregate Exercise Price for the total number of one ten-thousandths of a share of

Preferred Stock (or other securities, cash or other assets, as the case may be) as to which such surrendered Rights are then exercised, at or prior to the earlier of (i) the Close of Business on the fifteenth anniversary of the Record Date (the "Final Expiration Date"), (ii) the time at which the Rights are redeemed as provided in Section 23 hereof (the "Redemption Date") or (iii) the time at which such Rights are exchanged as provided in Section 24 hereof (the "Exchange Date") (the earliest of (i), (ii) or (iii) being herein referred to as the "Expiration Date"). Except as set forth in Section 7(e) hereof and notwithstanding any other provision of this Agreement, any Person who prior to the Distribution Date becomes a record holder of shares of Common Stock of the Company may exercise all of the rights of a registered holder of a Right Certificate with respect to the Rights associated with such shares of Common Stock of the Company in accordance with the provisions of this Agreement, as of the date such Person becomes a record holder of shares of Common Stock of the Company."

2. Ratification. The parties hereby ratify and confirm in all respects the Agreement, as amended by this Amendment.

3. Governing Law. This Amendment shall be deemed to be a contract made under the laws of the State of Delaware and for all purposes shall be governed by and construed in accordance with the laws of such State applicable to contracts to be made and performed entirely within such State.

4. Counterparts. This Amendment may be executed in any number of counterparts and each of such counterparts shall for all purposes be deemed to be an original, and all such counterparts shall together constitute but one and the same instrument.

5. Descriptive Headings. Descriptive headings of the several Sections of this Amendment are inserted for convenience only and shall not control or affect the meaning or construction of any of the provisions hereof.

[remainder left intentionally blank]

IN WITNESS WHEREOF, the parties have entered into this Amendment No. 13 to Shareholder Rights Agreement as of the date first stated above.

NEUROMETRIX, INC.

By: __
Name: Thomas T. Higgins
Title: Senior Vice President, Chief Financial Officer, Treasurer and Principal Accounting Officer

AMERICAN STOCK TRANSFER & TRUST COMPANY, LLC

By: __
Name: __
Title: __

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 and 333-236105) and on Form S-3 (Nos. 333-150087, 333-162303, 333-165784, 333-186855, 333-189392, 333-197405, 333-199359, 333-208923, 333-209528, 333-211919, 333-215792, 333-219783 and 333-229349) of our report dated January 28, 2021 relating to the financial statements and schedule of NeuroMetrix, Inc, (the "Company"), as of and for the years ended December 31, 2020 and 2019, which appears in the Company's Annual Report on Form 10-K for the year ended December 31, 2020. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ Moody, Famiglietti and Andronico, LLP

Moody, Famiglietti and Andronico, LLP
Tewksbury, Massachusetts
January 28, 2021

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

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: January 28, 2021

/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

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: January 28, 2021

/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, 2020 (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: January 28, 2021

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

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

Date: January 28, 2021

/s/ THOMAS T. HIGGINS

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