

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, 2018
OR

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

For the transition period from _____ to _____
Commission File Number 001-33351

NEUROMETRIX, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of
Incorporation or Organization)

04-3308180

(I.R.S. Employer
Identification No.)

1000 Winter Street, Waltham, Massachusetts

(Address of Principal Executive Offices)

02451

(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	Name of exchange on which registered
Common Stock, \$0.0001 par value per share	The Nasdaq Stock Market LLC
Preferred Stock Purchase Rights	The Nasdaq Stock Market LLC
Warrants to Purchase Common Stock	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 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," or "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

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, 2018, 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 approximately \$9,257,703 based on the closing sale price of the common stock as reported on the Nasdaq Capital Market on June 30, 2018.

As of January 23, 2019, there were 7,680,463 shares of Common Stock outstanding.

In addition, there were 454,781 warrants to purchase shares of Common Stock listed under NUROW on the Nasdaq Capital Market stock exchange outstanding as of January 23, 2019.

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 30, 2019, or the 2019 Annual Meeting of Stockholders.

NEUROMETRIX, INC.

ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2018

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“NEUROMETRIX”, “NC-STAT”, “OptiTherapy”, “ADVANCE”, “SENSUS”, “Quell”, stylized “Q”, “DPNCheck” and “NC-stat DPNCHECK” are the subject of either a trademark registration or application for registration in the United States. Other brands, names and trademarks contained in this Annual Report on Form 10-K are the property of their respective owners.

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 plan to make Quell more broadly available through retail distribution; 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 is a commercial stage, innovation driven healthcare company combining neurostimulation and digital medicine to address chronic health conditions including chronic pain, sleep disorders, and diabetes. Our core expertise in biomedical engineering has been refined over nearly 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 management of chronic pain. We have an experienced management team and Board of Directors. Our business is fully integrated with in-house capabilities spanning product research and development, manufacturing, regulatory affairs and compliance, sales and marketing, 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 lines:

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

Chronic pain is a significant public health problem. It is defined by the National Institutes of Health (NIH) as any 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. Pain signals continue to be transmitted in the nervous system over extended periods of time often leading to other health problems.

These can include fatigue, sleep disturbance, decreased appetite, 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 over 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 or opioid. The approach to treatment is individualized, drug combinations may be employed, and the results are often hit or miss. Side effects and the potential for addiction are real and the risks are substantial. Increasingly, restrictions are being imposed on access to prescription opioids. Reflecting the complexity of chronic pain and the difficulty in treating, 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 spending in the United States.

Nerve stimulation is a long-established category of treatment for chronic pain. In simplified terms, the mechanism of action involves triggering the body's central pain inhibition system to suppress pain. This treatment approach is available through implantable spinal cord stimulation requiring surgery with its attendant risks. Non-invasive approaches involving transcutaneous electrical nerve stimulation (TENS) have achieved limited efficacy in practice due to device limitations, ineffective dosing and low patient adherence. Our Quell wearable technology for chronic pain addresses these limitations and has demonstrated its efficacy in multiple clinical studies.

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 nerve disease or diabetic 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 DPN is important because there are no treatment options once the nerves have degenerated. Today's diagnostic methods for DPN 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 technology provides a rapid, low cost, quantitative test for peripheral nerve disease, including DPN. It addresses an important medical need and is particularly effective in screening large populations likely susceptible to DPN. DPNCheck has been validated in numerous clinical studies.

Goals and Strategy

We believe that personalized neurostimulation to suppress pain can provide a valuable complement to pain medications and other treatments. Our Quell technology addresses this important medical need and we are uniquely positioned to make Quell available to chronic pain sufferers in the United States. We also recognize the worldwide need for an accurate, cost-effective technique to screen for diabetic peripheral neuropathy. Our DPNCheck technology was designed to address this specific need and is supported by an extensive body of clinical evidence. Our overall business objective is profitable growth led by targeted marketing of Quell and supported by an important contribution from DPNCheck. Profitable growth in the near term should include gross margin expansion, efficient deployment of operating spending and declining net cash consumption from operations.

We are entering the second year of our collaboration with GlaxoSmithKline Healthcare (GSK). In early 2018 we entered into the Asset Purchase Agreement, the Development and Services Agreement and related documents with GSK, which we refer to as the "GSK collaboration," pursuant to which we sold to GSK the rights to Quell in markets outside the United States in exchange for \$26.5 million in milestone payments and an agreement to co-fund the Quell development program starting in 2019. We recently amended the GSK collaboration to restructure the milestones and related payments. This had the effect of accelerating the timing of the milestones and recognizing a time-value-of-money adjustment. Also, we agreed with GSK on the 2019 Quell development program which will be overseen by a joint development committee of NeuroMetrix and GSK representatives. In 2018 we received \$14.7 million in milestone funding from GSK. In 2019 we expect to receive GSK funding

from both milestone achievement and the Quell development program. While the payments are not determinable at this time, we believe that the GSK funding will be adequate to address our 2019 capital requirements.

Driving Profitable Growth with Key Proprietary Products.

- **Quell** is an advanced, wearable technology for treating chronic pain. It can be worn during the day while active and at night while sleeping. Quell is drug-free and has been cleared by the FDA for treatment of chronic pain without a prescription. Quell has been shown in multiple clinical studies to relieve chronic pain and, in a published study, 4 out of 5 users reported improvement in chronic pain. Quell users can personalize and manage therapy discreetly via the Quell app. Quell also offers health tracking relevant to chronic pain sufferers including pain, sleep, activity, and gait. Quell users can synchronize their data with the Quell Health Cloud™, which provides customized feedback and powers one of the world's largest chronic pain databases.

Quell was made commercially available in the United States in mid-2015. Quell product sales during 2018 totaled \$10.5 million and cumulatively from launch have totaled \$32.6 million. We have shipped over 180,000 Quell devices to customers. Quell is available via e-commerce on our QuellRelief website and Amazon, and at select retailers. We use television and digital promotion to expand brand awareness. In September 2018 we launched our next generation product Quell 2.0 with enhanced functionality. Quell 2.0 features a 50% reduction in device size and 20% increase in power capacity, an updated app with coaching, an intensive therapy option, and advanced personalization.

In 2018 we initiated several key efforts to improve profitability:

- User experience - launched Quell 2.0 with improved usability
 - User engagement - implemented focused, continuing user outreach to improve aftermarket sales
 - Distribution - restructured channels to emphasize e-commerce, minimize higher cost retail and home shopping
 - Cost of goods - launched Quell 2.0 incorporating a design for manufacturing efficiency
 - Pricing - launched Quell 2.0 at higher price and with bundling, subscription option for consumables
- **DPNCheck** is a fast, accurate, quantitative diagnostic test for peripheral neuropathies, including diabetic peripheral neuropathy.

DPNCheck was made commercially available in late 2011. DPNCheck product sales in 2018 totaled \$4.2 million and over the past three years totaled \$12.1 million. We have shipped nearly 5,000 devices to customers. Our DPNCheck revenues are dominated by sales of high margin patient test biosensors. Our U.S. sales efforts focus on Medicare Advantage 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 neuropathy allowing for earlier clinical intervention to help mitigate the effects of neuropathy on both patient quality of life and cost of care. Also, the diagnosis and documentation of neuropathy provided by DPNCheck helps clarify the patient health profile which, in turn, may have a direct, positive effect on the Medicare Advantage premium received by the provider. DPNCheck is marketed in Japan by our distribution partner Fukuda Denshi; in China by OMRON Medical (Beijing) Ltd.; and in Mexico by Scienta Farma.

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 in our unique competency of precision neurostimulation, is essential to profitable growth and to competitive advantage. In 2019 we will enter the joint development phase of our GSK collaboration. Quell projects will constitute the majority of our R&D development efforts and will be prioritized and overseen by a joint steering committee of NeuroMetrix and GSK representatives. Quell projects will be jointly funded as part of the GSK collaboration. In addition, our R&D team will provide DPNCheck engineering resources to address product maintenance and development requirements.

Our Business Model

Our products 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 orders 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, Quell and DPNCheck, conform to this model. Our Quell user engagement initiative also specifically targets increased aftermarket sales.

Primary Marketed Products

Quell

Quell is a wearable device for relief of chronic pain such as nerve pain due to diabetes, arthritis, fibromyalgia and lower back problems. It incorporates a collection of proprietary approaches designed to optimize the clinical efficacy 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 which may be used 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 clinical research. The 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 treatment of chronic pain and is available OTC. The device was made commercially available in June 2015. In a published clinical study, 81% of subjects reported an improvement in their chronic pain and health, and 67% reported a reduction in their use of pain medications. To encourage persons with chronic pain to try Quell, we offer a 60-day trial period during which the product can be returned for a full refund. To date, product returns have averaged approximately 25% which is broadly in line with the percentages of users who reported improvement in clinical results. Quell is available via e-commerce, select retailers and health care professionals. We utilize television promotion and digital advertising to expand product awareness. Cumulatively through 2018 over 180,000 Quell devices have been shipped to customers.

DPNCheck

DPNCheck is a fast, accurate, and quantitative nerve conduction test that is used to evaluate systemic neuropathies such as diabetic peripheral neuropathy. 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 DPN. The device measures nerve conduction velocity and response amplitude of the sural nerve, a nerve in the lower leg and ankle. These parameters are widely recognized as sensitive and specific biomarkers of DPN. DPNCheck is comprised of: (1) an electronic hand-held device and (2) a single patient-use biosensor. In addition, we provide users with PC-based software that links to the device via a USB connection thereby allowing physicians to generate reports and manage their test data.

DPNCheck is a modified version of our previously marketed NC-stat nerve testing device that has the same clinical indications with respect to DPN. 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 technology has been the subject of many published studies, including several studies specifically addressing the accuracy and clinical utility of the device in assessment of DPN. Cumulatively through 2018 nearly 5,000 DPNCheck 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 traditional 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, report generation, and other network services. 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 seven different nerve-specific electrode arrays but 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. Numerous papers have been published on the use of this technology in this clinical application. As of December 31, 2018, we had an installed base of approximately 250 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	Relief for chronic, intractable pain	> 180,000
SENSUS	Q1 2013 – present	Transcutaneous Electrical Nerve Stimulation	Relief for chronic, intractable pain	> 11,000
DPNCheck	Q4 2011 – present	Nerve Conduction	Diagnosis and evaluation of peripheral neuropathies, such as DPN	> 1,100,000
ADVANCE	Q2 2008 – present	Nerve Conduction	Diagnosis and evaluation of CTS, low back pain, peripheral neuropathies (including DPN)	> 1,900,000 (ADVANCE and NC-stat)
NC-stat	Q2 1999 – Q3 2010	Nerve Conduction	Diagnosis and evaluation of CTS, low back pain, peripheral neuropathies (including DPN)	

Customers

Quell customers include consumers, retail merchandisers, direct response TV promoters, and health care professionals (physicians and clinics) in the United States. Cumulatively through December 31, 2018, over 180,000 Quell devices have been shipped. 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, 2018 nearly 5,000 DPNCheck devices have been shipped to customers. Our legacy ADVANCE System customers include approximately 250 active accounts covering primary care, internal medicine, orthopedic and hand surgeons, pain medicine physicians, neurologists, physical medicine and rehabilitation physicians, and neurosurgeons.

At December 31, 2018, two customers accounted for 45% of accounts receivable and two customers accounted for 23% of revenue.

Sales, Marketing, and Distribution

Quell is distributed in the United States via e-commerce including the Company's website www.quellrelief.com and Amazon, and via select retailers and health care professionals. We utilize television promotion and digital advertising to expand product awareness.

Our U.S. sales efforts for DPNCheck focus on Medicare Advantage organizations and providers who assume financial responsibility and the associated risks for the health care costs of their patients. We believe that DPNCheck presents an attractive clinical case with early detection of neuropathy allowing for earlier clinical intervention to help mitigate the effects of neuropathy on both patient quality of life and cost of care. Also, the diagnosis and documentation of neuropathy provided by DPNCheck helps clarify the patient health profile which, in turn, may have a direct, positive effect on the Medicare Advantage premiums received by the provider. We believe that attractive growth opportunities exist outside the United States, including Japan where DPNCheck is sold by our distribution partner Fukuda Denshi; in China where DPNCheck is sold by Omron Beijing Ltd.; and in Mexico where DPNCheck is sold by Scienta Farma.

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

Quell sales and marketing efforts are led by our Senior Vice President and Chief Commercial Officer. 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 commercial employees including sales and marketing, and customer service.

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 us the sub-assemblies and components that we use in manufacturing Quell and DPNCheck, as well as our consumable products including biosensors and electrodes. We maintain alternative suppliers for some but not all of the sub-assemblies and key components. Consumable biosensors and electrodes are manufactured to our specifications by two long standing suppliers. 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.

Sunburst EMS, Inc., or Sunburst, has been manufacturing devices and providing sub-assemblies to us since 2005. Sunburst currently manufactures sub-assemblies for Quell and DPNCheck at a facility in Massachusetts. MC Assembly, Inc., or MC Assembly, has manufactured sub-assemblies for Quell at a facility in Massachusetts since 2016.

Johnson Medtech, LLC, or Johnson, has been manufacturing ADVANCE electrodes for us since 1999, currently at a facility in Ohio. Katecho, Inc., a full service original equipment manufacturer (or OEM) based in Iowa and specializing in medical and cosmetic devices, manufactures DPNCheck biosensors and Quell electrodes under normal commercial terms contained in our purchase orders.

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. Our neurostimulation systems for chronic pain, are cleared for marketing in the United States, Canada, the European Economic Area, and Australia; however, under terms of the agreements with GSK executed in 2018, our accessible market is restricted to 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 our marketing group and customers to design products that are focused on improving clinical outcomes. The team consists of ten people including two who hold M.D. degrees and three who hold Ph.D. degrees. Our founder and Chief Executive Officer is extensively involved with our R&D efforts. He holds both M.D. and Ph.D. degrees and coordinates the clinical programs that are supported by NeuroMetrix.

R&D efforts currently encompass the following areas:

- *Quell Innovation.* Quell utilizes our proprietary wearable nerve stimulation technology to provide relief from chronic pain which can encompass lower back problems, fibromyalgia, arthritis, painful diabetic neuropathy and others. Quell is unique among OTC neurostimulation products in its clinical indications, technology, personalization and digital health features. While our R&D efforts to date have provided us first-to-market advantage, we anticipate that success will attract competition and that we must continually innovate to maintain a leadership position. Starting in 2019 our Quell development efforts will be overseen by a joint steering committee of NeuroMetrix and GSK representatives and will be co-funded by both NeuroMetrix and GSK. Also, we intend to continually strengthen our intellectual property position with the development of additional know-how and a growing body of patent applications.

- *Cost of Goods Sold (COGS) Improvement.* We have identified specific opportunities to reduce Quell COGS, with both near-term and longer-term initiatives underway. Lower COGS would improve gross margins and product profitability. The COGS initiatives involve R&D support as well as investment in engineering design and equipment.
- *Support for DPNCheck.* DPNCheck, our quantitative nerve conduction test for peripheral neuropathies including DPN, has experienced growing demand in the Medicare Advantage market in the United States, in Japan and in Mexico. DPNCheck has regulatory clearance in China and is in the early stages of building the market. The characteristics of new markets often require device modification for local acceptance which, in turn, involves our R&D team.
- *Support clinical studies for our wearable technology.* Quell is an FDA-cleared Class 2 medical device. We plan to continue to build the body of evidence from clinical studies that is foundational to Quell credibility among health care professionals 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.

In a study published in 2016 in the *Journal of Pain Research*, 81% of subjects reported a general improvement in their chronic pain and 67% reported a reduction in pain medication use after 60 days of use of Quell. Additional study findings included decreased interference from pain with sleep and walking ability. Another study published in the *Journal of Pain Research* in 2017 examined changes in chronic pain outcomes following 60 days of Quell use. Study subjects reported statistically and clinically significant improvement in all pain outcomes and all pain outcomes exhibited a strong dose-response relationship. In particular, about 60% of subjects with high Quell therapy utilization reported a large (at least 2 point) improvement in pain interference with activity or mood. In a recently published study in the *Journal of Pain and Relief*, Quell users showed statistically and clinically significant decrease in pain outcome after 60 days of use. There were no differences in pain outcomes or dose-response associations between study participants with distal chronic pain (i.e., affecting the feet and legs) and proximal chronic pain (i.e., hips, lower back and upper body). This result suggests that Quell produces pain relief beyond the site of stimulation at the calf.

Results of an external study conducted at the Brigham and Women's Hospital Pain Management Center were presented at the 9th World Congress of the Work Institute of Pain. Key findings of this randomized clinical trial include: subjects with chronic low back pain in the experimental (Quell) group demonstrated reduced pain intensity compared to control (treatment as usual) subjects; subjects in the experimental group exhibited reduced pain interference with function and pain catastrophizing compared to the control group.

In addition, results of internal studies based on data from Quell Health Cloud™ have been presented at various research conferences.

- At the American Academy of Neurology Annual Meeting a poster entitled “Pilot Study of Sleep/Wake Classification by Leg-Worn Actigraphy” reported an accuracy study of the sleep monitoring technology in the Quell device by comparing it to the accuracy of gold standard polysomnography. The study was conducted in collaboration with researchers at the Massachusetts General Hospital.
- At the American Academy of Pain Medicine Annual Meeting, a poster entitled “Levels and Predictors of Activity in Users of Wearable Neurostimulators with Chronic Pain” explored activity levels in Quell users and associated health. A second poster entitled “Does Fixed-Site High-Frequency Transcutaneous Electrical Nerve Stimulation Provide Analgesia Beyond Application Site?” addressed the widespread analgesic effect of Quell neurostimulation.
- At the PAINWeek National Conference a poster entitled “Effectiveness of Fixed-Site High-Frequency Transcutaneous Electrical Nerve Stimulation among Individuals with Chronic Pain and Abnormal Sleep” addressed statistically and clinically significant improvement in all pain outcomes in study participants using the Quell device’s objective sleep tracking. In addition, Quell effectiveness was found to be generally independent of baseline sleep characteristics. A second poster entitled “Real-Word Effectiveness of Fixed-Site High-Frequency Transcutaneous Electrical Nerve

Stimulation in Chronic Low Back Pain” evaluated Quell’s effectiveness in a 10-week real-world retrospective study. A third poster entitled “Pilot Study of Fixed-Site High-Frequency Transcutaneous Electrical Nerve Stimulation in Fibromyalgia” evaluated Quell efficacy in an open-label study of subjects with confirmed fibromyalgia.

Competition

We believe there is no direct competition to our Quell wearable neurostimulation device for the treatment 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 hit or miss. Side effects and the potential for addiction are real and the risks 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, electrical stimulators, 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 supported by numerous clinical studies demonstrating efficacy. In simplified outline, the mechanism of action involves intensive nerve stimulation to activate the body’s central pain inhibition system resulting in widespread analgesia, or pain relief. The nerve stimulation activates brainstem pain centers leading to the release of endogenous opioids that act primarily through the delta opioid receptor to reduce pain signal transmission through the central nervous system. This therapeutic approach is available through implantable spinal cord stimulation; however, this approach requires surgery and has attendant risks. Non-invasive approaches to neurostimulation (transcutaneous electrical nerve stimulation, or TENS) have achieved limited efficacy in practice due to device limitations, ineffective dosing and low patient adherence. We believe that our clinical and market claims with respect to our wearable technology covering chronic pain and sleep, technical characteristics of 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 such as Sanofi’s IcyHot SmartRelief, Omron PM3030 and Aleve Direct Therapy.

We believe that DPNCheck is currently the only objective and standardized test for DPN 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, this screen is typically performed with a simple (5.07/10g) monofilament. This subjective method 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 compete with our ADVANCE System. These companies include Cadwell Laboratories, Inc. and Natus Medical Incorporated. Natus Medical Incorporated has substantially greater financial resources than we do. 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, 2018, we had 42 issued U.S. patents, five issued foreign patents, and 32 patent applications, including 29 U.S. applications, and three foreign applications. Our wearable therapeutic products have ten issued U.S. utility patents and three issued U.S. design patents plus 28 utility and design patent applications. The foreign patents for wearable therapeutics were assigned to GSK under the terms of our collaboration agreement. For our DPNCheck diagnostic device, nine utility patents 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. In particular, seven of our issued U.S. utility patents covering various aspects of the legacy neurodiagnostic products expired on the same date 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 will have patent terms extending beyond 2018.

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, OptiTherapy, DPNCheck, SENSUS, and NC-stat. We use a trademark for ADVANCE, Wearable Pain Relief Technology, and Quell Health Cloud. 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 2019 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 monthly 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 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 our legacy SENSUS pain management therapeutic system is considered a durable medical equipment (DME) benefit and is reimbursed for chronic pain by Medicare and many commercial insurers under the Healthcare Common Procedure Coding System (HCPCS) code EO730 for the device and under HCPCS code A4595 for the consumable electrodes. These pre-existing codes apply to DME benefits employing transcutaneous electrical nerve stimulation equipment. We expect that Quell will generally not be reimbursed by third party payers in the near future.

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. 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."*

In recent months, FDA has announced a series of efforts to modernize and streamline the 510(k) notification and regulatory review process and for monitoring device post-market safety, as well as issued a Proposed Rule to formalize the De Novo classification process to provide clarity to innovative device developers.

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.

On December 7, 2018, FDA issued a Proposed Rule that would formally codify requirements for the medical device De Novo process and the procedures and criteria for product developers to file a De Novo classification request. Over the past twenty years, the De Novo process has been implemented by FDA pursuant to statutory authorities and somewhat organically through informal guidance and iterative changes by Congress. The Proposed Rule now allows industry to participate in the development of FDA’s policies and procedures for De Novo requests through the notice-and-comment rulemaking process. Although this Proposed Rule, if finalized by FDA, would 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 posed by the device or to remedy a violation of the FDCA 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, the most recent 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. We believe 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. Under the FDA's published guidance on 510(k) requirements for modified devices, we do not believe that a 510(k) submission is required for DPNCheck.

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. While the SENSUS device is still marketed we have transitioned many SENSUS customers to the newer models of our transcutaneous electrical nerve stimulator, called 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, injunctions affecting the manner in which we would be able to market Quell in the future, or criminal prosecution. In 2017, the Company received a Civil Investigative Demand (CID) from the FTC. The CID requested information in connection with an FTC review for compliance of the Company's representations about Quell with Sections 5 and 12 of the FTC Act. The Company produced and supplied to the FTC all documents and information in response to the CID. To the knowledge of the Company, no complaint has been filed against the Company; however, no assurance can be given as to the timing or outcome of the investigation. FTC counsel has communicated that they continue to review our information and documents, but they have not provided a timeframe for completion of that review or for potential closure of the investigation.

Manufacturing Facilities

Our facility, and the facilities utilized by Sunburst and MC Assembly, our contract sub-assembly manufacturers, 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 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.

Legacy Products

We were founded in 1996 as a science-based health care company focused on the development of innovative products for the detection, diagnosis, and monitoring of peripheral nerve and spinal cord disorders, such as those associated with carpal tunnel syndrome, lumbosacral disc disease and spinal stenosis, and diabetes. Our NC-stat System for the performance of nerve conduction studies at the point-of-care was commercially launched in 1999 and the second generation NC-stat was released in 2002. In 2008, we brought to market the more sophisticated ADVANCE System for nerve conduction testing and performance of invasive needle electromyography. These systems were general purpose with broad application in evaluating and diagnosing nerve disorders. Numerous studies demonstrating the clinical accuracy and utility of these devices have been conducted and published in high quality peer-reviewed journals. Furthermore, these devices have been used in FDA sanctioned clinical trials for pharmacological agents and large-scale epidemiological studies sponsored by the NIH, Center for Disease Control and other governmental agencies. The products have been cleared by the FDA, field tested for over a decade and highly regarded for their ease of use, accuracy and reproducibility of results. The health market, particularly the physician office segment, embraced the opportunity to perform nerve conduction tests which previously had required referral to specialists. Point-of-care nerve testing was seen to provide a combination of improved patient care and patient convenience. However, significant changes to health reimbursement during 2006-2009 adversely affected the financial profile on our NC-stat and ADVANCE nerve conduction testing products, particularly when used by non-specialists. This resulted in declining Company revenues and ultimately our decision to discontinue investment in the products and to manage them for cash flow and not for growth. They are now classified as Legacy Products. Also, our initial prescription wearable technology for chronic pain called SENSUS has been classified as a Legacy Product since our 2015 launch of the OTC Quell product line. We reported revenue for our Legacy Products of \$1.4 million and \$1.5 million in 2018 and 2017, respectively.

Employees

As of December 31, 2018, we had a total of 42 full time employees. Of these employees, twelve were in research and development, twelve in sales and marketing, ten in production/distribution, and eight in general and administrative services. One employee holds both M.D. and Ph.D. degrees, one employee holds an M.D. degree and two additional employees hold Ph.D. degrees. 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. We believe that we have good relations with our employees.

Available Information

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

Corporate Information

NeuroMetrix was founded in June 1996 by our President and Chief Executive Officer, Shai N. Gozani, M.D., Ph.D. We originally were incorporated in Massachusetts in 1996, and we reincorporated in Delaware in 2001. Our principal offices are located at 1000 Winter Street, Waltham, Massachusetts 02451. 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, 2018, we had an accumulated deficit of \$191.0 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 and our independent auditor has expressed substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent on our ability to achieve GSK collaboration milestones or to raise additional capital and our operations could be curtailed if we are unable to obtain the required additional funding when needed. We may not be able to do so when necessary, and/or the terms of any financings may not be advantageous to us.

We held cash and cash equivalents of \$6.8 million as of December 31, 2018. We believe that these resources, future GSK collaboration milestones and payments, and the cash to be generated from future product sales will be sufficient to meet our projected operating requirements through 2019. However, the timing of GSK milestone achievement and the amount of our future product sales is difficult to predict and actual sales may not be in line with our forecasts. Accordingly, we may need to raise additional funds to support our future operating and capital needs in 2020.

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 commercialize Quell and we will be dependent on funding our operations through the achievement of milestones under the GSK collaboration, additional public or private financing, 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, 2018, the report of our independent registered public accounting firm in this Annual Report on Form 10-K for the years ended December 31, 2018 and 2017 includes a going concern 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 and the uncertainty of future revenues from new products; (b) changes we may make to the business that affect ongoing operating expenses; (c) changes we may make in our business strategy; (d) regulatory developments and inquiries affecting our existing products; (e) changes in our research and development spending plans; (f) delays in the anticipated timing of GSK milestones; and (g) other items affecting our forecasted level of expenditures and use of cash resources. We may attempt to obtain additional funding through the achievement of milestones under the GSK collaboration, public or private financing, collaborative arrangements with strategic partners, 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 grant licenses on terms that are not favorable to us. Without additional funds, we may be forced to delay, scale back or eliminate some of our sales and marketing efforts, research and development activities, or other operations and potentially delay product development in an effort to provide sufficient

funds to continue our operations. If any of these events occurs, our ability to achieve our development and commercialization goals would be adversely affected.

We are focused on the commercialization within the United States of Quell, our over-the-counter, or OTC, wearable device for chronic pain. We cannot assure you that we will be successful in this field or that our current commercial product for peripheral neuropathy, DPNCheck, or the product candidates or product enhancements in our development pipeline, will be successful.

We are focused on the commercialization within the United States of Quell, our OTC wearable device for pain relief. Quell is based on our prescription product for pain relief, SENSUS. Quell has been on the market since June 2015 and we have shipped over 180,000 Quell devices since then. We are also focused on the growth of DPNCheck, which was launched in 2011, and is a quantitative nerve conduction test for systemic neuropathies such as DPN. Our future prospects are closely tied to our success with Quell and DPNCheck, 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 efficiently create market demand for Quell at profitable pricing levels through our TV and digital marketing efforts;
- manufacturing issues with Quell or our other products;
- 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;
- unfavorable experiences by patients and physicians using 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 Quell and DPNCheck, 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 Quell by the market. 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 Quell, DPNCheck 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.

An inability to work together with GSK or delays in their commercialization timelines could materially and adversely affect our operations.

We are in the second year of our GSK collaboration following the Asset Purchase Agreement, the Development and Services Agreement and related documents, which were signed in January 2018. Under those agreements we sold to GSK the rights to market Quell outside the United States in exchange for \$26.5 million in milestone payments. In addition, we agreed to jointly fund the development of Quell during 2019 and 2020. In December 2018 we executed Amendment #1 to the Development and Services Agreement which restructured the milestones and had the effect of accelerating milestone timing and recognizing a time-value-of money adjustment. While we believe that we have a strong and mutually beneficial working relationship with GSK, we cannot predict whether that will continue in the future, whether we will be able to satisfy the milestone requirements, or whether GSK's commercialization plans will change resulting in an adverse effect on our ability to satisfy the milestone requirements. Our inability to achieve milestones or delays in timing outside our control would have a material and adverse effect on our operations.

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 DPNCheck 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 and DPNCheck, and to fully manufacture devices for the ADVANCE system. 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 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. We have a manufacturing and supply agreement with Johnson Medtech, LLC. for the manufacture of the ADVANCE electrodes for nerve conduction testing. Katecho, Inc. manufactures biosensors for use with our DPNCheck devices and manufactures electrodes for Quell, and Sunburst EMS, Inc. manufactures electronic boards and other components of our Quell and DPNCheck products which we assemble at our Massachusetts facility to produce completed devices. Moreover, due to the recent commercialization of Quell and the limited amount of our sales to date we do not have long-standing relationships with our manufacturers, other than Katecho, Inc., and may not be able to convince suppliers to continue to make components available to us unless there is demand for such components from their other customers. As a result, there is a risk that certain components could be discontinued and no longer available to us.

We have experienced transient inventory shortages on our products and essential parts, including Quell. 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, injunctions affecting the manner in which we would be able to market Quell in the future, or criminal prosecution.

In 2017 we received a Civil Investigative Demand (“CID”) from the FTC. The CID requested information in connection with an FTC review for compliance of our representations about Quell with Sections 5 and 12 of the FTC Act. We believe we have provided all requested documents to the FTC. To our knowledge, no complaint has been filed against us; however, no assurance can be given as to the timing or outcome of the investigation.

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. We have additional product candidates and enhancements of our existing products in our R&D pipeline. We expect that advancing our pipeline products will require significant time and resources. We may not be successful in our commercialization efforts for any of the product candidates or product enhancements currently in our pipeline and we may not be successful in developing, acquiring, or in-licensing additional product candidates, to the extent we decide to do so. If we are not successful 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 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 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 2018. We may not be able to protect our patent rights effectively in some foreign countries. For a variety of reasons, we may decide not to file for patent protection in the United States or in particular foreign countries. In addition, GSK has certain rights to control the filing of patents with respect to Quell in certain foreign countries. 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, including Shai N. Gozani, M.D., Ph.D., our founder, Chairman, President and Chief Executive Officer, Thomas T. Higgins, our Senior Vice President and Chief Financial Officer; and Francis X. McGillin, our Senior Vice President and Chief Commercial Officer. We do not maintain key person life insurance policies covering any of our employees. The loss of any 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 42 employees as of December 31, 2018, 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, such as Quell and DPNCheck, and 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. Quell and DPNCheck 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 with respect to products other than Quell, we will be affected by new business risks that may adversely impact our financial condition or results of operations.

Foreign markets represented approximately 12% and 7% of our revenues in 2018 and 2017, 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 other than Quell 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 other than Quell into foreign markets may not be successful, in which case we may have expended significant resources without realizing the expected benefit.

Our loan and security agreement with a bank, which we refer to as our credit facility, contains financial and operating restrictions that may limit our access to credit. If we fail to comply with covenants in the credit facility, we may be required to repay any indebtedness thereunder, which may have an adverse effect on our liquidity.

Although we have not borrowed any funds under the credit facility, provisions in the credit facility impose restrictions on our ability to, among other things:

- incur additional indebtedness;
- create liens;
- replace certain of our executive officers;
- enter into transactions with affiliates;
- transfer assets;
- pay dividends or make distributions on, or repurchase, our capital stock; and
- merge or consolidate.

In addition, we are required to meet certain financial covenants customary with this type of credit facility, including maintaining a minimum specified tangible net worth. The credit facility also contains other customary covenants, which we may not be able to comply with in the future. Our failure to comply with these covenants may result in the declaration of an event of default and could cause us to be unable to borrow under the credit facility. In addition to preventing additional borrowings under the credit facility, an event of default, if not cured or waived, may result in the acceleration of the maturity of indebtedness outstanding under the credit facility at the time of the default, which would require us to pay all amounts outstanding. If an event of default occurs, we may not be able to cure it within any applicable cure period, if at all. If the maturity of our indebtedness is accelerated, we may not have sufficient funds available for repayment or we may not have the ability to borrow or obtain sufficient funds to replace the accelerated indebtedness on terms acceptable to us, or at all. We have not borrowed any funds under this agreement; however, as of January 24, 2019, \$0.2 million of the amounts available under the agreement are restricted to support letters of credit issued in favor of our landlords.

If we sell additional shares, our stock price may decline as a result of the dilution which will occur to existing stockholders.

Until we are profitable, we will need significant additional funds to develop our business and sustain our operations. We sold shares of convertible preferred stock and warrants on several occasions, 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, 2018, our stock price has fluctuated from a low of \$0.60 to a high of \$7.20, 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 effectiveness of the GSK collaboration, particularly our ability to achieve development and commercialization milestones;
- 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 2017 we received notifications from Nasdaq informing us of certain listing deficiencies related to the minimum bid price listing requirements. Although we have since cured these deficiencies, 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 and engineering activities are located in an approximately 12,000 square foot leased facility in Waltham, Massachusetts and our manufacturing and fulfillment activities are located in a 10,000 square foot leased facility in Woburn, Massachusetts. We believe these facilities 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 23, 2019, there were approximately 39 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 23, 2019, the last reported sale price per share of our common stock on the Nasdaq Capital Market was \$1.29.

EQUITY COMPENSATION PLAN INFORMATION

The following table sets forth information as of December 31, 2018 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, 2018

	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⁾	494,101	\$ 4.08	517,820 (2)
Equity compensation plans not approved by security holders ⁽³⁾	—	—	12,500
Totals	494,101	\$ 4.08	530,320

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

(2)As of December 31, 2018, there were 390,045 shares available for future grant under the Tenth Amended and Restated 2004 Stock Option and Incentive Plan and 127,775 shares available under the Fourth Amended and Restated 2010 Employee Stock Purchase Plan. No new stock grants or awards will be made under the Amended and Restated 1996 Stock Option/Restricted Stock Plan or the Amended and Restated 1998 Equity Incentive 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 is a commercial stage, innovation driven healthcare company combining neurostimulation and digital medicine to address chronic health conditions including chronic pain, sleep disorders, and diabetes. Our core expertise in biomedical engineering has been refined over nearly 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 management of chronic pain. We have an experienced management team and Board of Directors. Our business is fully integrated with in-house capabilities spanning product research and development, manufacturing, regulatory affairs and compliance, sales and marketing, 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 lines:

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

Chronic pain is a significant public health problem. It is defined by the National Institutes of Health as any 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. Pain signals continue to be transmitted in the nervous system over extended periods of time often leading to other health problems. These can include fatigue, sleep disturbance, decreased appetite, 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 over 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 or opioid. The approach to treatment is individualized, drug combinations may be employed, and the results are often hit or miss. Side effects and the potential for addiction are real and the risks 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 spending in the United States.

Nerve stimulation is a long-established category of treatment for chronic pain. In simplified terms, the mechanism of action involves triggering the body's central pain inhibition system to suppress pain. This treatment approach is available through implantable spinal cord stimulation requiring surgery with its attendant risks. Non-invasive approaches involving transcutaneous electrical nerve stimulation (TENS) have achieved limited efficacy in practice due to device limitations, ineffective dosing and low patient adherence. Our Quell wearable technology for chronic pain addresses these limitations and has demonstrated its efficacy in multiple clinical studies.

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 nerve disease or diabetic 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 their feet and lower legs.

Early detection of DPN is important because there are no treatment options once the nerves have degenerated. Today's diagnostic methods for DPN 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 technology provides a rapid, low cost, quantitative test for peripheral nerve disease, including DPN. It addresses an important medical need and is particularly effective in mass screenings of populations that are likely susceptible to DPN. DPNCheck has been validated in numerous clinical studies.

Results of Operations

Comparison of Years Ended December 31, 2018 and December 31, 2017

Revenues

	Years Ended December 31,		Change	% Change
	2018	2017		
	(in thousands)			
Revenues	\$ 16,090.1	\$ 17,092.3	\$ (1,002.2)	(5.9)%

Revenues include sales from Quell, DPNCheck and our legacy neurodiagnostic products. During 2018 total revenues decreased by \$1.0 million, or 5.9%, from 2017. Quell revenues of \$10.5 million were the largest contributor to total revenue. Quell revenues were \$1.8 million, or 14.9%, below the comparable 2017 period. A significant factor contributing to the revenue decline was lower advertising spending during the first three quarters of 2018 leading up to the launch of our next generation wearable technology for chronic pain, Quell 2.0, in September 2018. DPNCheck revenues of \$4.2 million increased by \$1.1 million, or 34.3% from 2017. Our legacy products contributed \$1.4 million and \$1.5 million of revenue in 2018 and 2017, respectively.

In 2018 we adopted revenue recognition standard ASU 2014-09 and discontinued revenue deferral under the previously mandated sell-through revenue model. Generally, the new standard results in earlier recognition of revenues. Had we not changed our revenue recognition policy, revenue in 2018 would have been \$0.6 million higher than reported.

Cost of Revenues and Gross Profit

	Years Ended December 31,		Change	% Change
	2018	2017		
	(in thousands)			
Cost of revenues	\$ 8,707.1	\$ 10,235.5	\$ (1,528.4)	(14.9)%
Gross profit	\$ 7,383.1	\$ 6,856.8	\$ 526.3	7.7 %

Our gross profit margin was 45.9% in 2018 versus 40.1% in the prior year. The margin improvement of 580 basis points or 14.5% was due to the increased weight of our high margin DPNCheck business within total revenue plus improved Quell profitability from shedding high cost distribution channels and from launch of Quell 2.0 which carries higher margins.

Operating Expenses

	Years Ended December 31,		Change	% Change
	2018	2017		
	(in thousands)			
Operating expenses:				
Research and development	\$ 5,134.6	\$ 3,497.6	\$ 1,637.0	46.8 %
Sales and marketing	9,698.8	10,751.9	(1,053.1)	(9.8)%
General and administrative	4,841.2	5,689.9	(848.7)	(14.9)%
Total operating expenses	\$ 19,674.6	\$ 19,939.4	\$ (264.8)	(1.3)%

Research and Development

Research and development expenses for 2018 increased by 46.8% from 2017 due to increased engineering consulting services costs of \$1.3 million and increased personnel costs of \$0.3 million related to Quell product development and to support the GSK collaboration.

Sales and Marketing

Sales and marketing expense for 2018 decreased by 9.8% from 2017 primarily attributable to reduced Quell advertising spending of \$1.1 million prior to the September 2018 launch of Quell 2.0.

General and Administrative

General and administrative expense for 2018 decreased by 14.9% from 2017 due to lower professional service costs of \$0.8 million in 2018.

Collaboration income

	Years Ended December 31,		Change	% Change
	2018	2017		
	(in thousands)			
Collaboration income	\$ 12,255.7	\$ —	\$ 12,255.7	100.0%

In early 2018 we entered into the Asset Purchase Agreement, the Development and Services Agreement and related documents with GSK, which we refer to as the "GSK collaboration," pursuant to which we sold to GSK the rights to Quell in markets outside the United States in exchange for \$26.5 million in milestone payments and an agreement to co-fund the Quell development program starting in 2019. We recently amended the GSK collaboration to restructure the milestones. This had the effect of accelerating the timing of the milestones and recognizing a time-value-of-money adjustment. In 2018, we recorded \$12.3 million in collaboration income from GSK upon achievement of product development milestones.

Other Income

	Years Ended December 31,		Change	% Change
	2018	2017		
	(in thousands)			
Other income	\$ 59.5	\$ 223.4	\$ (163.9)	(73.4)%

Other income includes interest income and warrant liability fair value changes. The change in fair value of warrant liability was zero and \$0.2 million for 2018 and 2017, respectively.

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

Net income per common share applicable to common stockholders was \$0.003 and \$0.002, basic and diluted for 2018, respectively. Net loss per common share applicable to common stockholders was \$(11.598), basic and diluted for 2017. Weighted average shares outstanding used in computing per share amounts are included in Note 2 to the Financial Statements. In 2017, per share amounts reflected a deemed dividend attributable to preferred stockholders of \$6.9 million, or \$(4.040) per share, related to 2017 equity offerings, plus a net loss of \$12.9 million, or \$(7.558) per share.

Liquidity and Capital Resources

Our principal source of liquidity is cash of \$6.8 million at December 31, 2018. Funding for our operations largely depends on revenues from the sales of our commercial products for chronic pain and neuropathy, and on achievement of milestones under the GSK collaboration. A low level of market interest in Quell or DPNCheck, a decline in our consumables sales, unanticipated increases in our operating costs, or unanticipated setbacks toward the achievement of the GSK milestones would have an adverse effect on our liquidity and cash.

	December 31, 2018	December 31, 2017	Change	% Change
		(in thousands)		
Cash and cash equivalents	\$ 6,780.4	\$ 4,043.7	\$ 2,736.7	67.7%

During 2018 our cash and cash equivalents increased by \$2.7 million from 2017 reflecting \$2.9 million cash provided by operating activities, which included the net proceeds of \$14.2 million provided by our collaboration, and \$0.1 million used in investing activities.

We are party to a Loan and Security Agreement, or the credit facility, with a bank. As of December 31, 2018 the credit facility permitted us to borrow up to \$2.5 million on a revolving basis. The credit facility was subsequently amended, most recently on January 14, 2019, and extended until April 15, 2019. Amounts borrowed under the credit facility will bear interest equal to the prime rate plus 0.5%. Any borrowings under the credit facility will be collateralized by our cash, accounts receivable, inventory, and equipment. The credit facility also includes traditional lending and reporting covenants. We were in compliance with these covenants as of December 31, 2018.

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

	Years Ended December 31,	
	2018	2017
Days sales outstanding (days)	39	39
Inventory turnover rate (times per year)	3.5	6.0

Customer payment terms generally vary from payment-on-order for Quell e-commerce sales to 120 days from invoice date. Our inventory turnover rate declined during 2018 due to increase in purchased components and finished goods inventory related to Quell 2.0.

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

	Years Ended December 31,	
	2018	2017
	(in thousands)	
Net cash used in operating activities (excluding cash provided by GSK Collaboration)	\$ (11,350.5)	\$ (12,652.4)
Net cash provided by GSK collaboration	14,212.2	—
Net cash provided by (used in) operating activities	\$ 2,861.7	\$ (12,652.4)
Net cash used in investing activities	\$ (143.6)	\$ (163.1)
Net cash provided by financing activities	\$ 18.6	\$ 12,910.0

Our operating activities provided \$2.9 million for the year ended December 31, 2018. In 2018, net income of \$0.0 million included non-cash stock-based compensation of \$0.4 million. In addition, operating activities included an increase of \$2.0 million in deferred collaboration income and a decrease in accounts receivable of \$1.3 million partially offset by a decrease in accrued product returns of \$0.9 million and an increase in inventory of \$0.7 million.

During the year ended December 31, 2018, our investing activities reflected \$0.1 million spent for the acquisition of fixed assets, primarily related to production system upgrades.

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 \$6.8 million as of December 31, 2018. We believe that these resources, future GSK collaboration milestone payments, and the cash to be generated from future product sales will be sufficient to meet our projected operating requirements through 2019. Accordingly, we may need to raise additional funds to support our operating and capital needs in 2020. 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; (b) changes we may make to the business that affect ongoing operating expenses; (c) changes we may make in our business strategy; (d) regulatory developments affecting our existing products; (e) changes we may make in our research and development spending plans; (f) delays in the timing of achieving GSK milestones; 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 through additional credit lines 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 filed a shelf registration statement on Form S-3 with the SEC covering shares of our common stock and other securities for sale, 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. However, pursuant to the instructions to Form S-3, we only 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, 2018, the Company had federal and state net operating loss carryforwards (NOL) of approximately \$143.0 million and \$48.4 million, respectively, as well as federal and state tax credits of approximately \$1.7 million and \$1.1 million, respectively, which may be available to reduce future taxable income and related taxes. The federal NOL's, the state NOL's, and the federal and state R&D credits each begin to expire in 2019. 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.

Off-Balance Sheet Arrangements, Contractual Obligations, and Contingent Liabilities and Commitments

As of December 31, 2018, we did not have any off-balance sheet financing arrangements.

The following table summarizes our principal contractual obligations as of December 31, 2018 and the effects such obligations are expected to have on our liquidity and cash flows in future periods.

Contractual Obligations	Total	Payments due in			
		Less than 1 year	1 – 3 years	3 – 5 years	More than 5 years
Operating lease obligations	\$ 2,619,927	\$ 629,222	\$ 1,294,357	\$ 413,132	\$ 283,216
Purchase order obligations	4,988,383	4,988,383	—	—	—
Total contractual obligations	\$ 7,608,310	\$ 5,617,605	\$ 1,294,357	\$ 413,132	\$ 283,216

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, its 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 twenty-four month shelf life. Should current market and economic conditions deteriorate, our actual recoveries could be less than our estimates.

Recently Issued or Adopted Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, *Leases (Topic 842)* (“ASU 2016-02”). ASU 2016-02 requires that lessees recognize virtually all of their leases on the balance sheet, by recording a right-of-use asset and lease liability. The provisions of this guidance are effective for annual periods beginning after December 31, 2018, and for interim periods therein. We expect to adopt ASU 2016-02, using the modified retrospective method, upon its effective date of January 1, 2019. We anticipate the impact of adoption will be an increase to long-term assets and total liabilities of approximately \$1.9 million as of January 1, 2019.

In May 2014, the FASB and the International Accounting Standards Board (“IASB”) jointly issued Accounting Standards Update (“ASU”) No. 2014-09, *Revenue from Contracts with Customers* (“ASU 2014-09”), a comprehensive new revenue recognition standard that superseded nearly all existing revenue recognition guidance. We adopted this standard effective January 1, 2018, applying the modified retrospective method. Upon adoption, we discontinued revenue deferral under the sell-through model and commenced recording revenue upon delivery to distributors, net of estimated returns. The impact of adoption was a credit to accumulated deficit of \$0.3 million as of January 1, 2018.

ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk

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

ITEM 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, 2018 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, 2018.

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 quarter ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. Other Information

In 2017 the Company received a Civil Investigative Demand ("CID") from the United States Federal Trade Commission ("FTC"). The CID requested information in connection with an FTC review for compliance of the Company's representations about Quell with Sections 5 and 12 of the FTC Act. The Company has provided all requested documents. To the knowledge of the Company, no complaint has been filed against the Company; however, no assurance can be given as to the timing or outcome of the investigation.

The Company intends to repurchase, from time to time, warrants to purchase its common stock that are traded on Nasdaq under the symbol NUROW. The Company may expend up to \$25,000 in making these purchases on Nasdaq from time to time. Through December 31, 2018, the Company spent \$2,391 to repurchase 38,506 warrants to purchase its common stock.

On January 21, 2019, we entered into Amendment No. 11 to our Shareholder Rights Agreement ("Amendment No. 11") with American Stock Transfer & Trust Company, LLC dated as of March 7, 2007, as amended. Amendment No. 11 extends the term of the Shareholder Rights Agreement by an additional year. The foregoing description of Amendment No. 11 is subject to, and is qualified in its entirety by reference to, the full text of Amendment No. 11, a copy of which is set forth as Exhibit 4.2.11 to this Annual Report on Form 10-K and is incorporated herein by reference.

PART III

ITEM 10. Directors, Executive Officers and Corporate Governance

DIRECTORS AND EXECUTIVE OFFICERS

The following table and biographical descriptions set forth information regarding our executive officers and directors, based on information furnished to us by each executive officer and director, as of December 31, 2018:

Name	Age	Position
Shai N. Gozani, M.D., Ph.D.	54	Chairman of the Board, Chief Executive Officer, President and Secretary
Thomas T. Higgins	67	Senior Vice President, Chief Financial Officer and Treasurer
Francis X. McGillin	58	Senior Vice President and Chief Commercial Officer
David E. Goodman, M.D.(1)(2)	62	Director
Nancy E. Katz(1)	59	Director
Timothy R. Surgenor(1)(3)	59	Director
David Van Avermaete	67	Director

(1)Member of Audit Committee

(2)Member of Compensation Committee

(3)Member of Nominating and Corporate Governance Committee

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

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

Francis X. McGillin has served as Senior Vice President and Chief Commercial Officer since August 2014. Prior to joining NeuroMetrix, from September 2001 to January 2014, Mr. McGillin was Vice President and General Manager at Philips, having served in a number of senior marketing and management positions in the company's consumer and healthcare businesses. His last role with Philips, was leading the globalization of Philips Sonicare business. Before Philips, Mr. McGillin, was Executive Director, Marketing at Johnson & Johnson, working across a number of the company's global consumer brands. Mr. McGillin holds a MBA from Fordham University and a BS degree from Northeastern University.

David E. Goodman, M.D., M.S.E. has served as a member of our Board of Directors since June 2004. Since 2013, Dr. Goodman has served as co-founder and board member to FeetFirst, a technology-focused healthcare services company he co-founded that is committed to preventing the devastating and expensive microvascular complications of diabetes. From 2014 – 2016, Dr. Goodman served as a director of Xtant Medical (OTC QX: BONE), a comprehensive supplier of orthopedic and spine surgery products. From 2012 – 2015, Dr. Goodman served as CMO of FirstVitals, a healthcare services company focused on wellness and prevention. Since 2011, Dr. Goodman has also served as an independent consultant. During 2010, Dr. Goodman served as President and Chief Executive Officer of SEDline, Inc., a research-focused company with the mission to expand the scope and applications for neuromonitoring. From 2008 to 2009, Dr. Goodman served as Executive Vice President of Business Development for Masimo Corporation, a manufacturer of non-invasive patient monitors. From 2006 to 2008, Dr. Goodman served as an independent consultant providing product design, regulatory and analytical consulting services to medical device and biopharmaceutical companies and also served in this capacity from 2003 to 2004 and from 2001 to 2002. From 2005 to 2006, Dr. Goodman served as President and Chief Executive Officer of BaroSense, Inc., a medical device company focused on developing minimally invasive devices for the long-term treatment of obesity. From 2004 to 2005, Dr. Goodman served as President and Chief Executive Officer of Interventional Therapeutic Solutions, Inc., an implantable drug delivery systems company. From 2002 to 2003, Dr. Goodman served as Chairman, President and Chief Executive Officer of Pherin Pharmaceuticals, a pharmaceutical discovery and development company. From 1994 to 2001, Dr. Goodman held various positions, including Chief Executive Officer, Chief Medical Officer and director, for LifeMasters Supported SelfCare, Inc., a disease management services company that Dr. Goodman founded. Dr. Goodman also served as a director of Sound Surgical Technologies LLC, a private manufacturer of aesthetic surgical tools from 2011 until its acquisition by Solta Medical (Nasdaq:SLTM) in 2013. Dr. Goodman holds a B.A.S. in applied science and bioengineering and a M.S.E. in bioengineering from the University of Pennsylvania. He also received an M.D. from Harvard Medical School and the Harvard-M.I.T. Division of Health Sciences and Technology. Dr. Goodman holds 22 issued and pending patents and is a practicing physician with licenses in California and Hawaii. The Board has concluded that Dr. Goodman should serve as a director because Dr. Goodman's medical and engineering background and his many years of executive experience in the medical device industry provide important experience and expertise to the Board.

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

Timothy R. Surgenor has served as a member of our Board of Directors since April 2009. Since April 2009, Mr. Surgenor has been a partner at Red Sky Partners, LLC, a provider of general management consulting services to the biotechnology industry. Since July 2012 Mr. Surgenor has also served as a director of Precision Ventures, a developer of medical and consumer devices. From 2003 to 2009, Mr. Surgenor served as President, Chief Executive Officer and director of Cyberkinetics Neurotechnology Systems (OTC: CYKN.PK), a medical device company. From January 1999 to January 2003, Mr. Surgenor was Executive Vice President at Haemonetics Corporation, which is a medical device company. From 1994 to 1999, Mr. Surgenor was President of Genzyme Tissue Repair, the cell therapy division of Genzyme Corporation. Previously, Mr. Surgenor was Executive Vice President and Chief Financial Officer of BioSurface Technology, Inc. and also held various positions in operations at Integrated Genetics. Mr. Surgenor received a B.A. in Biochemistry from Williams College and an M.B.A. from Harvard Business School. The Board has concluded that Mr. Surgenor should serve as a director because Mr. Surgenor's long career in the medical device and biotechnology business as both an entrepreneur and in senior executive positions in public companies provides the Board with important industry experience as well as valuable finance, accounting and executive management expertise.

David Van Avermaete has served as a member of our Board of Directors since September 2013. Since January 2015, Mr. Van Avermaete has served as President of Inject Safe Technologies, a privately held company that has developed a bandage specifically designed to support injections. From April 2004 to February 2013, Mr. Van Avermaete served as Chief Executive Officer of VeraLight, Inc., a medical device company he founded, that focuses on non-invasive screening for type 2 diabetes.

From 2000 to 2004, Mr. Van Avermaete served as Senior Vice President Non-Invasive Technology of InLight Solutions, a Johnson & Johnson company focused on transformational technology in the diabetes field. From 1998 to 2000, Mr. Van Avermaete served as U.S. President of the LifeScan division of Johnson & Johnson and, from 1990 to 1998, in various senior level positions at LifeScan concentrating in sales and marketing. Previously, Mr. Van Avermaete served as Vice President Sales and Marketing at Biotope, Director of Marketing at Roche Diagnostics, and Director of Marketing and Sales at Syntex Medical Diagnostics. Mr. Van Avermaete received a Master of Business Administration and a Master of Science Degree in Microbiology from the University of Arizona and a Bachelor of Science Degree in medical technology and chemistry from Ball State University. The Board has concluded that Mr. Van Avermaete should serve as a director because his executive level experience in the medical device and diabetes field, as well as in entrepreneurial ventures, provides the Board with a valuable perspective in commercializing medical device products.

BOARD MATTERS AND CORPORATE GOVERNANCE

Board of Directors

Our amended and restated certificate of incorporation, as amended, provides for a classified board of directors consisting of three staggered classes of directors (Class I, Class II and Class III). The members of each class of our Board of Directors serve for staggered three-year terms, with the terms of our Class III, Class I and Class II directors expiring upon the election and qualification of directors at the annual meetings of stockholders to be held in 2019, 2020, and 2021, respectively. Currently:

- our Class I director is Timothy R. Surgenor;
- our Class II directors are Shai N. Gozani, M.D., Ph.D. and David Van Avermaete; and
- our Class III directors are David E. Goodman, M.D. and Nancy E. Katz.

Our Board of Directors has determined that Dr. Goodman, Mr. Surgenor, Ms. Katz, and Mr. Van Avermaete are independent directors for purposes of the corporate governance rules contained in the Nasdaq Marketplace Rules, or the Nasdaq rules.

Our Board of Directors has an Audit Committee, a Compensation Committee, and a Nominating and Corporate Governance Committee.

The Audit Committee currently consists of Mr. Surgenor, Chairman, Dr. Goodman, and Ms. Katz. The Audit Committee operates pursuant to a charter that was approved by our Board of Directors, a copy of which is available on our website at <http://www.neurometrix.com> under the heading “Investor Relations” and subheading “Corporate Governance”. The purposes of the Audit Committee are to, among other functions, assist the Board of Directors in overseeing the operation of a comprehensive system of internal controls covering the integrity of our financial statements and reports, compliance with laws, regulations and corporate policies, and the qualifications, performance and independence of our registered public accounting firm. Mr. Surgenor, Dr. Goodman, and Ms. Katz are all “independent” as that term is defined in the rules of the SEC and the applicable Nasdaq rules relating to audit committee members. Our Board of Directors has determined that Mr. Surgenor qualifies as an “audit committee financial expert” as such term is defined in the rules of the SEC. The Audit Committee held five meetings during 2018.

Procedures by which Stockholders May Nominate Directors

There have been no changes to the procedures disclosed in our proxy statement for the 2018 annual meeting of stockholders by which stockholders may nominate directors.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller and persons performing similar functions. A current copy of the Code of Business Conduct and Ethics is available on our website at <http://www.neurometrix.com> under the heading “Investor Relations” and subheading “Corporate Governance,” and we intend to disclose on this website any amendment to, or waiver of, any provision of the Code of Business Conduct and Ethics applicable to our directors or executive officers that would otherwise be required to be disclosed under the SEC rules, to the extent permitted, by the Nasdaq rules. A current copy of the Code of Business Conduct and Ethics may also be obtained, without charge, upon written request directed to us at: NeuroMetrix, Inc., 1000 Winter Street, Waltham, Massachusetts 02451, Attention: Compliance Officer.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and executive officers and holders of more than 10% of our common stock (collectively, “Reporting Persons”) to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock. Such Reporting Persons are required by regulations of the SEC to furnish us with copies of all such filings. Our records reflect that all reports which were required to be filed pursuant to Section 16(a) of the Exchange Act were filed on a timely basis. We received a written statement from our directors, officers, and 10% stockholders or know from other means that any required Forms 5 were filed or that no Forms 5 were required to be filed.

ITEM 11. Executive Compensation

Directors’ Compensation

As of December 31, 2018, the non-employee members of our Board of Directors were entitled to receive annual cash compensation in the amount of \$15,000 for service as a member of our Board of Directors, which is paid in four quarterly installments. In addition, these non-employee directors were entitled to receive \$2,000 for each board or committee meeting that they attend, provided that they are not entitled to additional compensation for attending committee meetings that occur on the same day as a board meeting which they attend. This cash compensation is in addition to any stock options or other equity compensation that we determine to grant to our directors. Dr. Gozani, the only member of our Board of Directors who is also an employee, is not separately compensated for his service on our Board of Directors.

In addition to the compensation described above, we reimburse all non-employee directors for their reasonable out-of-pocket expenses incurred in attending meetings of our Board of Directors or any committees thereof.

The following table shows compensation information with respect to services rendered to us in all capacities during the fiscal year ended December 31, 2018 for each non-employee member of the Board of Directors.

Director Compensation Table — 2018

Name	Fees Earned or Paid in Cash (\$)	Option Awards \$(1)	Total Compensation (\$)
David E. Goodman, M.D.(2)	33,000	12,572	45,572
Nancy E. Katz(3)	31,000	12,572	43,572
Timothy R. Surgenor(4)	36,000	12,572	48,572
David Van Avermaete(5)	27,000	12,572	39,572

(1)These amounts represent the aggregate grant date fair value for 15,000 stock options granted to each director during fiscal year 2018.

(2)As of December 31, 2018, Dr. Goodman held options to purchase 16,971 shares of common stock, 10,954 of which were vested.

(3)As of December 31, 2018, Ms. Katz held options to purchase 16,971 shares of common stock, 10,954 of which were vested.

(4)As of December 31, 2018, Mr. Surgenor held options to purchase 16,971 shares of common stock, 10,954 of which were vested.

(5)As of December 31, 2018, Mr. Van Avermaete held options to purchase 17,252 shares of common stock, 11,235 of which were vested.

Summary of Executive Compensation

The following table sets forth the total compensation paid or accrued during the fiscal years ended December 31, 2018 and 2017 to (i) our Chief Executive Officer, and (ii) our two next most highly compensated executive officers who earned more than \$100,000 during the fiscal year ended December 31, 2018 and were serving as executive officers as of such date (we refer to these individuals as the “named executive officers”):

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Option Awards(1) (\$)	All Other Compensation (\$)	Total (\$)
Shai N. Gozani, M.D. Ph.D. Chairman of the Board, Chief Executive Officer, President and Secretary	2018	415,000	—	63,211	—	478,211
	2017	415,000	194,531	—	—	609,531
Thomas T. Higgins Senior Vice President, Chief Financial Officer and Treasurer	2018	325,000	—	31,606	—	356,606
	2017	325,000	121,875	—	—	446,875
Frank McGillin Senior Vice President, Chief Commercial Officer	2018	341,250	—	31,606	—	372,856
	2017	325,000	97,500	—	—	422,500

(1)These amounts include the aggregate grant date fair value for option awards granted during fiscal years 2018 and 2017 computed in accordance with FASB ASC Topic 718. The amount of each grant is set forth below under “Discussion of Summary Compensation Table — Long-Term Incentive Compensation.” A discussion of the assumptions used in determining grant date fair value may be found in Note 3 to our Financial Statements, included elsewhere in this Annual Report on Form 10-K.

Discussion of Summary Compensation Table

The compensation paid to the named executive officers may include salary, cash incentive compensation, and equity incentive compensation. The terms of employment agreements that we have entered into with our named executive officers are described below under “Employment Agreements and Potential Payments upon Termination or Change-in-Control.”

Cash Compensation

We pay our executive officers a base salary which we review and determine annually. As of December 31, 2018, base salaries for our executive officers are Dr. Gozani — \$415,000, Mr. Higgins — \$325,000, and Mr. McGillin — \$357,500.

Bonus Payments

Each executive officer has an annual bonus target which is expressed as a percentage of base salary. For 2018, executive officer bonus targets as a percentage of base salary were as follows: Dr. Gozani — 62.5%; Mr. Higgins — 50%; and Mr. McGillin — 40%.

The Compensation Committee has established a process for annual assessment of corporate performance which is the foundation for decisions regarding bonus payments to executive officers. Metrics are established following approval by the Board of Directors of the annual operating budget. These are monitored quarterly during the year and assessed after the end of the year. The Compensation Committee evaluates performance against these metrics and also applies judgment in arriving at an overall corporate performance rating or “factor”. In concept, the management bonus pool is activated by achievement of a single threshold or “gating” metric. Following activation, value is then created within the pool by achievement toward specific performance metrics.

The management pool metrics for 2018 encompassed targets for collaboration milestone attainment, sales revenue, product development, gross margins and Quell user engagement. The Compensation Committee concluded that the gating metric for 2018 had been met; however, there was inadequate progress toward other performance metrics. Consequently, a management bonus pool was not created for 2018.

Long-Term Incentive Compensation

We grant long-term equity incentive awards in the form of stock options and restricted shares to executives as part of our total compensation package. The Compensation Committee awarded in January 2018 the following equity grants comprised of stock options, to our named executive officers under our 2004 Stock Plan in the following amounts: Dr. Gozani — 75,000 options; Mr. Higgins — 37,500 options; and Mr. McGillin — 37,500 options. During 2017 there were no equity grants to the executive officers.

Stock options referred to above have a term of three years and were 100% vested on grant date. Generally, to the extent vested, each stock option is exercisable during the term of the option while the grantee is employed by us and for a period of three months thereafter, unless such termination is upon death or disability, in which case the grantee may continue to exercise the option for a period of 12 months, or for cause, in which case the option terminates immediately. Vesting of stock options is also subject to acceleration in some certain circumstances in connection with a change-in-control as described below in “Employment Agreements and Potential Payments upon Termination or Change-in-Control.”

Management Retention and Incentive Plan

Our board of directors implemented the Management Retention and Incentive Plan, or the MRIP, under which a portion of the consideration payable upon a change of control transaction, as defined in the MRIP, would be paid to our executive officers and certain other key employees. The MRIP was designed to retain these individuals during the critical, early commercialization phases of our diabetes and pain initiatives while providing management with an incentive to rapidly build corporate value potentially leading to a change of control transaction. The MRIP has been structured to work in conjunction with, and not replace, our other incentive programs such as our equity plans, severance arrangements, compensation and bonus plan, and other benefits. The MRIP is designed to provide an appropriate, market-based incentive to our executive officers and key employees which will be reduced over time as a result of any future equity grants to participants. Effectively, the MRIP has an embedded self-liquidation feature.

In the event of a change of control transaction, subject to the participant's continued employment or service with us, the participant shall receive cash consideration equal to a fixed percentage of the value of the change of control transaction to be received by the Corporation or our stockholders, net of expenses. Each participant's payment shall be reduced by (i) any payments to be made to the participant in the change of control transaction as a result of securities issued pursuant to our equity plans, (ii) the value then held by the participant of securities previously issued to the participant under our equity plans; and (iii) the then current value of shares issued to the participant under our equity plans and previously sold by the participant, excluding any founders shares.

Outstanding Equity Awards at Fiscal Year-End

The table below sets forth information with respect to our named executive officers concerning the outstanding equity awards as of December 31, 2018.

	Option Awards				
	Number of Securities Underlying Unexercised Options			Option Exercise Price (\$)	Option Expiration Date
	Exercisable (#)	Unexercisable (#)	(1)		
Shai N. Gozani, M.D., Ph.D.	14,065	10,935	(1)	11.76	8/22/2026
	75,000	—		1.78	1/25/2021
Thomas T. Higgins	7,033	5,467	(2)	11.76	8/22/2026
	37,500	—		1.78	1/25/2021
Frank McGillin	7,033	5,467	(2)	11.76	8/22/2026
	37,500	—		1.78	1/25/2021

(1) Reflects the unexercised portion of a stock option for 25,000 shares of common stock that was granted on August 22, 2016. The option vests 25% on the first anniversary of the vesting start date and then 1/16th each quarter thereafter until fully vested.

(2) Reflects the unexercised portion of a stock option for 12,500 shares of common stock that was granted on August 22, 2016. The option vests 25% on the first anniversary of the vesting start date and then 1/16th each quarter thereafter until fully vested.

Employment Agreements and Potential Payments upon Termination or Change-in-Control

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

We entered into an employment agreement with Dr. Gozani, effective as of June 21, 2004 and amended on December 31, 2008. Under the terms of the employment agreement, Dr. Gozani is to be paid an annual base salary determined by the Compensation Committee. Dr. Gozani's salary for 2018 was \$415,000. Dr. Gozani is also eligible to receive an annual cash performance bonus of up to 62.5% of his annual salary if certain performance objectives, determined by Dr. Gozani and our Compensation Committee, are met.

The employment agreement may be terminated by us with or without cause or by Dr. Gozani. Under the terms of the employment agreement, if (1) we terminate Dr. Gozani for any reason other than willful non-performance of his duties under the employment agreement, intentional fraud or dishonesty with respect to our business or conviction of a felony, which we refer to as a termination without cause, or (2) Dr. Gozani resigns as a result of a reduction in his responsibilities with us, reduction in his status with us, reduction of his salary, relocation of our corporate offices more than 35 miles from their current location or breach by us of the employment agreement, which we refer to as a termination for good reason, Dr. Gozani will be entitled to his full base salary at his then-current annual rate of pay, plus benefits and applicable bonus payments, through the date of his termination. In addition, in the event of such a termination, we will continue to pay Dr. Gozani his then-current annual base salary for one year following the termination. Additionally, Dr. Gozani will be entitled to his full annual cash performance bonus in the year that any of the following transactions occurs:

- a sale of substantially all of our assets;

- a merger or combination with another entity, unless the merger or combination does not result in a change in ownership of our voting securities of more than 50%; or
- the sale or transfer of more than 50% of our voting securities.

Thomas T. Higgins

We entered an Employment Agreement with Mr. Higgins on October 27, 2014 which provides for our employment of Mr. Higgins as our Senior Vice President, Chief Financial Officer and Treasurer at an annual salary of \$325,000, subject to periodic review and adjustment at our discretion. Under the Employment Agreement, Mr. Higgins is also eligible to receive an annual performance bonus, payable in cash or stock, of up to 50% of his annual salary. Under the terms of the Employment Agreement, if (1) we terminate Mr. Higgins for cause or if he resigns for other than good reason, Mr. Higgins will not be entitled to any separation benefits; (2) we terminate Mr. Higgins' employment without cause other than within 6 months prior to or 12 months following a change in control of the company or Mr. Higgins resigns for good reason, he will be entitled to receive separation benefits equal to his base salary, target bonus amount and continuation of health benefits for a period of twelve months from the date of such termination; (3) we terminate Mr. Higgins' employment within 6 months prior to or 12 months following a change in control of the company or Mr. Higgins resigns for good reason, he will be entitled to the same benefits as described in (2) above, and in addition, we will accelerate his rights to exercise shares under any stock option grants; and (4) Mr. Higgins dies or becomes totally disabled, we will accelerate the rights of his representative to exercise shares under and stock option grants. In connection with the Employment Agreement, Mr. Higgins executed a Confidentiality & Non-Compete Agreement with the Company.

Frank McGillin

We entered an Employment Agreement with Mr. McGillin on August 14, 2014 in connection with his joining the Company which provides for our employment of Mr. McGillin as our Senior Vice President and Chief Commercial Officer. On December 31, 2018, Mr. McGillin's annual salary was \$357,500, subject to periodic review and adjustment at our discretion. Under the Employment Agreement, Mr. McGillin is also eligible to receive an annual performance bonus, payable in cash or stock, of up to 40% of his annual salary. Under the terms of the Employment Agreement, if (1) we terminate Mr. McGillin for cause or if he resigns for other than good reason, Mr. McGillin will not be entitled to any separation benefits; (2) we terminate Mr. McGillin's employment without cause other than within 6 months prior to or 12 months following a change in control of the company or Mr. McGillin resigns for good reason, he will be entitled to receive separation benefits equal to his base salary, target bonus amount and continuation of health benefits for a period of twelve months from the date of such termination; (3) we terminate Mr. McGillin's employment within 6 months prior to or 12 months following a change in control of the company or Mr. McGillin resigns for good reason, he will be entitled to the same benefits as described in (2) above, and in addition, we will accelerate his rights to exercise shares under any stock option grants; and (4) Mr. McGillin dies or becomes totally disabled, we will accelerate the rights of his representative to exercise shares under and stock option grants. In connection with the Employment Agreement, Mr. McGillin executed a Confidentiality & Non-Compete Agreement with the Company.

Confidentiality and Non-Competition Agreements

Dr. Gozani, Mr. Higgins, and Mr. McGillin have each entered into a confidentiality and non-competition agreement with us, which provides for protection of our confidential information, assignment to us of intellectual property developed by the executive officer and non-compete and non-solicitation obligations that are effective during, and for 12 months following termination of, the executive officer's employment.

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

PRINCIPAL AND MANAGEMENT STOCKHOLDERS

The following table sets forth certain information concerning beneficial ownership as of January 23, 2019, except as noted below, of our common stock by:

- each of our directors;
- each of our named executive officers;
- all of our directors and executive officers as a group; and
- each stockholder known by us to beneficially own more than five percent of our common stock.

The number of common shares “beneficially owned” by each stockholder is determined under rules issued by the SEC regarding the beneficial ownership of securities. This information is not necessarily indicative of beneficial ownership for any other purpose. Under these rules, beneficial ownership of common stock includes (1) any shares as to which the person or entity has sole or shared voting power or investment power and (2) any shares as to which the person or entity has the right to acquire beneficial ownership within 60 days after January 23, 2019, including any shares that could be purchased by the exercise of options or warrants on or within 60 days after January 23, 2019. Each stockholder’s percentage ownership is based on 7,680,463 shares of our common stock outstanding as of January 23, 2019, plus the number of shares of common stock that may be acquired by such stockholder upon exercise of options or warrants that are exercisable on or within 60 days after January 23, 2019.

Unless otherwise indicated below, to our knowledge, all persons named in the table have sole voting and investment power with respect to their shares of common stock, except to the extent authority is shared by spouses under community property laws.

Name and Address(1) of Beneficial Owner	Amount and Nature of Beneficial Ownership			Percent of Class of Total
	Common Stock	Options(2)	Total	
Directors and Executive Officers				
Shai N. Gozani, M.D., Ph.D.	153,803	90,628	244,431	3.1%
Thomas T. Higgins	83,441	45,314	128,755	1.7%
Francis X. McGillin	48,497	45,314	93,811	1.2%
David E. Goodman, M.D.	26	10,998	11,024	*
Timothy R. Surgenor	229	11,025	11,254	*
Nancy E. Katz	26	11,025	11,051	*
David Van Avermaete	—	11,306	11,306	*
All Current Directors and Executive Officers as a group (7 persons)	286,022	225,610	511,632	6.5%

Name and Address(1) of Beneficial Owner	Amount and Nature of Beneficial Ownership			Percent of Class of Total
	Common Stock	Preferred Stock(3)	Total	
Beneficial Owner of 5% or More Other than Directors and Executive Officers				
Sabby Management, LLC(3)	—	852,437	852,437	9.99%

* Represents less than 1% of the outstanding shares of common stock.

(1)Unless otherwise indicated, the address of each stockholder is c/o NeuroMetrix, Inc., 1000 Winter Street, Waltham, Massachusetts 02451.

(2)Includes all options that are exercisable on or within 60 days from January 23, 2019 by the beneficial owner, except as otherwise noted.

(3)Reflects shares of common stock issuable upon the conversion of preferred stock beneficially owned by Sabby Healthcare Master Fund, Ltd. ("SHMF") and Sabby Volatility Warrant Master Fund ("SVWMF"). The amount does not include 59,307 shares of common stock issuable upon the exercise of warrants issued to SHMF and SVWMF in 2015 and an aggregate of 5,430,690 shares of common stock issuable upon the conversion of 14,052.93 shares of Series D convertible preferred stock and 2,471.70 shares of Series E convertible preferred stock issued to SHMF and SVWMF. All convertible preferred stock held by SHMF and SVWMF is subject to a 9.99% beneficial ownership limitation. Sabby Management, LLC and Hal Mintz do not directly own shares of common stock, but are deemed to have beneficial ownership over these shares of common stock because Sabby Management, LLC is the investment manager for both SHMF and SVWMF and Hal Mintz is the manager of Sabby Management, LLC. The address for the reporting persons is 10 Mountainview Road, Suite 205, Upper Saddle River, New Jersey 07458.

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

TRANSACTIONS WITH RELATED PERSONS

Except as otherwise set forth below, we did not engage in any related person transactions during the years ended December 31, 2018 and December 31, 2017. Pursuant to our audit committee charter currently in effect, the audit committee is responsible for reviewing and approving, prior to our entry into any such transaction, all transactions in which we are a participant and in which any parties related to us has or will have a direct or indirect material interest.

Private Offering of Convertible Preferred Stock; exchange of Warrants for Convertible Preferred Stock;

In the third quarter of 2017, we completed a private equity offering, or the Q3 2017 Offering, with entities affiliated with Sabby Management, LLC and its affiliates, or Sabby, a principal stockholder, providing for the issuance of (i) 7,000 shares of Series F convertible preferred stock at a price of \$1,000 per share and (ii) 3,621 shares of Series F Preferred Stock in exchange for the repurchase and retirement of 4,184,483 warrants to purchase common stock valued by an independent party at \$3,622,219. The Q3 2017 Offering also reset the conversion price of 14,052.93 shares of Series D convertible preferred stock and 7,000 shares of Series E convertible preferred stock that were held by Sabby to \$2.63 per share. The Q3 2017 Offering resulted in gross proceeds of \$7.0 million, and after deducting fees and expenses, net proceeds were \$6.6 million. Each share of Series F convertible preferred stock has a stated value of \$1,000 and is convertible, at any time at the option of the holder thereof, into a number of shares of our common stock determined by dividing the stated value by the initial conversion price of \$2.63, subject to a 4.99% beneficial ownership limitation.

Private Offering of Convertible Preferred Stock and Warrants;

In the first quarter of 2017, we completed a private equity offering, or the Q1 2017 Offering, with Sabby, providing for the issuance of (i) 7,000 shares of Series E convertible preferred stock at a price of \$1,000 per share, and (ii) warrants to purchase up to 1,250,000 shares of common stock, par value \$0.0001 per share (the “Common Stock”), at an exercise price of \$5.60 per share. As a part of this offering, the Company reset (i) the conversion price of 19,458.90 shares of Series D convertible preferred stock that were held by Sabby to \$5.60 per share, and (ii) the exercise price of warrants to purchase up to 2,934,484 shares of Common Stock that were held by Sabby to \$5.60 per share. The Q1 2017 Offering resulted in gross proceeds of \$7.0 million, and after deducting fees and expenses, net proceeds were \$6.3 million. Each share of Series E convertible preferred stock has a stated value of \$1,000 and is convertible, at any time at the option of the holder thereof, into a number of shares of our common stock determined by dividing the stated value by the adjusted conversion price of \$2.63, subject to a 4.99% beneficial ownership limitation.

DIRECTOR INDEPENDENCE

See Item 10, “Directors, Executive Officers and Corporate Governance — Board Matters and Corporate Governance”.

ITEM 14. Principal Accounting Fees and Services

ACCOUNTING FEES

Aggregate fees for professional services rendered by Moody, Famiglietti, & Andronico, LLP for the years ended December 31, 2018 and 2017 are as follows:

Audit Fees

The audit fees for Moody, Famiglietti, & Andronico, LLP for professional services rendered for the 2018 audit of our annual financial statements and the review of the financial statements included in our quarterly reports on Form 10-Q, issuance of consents, and review of documents filed with the SEC totaled \$141,614, of which \$47,364 was billed in 2018 and \$94,250 was billed in 2019.

The audit fees for Moody, Famiglietti, & Andronico, LLP for professional services rendered for the 2017 audit of our annual financial statements and the review of the financial statements included in our quarterly reports on Form 10-Q, issuance of consents, and review of documents filed with the SEC totaled \$107,600, of which \$54,800 was billed in 2017 and \$52,800 was billed in 2018.

Audit-Related Fees

There were no audit-related fees for Moody, Famiglietti, & Andronico, LLP in 2018 and 2017.

All Other Fees

There were no other fees for Moody, Famiglietti, & Andronico, LLP in 2018 and 2017.

Tax Fees

There were no tax fees for Moody, Famiglietti, & Andronico, LLP in 2018 and 2017.

Pre-Approval Policies and Procedures

The Audit Committee approved all audit and non-audit services provided to us by Moody, Famiglietti, & Andronico, LLP during the 2018 and 2017 fiscal years.

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:

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Filed with this Report</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File/Registration Number</u>
3.1.1	Third Amended and Restated Certificate of Incorporation of NeuroMetrix, Inc. dated July 27, 2004	S-8	(Exhibit 4.1)	8/9/2004	333-118059
3.1.2	Certificate of Designations for Series A Junior Cumulative Preferred Stock, par value \$0.001 per share, dated March 7, 2007	8-A12(b)	(Exhibit 3.1)	3/8/2007	001-33351
3.1.3	Certificate of Amendment to Restated Certificate of Incorporation of NeuroMetrix, Inc. dated September 1, 2011	8-K	(Exhibit 3.1)	9/1/2011	001-33351
3.1.4	Certificate of Amendment to Restated Certificate of Incorporation of NeuroMetrix, Inc. dated February 15, 2013	8-K	(Exhibit 3.1)	2/15/2013	001-33351
3.1.5	Certificate of Amendment to Restated Certificate of Incorporation of NeuroMetrix, Inc. dated December 1, 2015	8-K	(Exhibit 3.1)	12/1/2015	001-33351
3.1.6	Certificate of 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
3.1.7	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
3.1.8	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
3.1.9	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
3.1.10	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

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Filed with this Report</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File/Registration Number</u>
3.1.11	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
3.1.12	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
3.1.12	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
3.2.1	Second Amended and Restated Bylaws of NeuroMetrix, Inc.		S-8 (Exhibit 4.2)	8/9/2004	333-118059
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	Specimen Certificate for Shares of Common Stock		S-1/A (Exhibit 4.1)	7/19/2004	333-115440
4.2.1	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
4.2.2	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
4.2.3	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
4.2.4	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
4.2.5	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
4.2.6	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
4.2.7	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
4.2.8	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

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Filed with this Report</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File/Registration Number</u>
4.2.9	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
4.2.10	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
4.2.11	Amendment No. 10 to Shareholder Rights Agreement, dated February 5, 2018, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent		10-K (Exhibit 4.2.11)	2/8/2018	001-33351
4.2.12	Amendment No. 11 to Shareholder Rights Agreement, dated January 21, 2019, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent	X			
4.3.1	Form of Unit Warrant to purchase Common Stock (February 2012)		S-1/A (Exhibit 4.5)	1/31/2012	333-178165
4.3.2	Form of Placement Agent Warrant (February 2012)		S-1/A (Exhibit 4.6)	1/31/2012	333-178165
4.4	Form of Common Stock Purchase Warrant (June 2013)		8-K/A (Exhibit 4.1)	6/7/2013	001-33351
4.5	Form of Common Stock Purchase Warrant (June 2014)		8-K (Exhibit 4.1)	6/25/2014	001-33351
4.6.1	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
4.6.2	Form of Underwriter's Warrant (2015) issued on May 29, 2015		S-1/A (Exhibit 4.5)	4/13/2015	333-188133
4.7	Form of Series A Common Stock Purchase Warrant (December 2015)		8-K (Exhibit 4.1)	12/30/2015	001-33351
4.8	Form of Series B Common Stock Purchase Warrant (December 2015)		8-K (Exhibit 4.2)	12/30/2015	001-33351
4.9	Form of Common Stock Purchase Warrant (June 2016)		8-K (Exhibit 4.1)	6/3/2016	001-33351
4.10	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
Credit Facilities, Loan and Equity Agreements					
10.2.1	Loan and Security Agreement between NeuroMetrix, Inc. and Comerica Bank, dated March 5, 2010		10-Q (Exhibit 10.1)	5/14/2010	001-33351

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Filed with this Report</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File/Registration Number</u>
10.2.2	First Modification to Loan and Security Agreement between NeuroMetrix, Inc. and Comerica Bank, dated March 1, 2011		8-K (Exhibit 10.1)	3/3/2011	001-33351
10.2.3	Fifth Modification to Loan and Security Agreement between NeuroMetrix, Inc. and Comerica Bank, dated January 31, 2014		10-Q (Exhibit 10.1)	4/24/2014	001-33351
10.2.4	Sixth Modification to Loan and Security Agreement with Comerica Bank, dated January 23, 2015		10-Q (Exhibit 10.1)	4/24/2015	001-33351
10.2.5	Seventh Modification to Loan and Security Agreement with Comerica Bank, dated January 14, 2016		10-K (Exhibit 10.2.5)	2/12/2016	001-33351
10.2.6	Eighth Modification to Loan and Security Agreement with Comerica Bank, dated December 27, 2016		10-K (Exhibit 10.2.6)	2/9/2017	001-33351
10.2.7	Ninth Modification to Loan and Security Agreement with Comerica Bank, dated January 17, 2018		10-K (Exhibit 10.2.7)	2/8/2018	001-33351
10.2.8	Tenth Modification to Loan and Security Agreement with Comerica Bank, dated January 14, 2019	X			
10.3	Repurchase and Forfeiture Agreement by and between NeuroMetrix, Inc. and the parties named therein		10-Q (Exhibit 10.1)	7/23/2015	001-33351
10.4.1	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
10.4.2	Registration Rights Agreement by and between NeuroMetrix, Inc. and the purchasers named therein, dated December 29, 2015		8-K (Exhibit 10.2)	12/30/2015	001-33351
10.5.1	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
10.5.2	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
10.6.1	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
10.6.2	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
10.7.1	Engagement Agreement with Rodman & Renshaw, dated as of June 2, 2016		S-1/A (Exhibit 10.8.1)	11/23/2016	333-207566
10.7.2	Amendment to Engagement Agreement with Rodman & Renshaw, dated as of December 19, 2016		8-K (Exhibit 1.1)	12/29/2016	001-33351

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Filed with this Report</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File/Registration Number</u>
10.7.3	Amendment to Engagement Agreement with Rodman & Renshaw, as amended, dated as of January 3, 2017		S-3 (Exhibit 10.3)	1/27/2017	333-215792
<i>Equity Compensation Plans</i>					
10.8+	Amended and Restated 1996 Stock Option/Restricted Stock Plan		S-1/A (Exhibit 10.2)	6/22/2004	333-115440
10.9.1+	Amended and Restated 1998 Equity Incentive Plan		S-1/A (Exhibit 10.3)	6/22/2004	333-115440
10.9.2+	Second Amendment to Amended and Restated 1998 Equity Incentive Plan		S-1 (Exhibit 10.18)	6/22/2004	333-115440
10.10.1+	Seventh Amended and Restated 2004 Stock Option and Incentive Plan		14A (Appendix A)	3/30/2015	001-33351
10.10.2+	Form of Restricted Stock Agreement		10-Q (Exhibit 10.4)	5/14/2010	001-33351
10.10.3+	Form of Incentive Stock Option Agreement		10-Q (Exhibit 10.1)	11/15/2004	000-50856
10.10.4+	Form of Non-Qualified Stock Option Agreement For Company Employees		10-Q (Exhibit 10.2)	11/15/2004	000-50856
10.10.5+	Form of Non-Qualified Stock Option Agreement For Non-Employee Directors		10-Q (Exhibit 10.3)	11/15/2004	000-50856
10.11+	2009 Non-Qualified Inducement Stock Plan		S-8 (Exhibit 99.1)	6/3/2009	333-159712
10.12.1+	Third Amended and Restated 2010 Employee Stock Purchase Plan		14A (Appendix B)	3/17/2016	001-33351
<i>Agreements with Executive Officers and Directors</i>					
10.13+	Form of Indemnification Agreement between NeuroMetrix, Inc. and each of its directors		S-1/A (Exhibit 10.8)	6/22/2004	333-115440
10.14.1+	Employment Agreement, dated June 21, 2004, by and between NeuroMetrix, Inc. and Shai N. Gozani, M.D., Ph.D.		S-1/A (Exhibit 10.9)	6/22/2004	333-115440
10.14.2+	First Amendment to Employment Agreement dated December 31, 2008, by and between NeuroMetrix, Inc. and Shai N. Gozani, M.D., Ph.D.		10-K (Exhibit 10.11)	3/20/2009	001-33351
10.14.3+	Indemnification Agreement dated June 21, 2004, by and between Shai N. Gozani, M.D., Ph.D., and NeuroMetrix, Inc.		S-1/A (Exhibit 10.20)	6/22/2004	333-115440
10.14.4+	NeuroMetrix, Inc. Non-Statutory Stock Option Agreement (pursuant to the Amended and Restated 1998 Equity Incentive Plan), dated as of June 21, 2004, by and between Shai N. Gozani M.D., Ph.D., and NeuroMetrix, Inc.		S-1/A (Exhibit 10.17)	6/22/2004	333-115440
10.15.1+	Letter Agreement, dated August 31, 2009, between NeuroMetrix, Inc. and Thomas T. Higgins		8-K (Exhibit 10.1)	9/15/2009	001-33351

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Registration Number
10.15.2+	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
10.15.3+	Employment Agreement, dated October 27, 2014 by and between NeuroMetrix, Inc. and Thomas T. Higgins		10-Q (Exhibit 10.4)	10/28/2014	001-33351
10.16.1+	Letter Agreement, dated August 14, 2014, between NeuroMetrix, Inc. and Francis X. McGillin		10-Q (Exhibit 10.5)	10/28/2014	001-33351
10.17+	Amended and Restated Management Retention and Incentive Plan, as modified, dated February 3, 2017		10-K (Exhibit 10.17)	2/9/2017	001-33351

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Registration Number
<i>Agreements with Respect to Collaborations, Licenses, Research and Development</i>					
10.18 †	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
10.19 †	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
10.20 †	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
10.21 †	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
10.22 †	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
10.23	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
10.24	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
10.25	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
10.26 *	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.	X			
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			

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Registration Number
101	The following materials from NeuroMetrix, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2018, formatted in XBRL (Extensible Business Reporting Language): (i) Balance Sheets as of December 31, 2018 and 2017, (ii) Statements of Operations for the years ended December 31, 2018 and 2017, (iii) Statements of Changes in Stockholders' Equity for the years ended December 31, 2018 and 2017, (iv) Statements of Cash Flows for the years ended December 31, 2018 and 2017, 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.

* Confidential treatment has been requested 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.

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 24, 2019

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 24, 2019 in the capacities indicated below.

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

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NeuroMetrix, Inc.

Years ended December 31, 2018 and 2017

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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, 2018 and 2017, and the related statements of operations, changes in stockholders' equity, and cash flows for each of the years then ended, 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, 2018 and 2017, and the results of its operations and its cash flows for the years then ended, 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.

We have served as the Company's auditor since 2017.

/s/ Moody, Famiglietti, & Andronico, LLP

Moody, Famiglietti, & Andronico, LLP
Tewksbury, Massachusetts
January 24, 2019

NeuroMetrix, Inc.

Balance Sheets

	December 31,	
	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 6,780,429	\$ 4,043,681
Accounts receivable, net of allowances of \$25,000 at December 31, 2018 and 2017	1,082,957	1,049,329
Inventories	2,861,864	2,142,561
Prepaid expenses and other current assets	905,767	1,867,803
Total current assets	11,631,017	9,103,374
Fixed assets, net	407,339	440,842
Other long-term assets	74,892	55,008
Total assets	\$ 12,113,248	\$ 9,599,224
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,298,084	\$ 733,305
Accrued expenses and compensation	1,659,173	2,362,124
Accrued product returns	1,101,658	666,375
Deferred revenue	—	820,031
Deferred collaboration income	1,956,522	—
Total current liabilities	6,015,437	4,581,835
Total liabilities	6,015,437	4,581,835
Commitments and contingencies (Note 8)		
Stockholders' equity		
Preferred stock	—	—
Convertible preferred stock	18	30
Common stock, \$0.0001 par value; 100,000,000 authorized at December 31, 2018 and 2017; 7,380,463 and 2,706,066 shares issued and outstanding at December 31, 2018 and 2017, respectively	738	271
Additional paid-in capital	197,113,646	196,355,142
Accumulated deficit	(191,016,591)	(191,338,054)
Total stockholders' equity	6,097,811	5,017,389
Total liabilities and stockholders' equity	\$ 12,113,248	\$ 9,599,224

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

NeuroMetrix, Inc.

Statements of Operations

	Years Ended December 31,	
	2018	2017
Revenues	\$ 16,090,138	\$ 17,092,336
Cost of revenues	8,707,082	10,235,538
Gross profit	7,383,056	6,856,798
Operating expenses:		
Research and development	5,134,592	3,497,636
Sales and marketing	9,698,753	10,751,863
General and administrative	4,841,278	5,689,917
Total operating expenses	19,674,623	19,939,416
Loss from operations	(12,291,567)	(13,082,618)
Other income:		
Collaboration income	12,255,704	—
Other income	59,468	223,365
Total other income	12,315,172	223,365
Net income (loss)	23,605	(12,859,253)
Net income (loss) applicable to common stockholders:		
Deemed dividends attributable to preferred shareholders (Note 12)	—	(6,874,780)
Net income (loss) applicable to common stockholders	\$ 23,605	\$ (19,734,033)
Net income (loss) per common share applicable to common stockholders:		
Basic	\$ 0.003	\$ (11.598)
Diluted	\$ 0.002	\$ (11.598)

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, 2016	17,702.65	\$ 18	836,863	\$ 84	\$ 183,439,463	\$ (178,478,801)	\$ 4,960,764
Stock-based compensation expense	—	—	—	—	209,691	—	209,691
Issuance of Series E preferred stock and warrants and repricing other holdings under purchase agreement	7,000.00	7	—	—	6,057,382	—	6,057,389
Issuance of Series F preferred stock and repurchase of certain warrants under purchase agreement	10,621.00	11	—	—	6,628,019	—	6,628,030
Issuance of common stock upon conversion of preferred stock	(5,843.67)	(6)	1,833,240	184	(178)	—	—
Issuance of common stock under employees stock purchase plan	—	—	11,583	1	20,767	—	20,768
Issuance of common stock in exchange for warrants	—	—	24,380	2	(2)	—	—
Net loss	—	—	—	—	—	(12,859,253)	(12,859,253)
Balance at December 31, 2017	29,479.98	30	2,706,066	271	196,355,142	(191,338,054)	5,017,389
Stock-based compensation expense	—	—	—	—	446,077	—	446,077
Issuance of common stock upon conversion of preferred stock	(11,966.35)	(12)	4,436,802	444	(432)	—	—
Common stock issued to settle employee incentive compensation obligations	—	—	214,791	21	294,243	—	294,264
Issuance of common stock under employees stock purchase plan	—	—	22,804	2	18,616	—	18,618
Adoption of ASC606	—	—	—	—	—	297,858	297,858
Net income	—	—	—	—	—	23,605	23,605
Balance at December 31, 2018	17,513.63	\$ 18	7,380,463	\$ 738	\$ 197,113,646	\$ (191,016,591)	\$ 6,097,811

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

NeuroMetrix, Inc.

Statements of Cash Flows

	Years Ended December 31,	
	2018	2017
Cash flows for operating activities:		
Net income (loss)	\$ 23,605	\$ (12,859,253)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	169,712	262,334
Stock-based compensation	446,077	209,691
Change in fair value of warrant liability	—	(208,480)
Changes in operating assets and liabilities:		
Accounts receivable	1,319,871	(310,600)
Inventories	(719,303)	(117,409)
Prepaid expenses and other current and long-term assets	358,661	(884,642)
Accounts payable	572,153	(8,117)
Accrued expenses and compensation	(408,687)	891,181
Accrued product returns	(856,898)	181,116
Deferred revenue	—	191,795
Deferred collaboration income	1,956,522	—
Net cash provided by (used in) operating activities	<u>2,861,713</u>	<u>(12,652,384)</u>
Cash flows for investing activities:		
Purchases of fixed assets	(143,583)	(163,096)
Net cash used in investing activities	<u>(143,583)</u>	<u>(163,096)</u>
Cash flows from financing activities:		
Net proceeds from issuance of stock and warrants, including private offerings and equity plans	18,618	12,910,026
Net cash provided by financing activities	<u>18,618</u>	<u>12,910,026</u>
Net increase in cash and cash equivalents	2,736,748	94,546
Cash and cash equivalents, beginning of year	4,043,681	3,949,135
Cash and cash equivalents, end of year	<u>\$ 6,780,429</u>	<u>\$ 4,043,681</u>
Supplemental disclosure of cash flow information:		
Fixed asset additions included in accounts payable	\$ —	\$ 7,374
Change in fair value of warrant liability from repricing	\$ —	\$ 244,611
Exchange of warrant liability for Series F Preferred Stock	\$ —	\$ 40,772
Common stock issued to settle employee incentive compensation obligations	<u>\$ 294,264</u>	<u>\$ —</u>

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

Notes to Financial Statements

1. Description of Business and Basis of Presentation

NeuroMetrix, Inc., or the Company, is a commercial stage, innovation driven healthcare company combining neurostimulation and digital medicine to address chronic health conditions including chronic pain, sleep disorders, and diabetes. The Company has two primary products. Quell is an over-the-counter wearable therapeutic device for chronic pain. DPNCheck® is a rapid point-of-care test for diabetic neuropathy which is the most common long-term complication of Type 2 diabetes.

In 2018, the Company entered into a collaboration with GlaxoSmithKline ("GSK"). The GSK collaboration set up a framework for the joint development of the next generation of Quell, recently launched in the United States in September 2018, and the assignment of areas of marketing responsibility. The initial term of the GSK collaboration runs through 2020. Through December 31, 2018, GSK has paid the Company \$14.7 million, committed to future performance milestone payments totaling up to \$10.2 million, and agreed to co-fund Quell development costs starting in 2019.

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, 2018, the Company had an accumulated deficit of \$191.0 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, 2018, the Company held cash and cash equivalents of \$6.8 million. The Company believes that these resources, future GSK collaboration milestone payments, and the cash to be generated from future product sales will be sufficient to meet its projected operating requirements through 2019. Accordingly, the Company may need to raise additional funds to support its operating and capital needs in 2020. 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 and the uncertainty of future revenues from new products; (b) changes the Company may make to the business that affect ongoing operating expenses; (c) changes the Company may make in its business strategy; (d) regulatory developments affecting the Company's existing products; (e) changes the Company may make in its research and development spending plans; (f) delays in the anticipated timing of GSK milestones; 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 through achievement of milestones under the GSK collaboration, public or private financing, collaborative arrangements with strategic partners, 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 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.

Notes to Financial Statements

2. Summary of Significant Accounting Policies - (continued)

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 which management believes are subject to minimal credit and market risk.

Concentrations of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents in bank deposit accounts and trade receivables. The Company invests its funds in highly rated institutions and limits its investment in any individual account so that they do not exceed FDIC limits. The Company has not experienced significant losses related to cash and cash equivalents and does not believe it is exposed to any significant credit risks relating to its cash and cash equivalents.

At December 31, 2018 and 2017, two customers accounted for 45% and 66% of accounts receivable, respectively. Two customers accounted 23% of revenues for the year ended December 31, 2018 and one customer accounted for 19% of revenues, for the year ended December 31, 2017.

The Company relies on in-house assembly and four 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 results of operations.

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 Company writes down inventory to its net realizable value for excess or obsolete inventory.

Fair Value

The carrying amounts of the Company's accounts receivable, accounts payable, and accrued expenses approximate their fair value at December 31, 2018 and 2017 due to the short-term nature of these assets and liabilities. The Company's cash equivalents are carried at fair value determined according to the fair value hierarchy described in Note 9.

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.

Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers ("ASU 2014-09"), is a comprehensive revenue recognition standard that superseded nearly all existing revenue recognition guidance. The Company adopted this standard effective January 1, 2018, applying the modified retrospective method. Upon adoption, the Company discontinued revenue deferral under the sell-through model and commenced recording revenue upon delivery to distributors, net of estimated returns. Generally, the new standard results in earlier recognition of revenues.

Notes to Financial Statements

2. Summary of Significant Accounting Policies - (continued)

Upon adoption of ASU 2014-09, the Company recorded a decrease in accumulated deficit of \$297,858 as detailed in the following table:

	As reported December 31, 2017	ASU 2014-09 Impact	After adoption January 1, 2018
Accounts receivable, net	\$ 1,049,329	\$ 1,353,499	\$ 2,402,828
Prepaid expenses and other current assets	\$ 1,867,803	\$ (583,491)	\$ 1,284,312
Total current assets	\$ 9,103,374	\$ 770,008	\$ 9,873,382
Accrued product returns	\$ 666,375	\$ 1,292,181	\$ 1,958,556
Deferred revenue	\$ 820,031	\$ (820,031)	\$ —
Total current liabilities	\$ 4,581,835	\$ 472,150	\$ 5,053,985
Accumulated deficit	\$ (191,338,054)	\$ 297,858	\$ (191,040,196)
Total stockholders' equity	\$ 5,017,389	\$ 297,858	\$ 5,315,247

The following table summarizes the effects of adopting ASU 2014-09 on the Company's statement of operations for the year ended December 31, 2018:

	As reported	Adjustments	Amounts under prior GAAP
Revenues	\$ 16,090,138	\$ 558,161	\$ 16,648,299
Cost of revenues	\$ 8,707,082	\$ 419,709	\$ 9,126,791
Gross profit	\$ 7,383,056	\$ 138,452	\$ 7,521,508
Net income applicable to common stockholders	\$ 23,605	\$ 138,452	\$ 162,057
Net income per common share applicable to common stockholders,			
Basic	\$ 0.003	\$ 0.020	\$ 0.023
Diluted	\$ 0.002	\$ 0.010	\$ 0.012

The following table summarizes the effects of adopting ASU 2014-09 on the Company's balance sheet as of December 31, 2018:

	As reported	Adjustments	Amounts under prior GAAP
Accounts receivable, net	\$ 1,082,957	\$ (277,637)	\$ 805,320
Prepaid expenses and other current assets	\$ 905,767	\$ 163,782	\$ 1,069,549
Total current assets	\$ 11,631,017	\$ (113,855)	\$ 11,517,162
Accrued product returns	\$ 1,101,658	\$ (551,000)	\$ 550,658
Deferred revenue	\$ —	\$ 596,551	\$ 596,551
Total current liabilities	\$ 6,015,437	\$ 45,551	\$ 6,060,988
Accumulated deficit	\$ (191,016,591)	\$ (159,406)	\$ (191,175,997)
Total stockholders' equity	\$ 6,097,811	\$ (159,406)	\$ 5,938,405

Notes to Financial Statements

2. Summary of Significant Accounting Policies - (continued)

Adoption of the standard had no impact on total net cash provided by or used in operating, investing, or financing activities within the statements of cash flows.

Accounts Receivable

Accounts receivable are recorded 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 in its existing accounts receivable. The Company reviews the allowance for doubtful accounts and determines the allowance based on an analysis of customer past payment history, product usage activity, and recent communications with 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 the Company feels it is probable the receivable will not be recovered. 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, 2018 and 2017.

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.

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.

Notes to Financial Statements

2. Summary of Significant Accounting Policies - (continued)***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. The company recognized \$12,255,704 of collaboration income in 2018 and recorded \$1,956,522 of deferred collaboration income liability as of December 31, 2018.

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 of \$129,837 and \$127,361 at December 31, 2018 and 2017, respectively, are included in accrued expenses 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 (See Note 3 — Stock-Based Compensation).

Notes to Financial Statements

2. Summary of Significant Accounting Policies - (continued)

Net Income (Loss) per Common Share

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

	Years Ended December 31,	
	2018	2017
Net income (loss) applicable to common stockholders	\$ 23,605	\$ (19,734,033)
Weighted average number of common shares outstanding, basic	7,104,574	1,701,481
Dilutive convertible preferred stock	6,780,995	—
Weighted average number of common shares outstanding, dilutive	13,885,569	1,701,481
Net income (loss) per common share applicable to common stockholders, basic	\$ 0.003	\$ (11.598)
Net income (loss) per common share applicable to common stockholders, diluted	\$ 0.002	\$ (11.598)

The 2017 earnings per share amounts have been reformatted to conform to current year presentation.

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

	Years Ended December 31,	
	2018	2017
Options	441,990	99,344
Warrants	459,375	2,742,266
Convertible preferred stock	—	5,961,679
Total	901,365	8,803,289

Advertising and Promotional Costs

Advertising and promotional costs are expensed as incurred. Advertising and promotion expense were \$5,766,982 and \$6,851,082, in 2018 and 2017, respectively.

Accumulated Other Comprehensive Items

For 2018 and 2017, the Company had no components of other comprehensive income or loss other than net income (loss).

Segments

The Company operates in one segment for the sale of medical equipment and consumables. Substantially all of the Company's assets, revenues, and expenses for 2018 and 2017 were located at or derived from operations in the United States. Revenues from sales outside the United States accounted for approximately 12% and 7% of total revenues in 2018 and 2017, respectively.

Risks and Uncertainties

The Company is subject to risks common to companies in the medical device industry, including, but not limited to, 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 and other governmental agencies.

Notes to Financial Statements

2. Summary of Significant Accounting Policies - (continued)***Recently Issued or Adopted Accounting Pronouncements***

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, *Leases (Topic 842)* (“ASU 2016-02”). ASU 2016-02 requires that lessees recognize virtually all of their leases on the balance sheet, by recording a right-of-use asset and lease liability. The provisions of this guidance are effective for annual periods beginning after December 31, 2018, and for interim periods therein. The Company expects to adopt ASU 2016-02, using the modified retrospective method, upon its effective date of January 1, 2019. The Company anticipates the impact of adoption will be an increase to long-term assets and total liabilities of approximately \$1.9 million as of January 1, 2019.

3. Stock-Based Compensation

The Company's 2004 Stock Option and Incentive Plan was amended and restated most recently in 2018. At the Annual Meeting of Stockholders held on May 1, 2018, the stockholders of the Company approved the Company's Tenth Amended and Restated 2004 Stock Option and Incentive Plan (the “2004 Stock Plan”), which, among other things, increased the number of shares of the Company's common stock authorized for issuance thereunder by 400,000 shares. The 2004 Stock Plan, among other things, provides for granting of incentive and nonqualified stock option and stock bonus awards to officers, employees and outside consultants. Outstanding options under the 2004 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, as applicable, of the Company. As of December 31, 2018, 1,128,946 shares of common stock were authorized for issuance under the 2004 Stock Plan, of which 244,800 shares had been issued, 494,101 shares were subject to outstanding options at a weighted average exercise price of \$4.08 per share and 390,045 shares were available for future grant.

The Company's 2009 Non-Qualified Inducement Stock Plan (the “2009 Inducement Plan”) is intended to encourage and enable employees, including prospective employees, of the Company upon whose judgment, initiative, and efforts the Company largely depends for the successful conduct of its business to acquire a proprietary interest in the Company. The 2009 Inducement Plan, among other things, provides for the granting of awards, including non-qualified stock options, restricted stock, and unrestricted stock. As of December 31, 2018, 12,500 shares of common stock were authorized for issuance and were available for future grant under the 2009 Inducement Plan.

The exercise price of stock options awarded under the 2004 Stock Plan and the 2009 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 at the date of grant and for a term not to exceed five years.

The Company's 2004 Employee Stock Purchase Plan (the “2004 ESPP”) provides the Company's employees an opportunity to acquire a proprietary interest in the Company. Company employees who have been employed by the Company for at least 60 days and whose customary employment is for more than 20 hours per week and for more than five months in any calendar year were eligible to participate and any employee who owns 5% or more of the voting power or value of the Company's stock were not eligible to participate. The 2004 ESPP authorized the issuance of up to a total of 326 shares of the Company's common stock to participating employees.

The Company's 2010 Employee Stock Purchase Plan was amended and restated most recently in 2018. At the Annual Meeting of Stockholders held on May 1, 2018, the stockholders of the Company approved the Company's Fourth Amended and Restated 2010 Employee Stock Purchase Plan (the “2010 ESPP”), which, among other things, increased the number of shares of the Company's common stock authorized for issuance thereunder by 150,000 shares. The 2010 ESPP initially authorized the issuance of up to a total of 217 shares, of the Company's common stock to participating employees plus an annual increase on the first day of each of the Company's fiscal years beginning in 2019, equal to the lesser of (i) 25,000 shares, (ii) 1 percent of the shares of common stock outstanding on the last day of the immediately preceding fiscal year, or (iii) such lesser number of shares as is determined by the Board. All of the Company's full-time employees and certain part-time employees are eligible to participate in the 2010 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 2010 ESPP, would own shares representing 5% or more of the voting power of the Company's common stock, are ineligible to participate.

Notes to Financial Statements

3. Stock-Based Compensation - (continued)

Under the 2010 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 2010 ESPP is regarded as a compensatory plan. For the years ended December 31, 2018 and 2017 the Company issued 22,804 and 11,583 shares of its common stock, respectively, under the 2010 ESPP. As of December 31, 2018, there were 127,775 remaining shares to be issued under the 2010 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 2010 ESPP. The following assumptions are used in determining fair value: The risk-free interest rate assumption is based on the United States Treasury's constant maturity rate for a six month term (corresponding to the expected option term) on the date the option was granted. The expected dividend yield is zero because the Company does not currently pay dividends nor expects to do so during the expected option term. An expected term of six months is used based on the duration of each plan offering period. The volatility assumption is based on a consideration of stock price volatility over the most recent period of time corresponding to the expected term and is also based on expected future stock price volatility.

The weighted average grant-date fair value of stock options used in the calculation of stock-based compensation expense in the accompanying statement of operations for the years ended December 31, 2018 and 2017 is calculated using the following assumptions:

	Years Ended December 31,	
	2018	2017
Risk-free interest rate	2.2- 3.0%	1.8- 2.1%
Expected dividend yield	—	—
Expected option term	3 - 5 years	5 years
Volatility	70.0%	70.0%

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.

A summary of option activity for the year ended December 31, 2018 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2017	80,537	\$ 19.32		
Granted	418,950	1.71		
Exercised	—	—		
Forfeited	(5,317)	18.77		
Expired	(69)	2,254.91		
Outstanding at December 31, 2018	494,101	\$ 4.08	3.91	\$ —
Vested or expected to vest at December 31, 2018	494,101	\$ 4.08	3.91	\$ —
Exercisable at December 31, 2018	396,676	\$ 3.94	2.68	\$ —

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, 2018, 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, 2018.

Notes to Financial Statements

3. Stock-Based Compensation - (continued)

The weighted average per share grant-date fair values of options granted during 2018 and 2017 was \$1.71 and \$2.37, respectively.

The aggregate intrinsic value of options issued or exercised during 2018 and 2017 was \$0.

Total unrecognized stock-based compensation costs related to non-vested stock options was \$244,422, which related to 494,101 shares with a per share weighted fair value of \$4.08 as of December 31, 2018. This unrecognized cost is expected to be recognized over a weighted average period of approximately 2.0 years.

Cash received from option exercises and purchases under the 2004 ESPP and the 2010 ESPP for 2018 and 2017, was \$18,618 and \$20,768, respectively. The Company issues new shares upon option exercises, purchases under the Company's ESPPs, and vesting of restricted stock.

The Company recorded stock-based compensation expense of \$446,077 and \$209,691 for 2018 and 2017, respectively.

4. Inventories

Inventories consist of the following:

	December 31,	
	2018	2017
Purchased components	\$ 1,767,674	\$ 505,293
Finished goods	1,094,190	1,637,268
	<u>\$ 2,861,864</u>	<u>\$ 2,142,561</u>

5. Fixed Assets

Fixed assets consist of the following:

	Estimated Useful Life (Years)	December 31,	
		2018	2017
Computer and laboratory equipment	3	\$ 857,889	\$ 881,969
Furniture and equipment	3	241,413	227,845
Production equipment	7	327,000	346,469
Leasehold improvements	*	141,485	117,994
		1,567,787	1,574,277
Less – accumulated depreciation		(1,160,448)	(1,133,435)
		<u>\$ 407,339</u>	<u>\$ 440,842</u>

* Lesser of life of lease or estimated useful life.

Depreciation expense was \$169,712 and \$262,334 for 2018 and 2017, respectively.

Notes to Financial Statements

6. Accrued Expenses and Compensation

Accrued expenses and compensation consist of the following for the years ended December 31, 2018 and 2017:

	December 31,	
	2018	2017
Technology fees	\$ 450,000	\$ 450,000
Professional services	391,000	603,000
Compensation	213,756	786,184
Advertising	171,000	160,800
Warranty	129,837	127,361
Other	303,580	234,779
	<u>\$ 1,659,173</u>	<u>\$ 2,362,124</u>

7. Income Taxes

Current income tax expense (benefit) attributable to continuing operations was zero for the years ended December 31, 2018 and 2017.

The Company's effective income tax rate differs from the statutory federal income tax rate as follows for the years ended December 31, 2018 and 2017.

	Years Ended December 31,	
	2018	2017
Federal tax provision (benefit) rate	(21.0)%	(34.0)%
State tax provision, net of federal provision	(19.6)	(5.9)
Permanent items	(315.0)	(0.1)
Federal research and development credits	659.2	(0.7)
Change in statutory tax rate	—	150.3
Valuation allowance	(303.6)	(109.6)
Effective income tax rate	<u>—</u>	<u>—</u>

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

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	\$ 31,239,750	\$ 31,902,006
Research and development credit carryforwards	2,599,358	2,432,058
Accrued expenses	965,191	748,334
Stock-based compensation	227,843	229,676
Other	9,158	19,240
Total gross deferred tax assets	35,041,300	35,331,314
Valuation allowance	(35,041,300)	(35,331,314)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

At December 31, 2018, the Company has federal and state net operating loss carryforwards ("NOL") of \$143.0 million and \$48.4 million, respectively, as well as federal and state tax credits of \$1.7 million and \$1.1 million, respectively, which may be available to reduce future taxable income and related taxes. This amount includes tax benefits of \$2.5 million and \$75,482 attributable to NOL and tax credit carryforwards, respectively, that result from the exercise of employee stock options. The tax benefit of these items will be recorded as a credit to additional paid-in capital upon realization of the deferred tax asset or

Notes to Financial Statements

7. Income Taxes - (continued)

reduction in income taxes payable. The federal NOLs, the state NOLs, and the federal and state research and development credits each begin to expire in 2019.

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 \$35.0 million and \$35.3 million has been established at December 31, 2018 and 2017, respectively. In December 2017, the Tax Cuts and Jobs Act of 2017 (the "Tax Act") was enacted and included changes which reduced the federal corporate tax rate to 21% effective January 1, 2018. Deferred income tax assets and liabilities are measured using enacted tax laws and rates applicable to the periods in which differences are expected to reverse. Accordingly, deferred tax assets and liabilities have been remeasured as of December 31, 2017 and the effect of the remeasurement has been reflected in the provision for income taxes for the year ended December 31, 2017. 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. The Company has not recorded any amounts for unrecognized tax benefits as of December 31, 2018 or 2017. 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, 2015 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*

In June 2018, the Company extended the lease on its Woburn, Massachusetts manufacturing facilities (the "Woburn Lease") through September 2025. The Woburn Lease has a monthly base rent of \$13,846 and a 5-year extension option. In September 2014, the Company entered into a 7-year operating lease agreement with one 5-year extension option for its corporate office and product development activities in Waltham, Massachusetts (the "Waltham Lease"). The term of the Waltham Lease commenced on February 20, 2015 and includes fixed payment obligations that escalate over the initial lease term. Average monthly base rent under the 7-year lease is approximately \$41,074.

Notes to Financial Statements

8. Commitments and Contingencies - (continued)

Future minimum lease payments under non-cancellable operating leases as of December 31, 2018 are as follows:

2019	\$	629,222
2020		641,193
2021		653,164
2022		247,347
2023		165,785
2024		165,785
2025		117,431
Total minimum lease payments	\$	<u>2,619,927</u>

Total recorded rent expense was \$627,732 and \$670,860, for 2018 and 2017, respectively. The Company records rent expense on its facility leases on a straight-line basis over the lease term.

Other Commitments

At December 31, 2018, other commitments, comprised of purchase orders, totaled approximately \$4,988,383.

9. Fair Value Measurements

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

	December 31, 2018	Fair Value Measurements at December 31, 2018 Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	\$ 4,284,928	\$ 4,284,928	\$ —	\$ —
Total	<u>\$ 4,284,928</u>	<u>\$ 4,284,928</u>	<u>\$ —</u>	<u>\$ —</u>

	December 31, 2017	Fair Value Measurements at December 31, 2017 Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	\$ 1,744,965	\$ 1,744,965	\$ —	\$ —
Total	<u>\$ 1,744,965</u>	<u>\$ 1,744,965</u>	<u>\$ —</u>	<u>\$ —</u>

Notes to Financial Statements

9. Fair Value Measurements - (continued)

The following table provides a summary of changes in the fair value of the Company's Level 3 financial liabilities between December 31, 2016 and December 31, 2017.

	Total
Balance at December 31, 2016	\$ 4,641
Change in fair value of warrant liability from repricing	244,611
Change in fair value of warrant liability	(208,480)
Repurchase and retirement of warrants	(40,772)
Balance at December 31, 2017	<u>\$ —</u>

10. Retirement Plan

The Company has established 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 2018 and 2017 the Company made no contributions to the plan.

11. Credit Facility

The Company is party to a Loan and Security Agreement, or the Credit Facility, with a bank. As of December 31, 2018, the Credit Facility permitted the Company to borrow up to \$2.5 million on a revolving basis. The Credit Facility was subsequently amended, most recently on January 14, 2019 and extended until April 15, 2019. Amounts borrowed under the Credit Facility will bear interest equal to the prime rate plus 0.5%. Any borrowings under the Credit Facility will be collateralized by the Company's cash, accounts receivable, inventory, and equipment. The Credit Facility also includes traditional lending and reporting covenants. These include certain financial covenants applicable to liquidity that are to be maintained by the Company. As of December 31, 2018, the Company was in compliance with these covenants and had not borrowed any funds under the Credit Facility. However, \$0.2 million of the amount under the Credit Facility is restricted to support letters of credit issued in favor of the landlords of the Company's facilities. Consequently, the amount available for borrowing under the Credit Facility as of December 31, 2018 was approximately \$2.3 million.

12. Stockholders' Equity

Preferred stock and convertible preferred stock consist of the following:

	December 31,	
	2018	2017
Preferred stock, \$0.001 par value; 5,000,000 shares authorized at December 31, 2018 and 2017; no shares issued and outstanding at December 31, 2018 and 2017	\$ —	\$ —
Series B convertible preferred stock, \$0.001 par value, 147,000 shares designated at December 31, 2018 and 2017, and 200 and 500 shares issued and outstanding at December 31, 2018 and 2017, respectively	1	1
Series D convertible preferred stock, \$0.001 par value, 21,300 shares designated at December 31, 2018 and 2017, 14,052.93 shares issued and outstanding at December 31, 2018 and 2017	14	14
Series E convertible preferred stock, \$0.001 par value, 7,000 designated at December 31, 2018 and 2017, and 3,260.70 and 7,000 shares issued and outstanding at December 31, 2018 and 2017, respectively	3	7
Series F convertible preferred stock, \$0.001 par value, 10,621 shares designated at December 31, 2018 and 2017, and zero and 7,927.05 shares issued and outstanding at December 31, 2018 and 2017, respectively	—	8

Notes to Financial Statements

12. Stockholder's Equity - (continued)*Private and Public Offerings of Common Stock and Warrants***2017 activity**

In 2017, the Company entered into agreements with respect to a private equity offering (the "Q3 2017 Offering") with an institutional investor and its affiliates (collectively the "Investor"). In the Q3 2017 Offering, the Company issued 7,000 shares of Series F convertible preferred stock (the "Series F Preferred Stock") at a price of \$1,000 per share. The Q3 2017 Offering also reset the conversion price of 14,052.93 shares of Series D convertible preferred stock and 7,000 shares of Series E convertible preferred stock that were held by the Investor to \$2.63 per share. The Q3 2017 Offering resulted in gross proceeds of \$7.0 million, and after deducting fees and expenses, net proceeds were \$6.6 million. In the third quarter of 2017, the Company also entered into an exchange agreement pursuant to which it issued the Investor 3,621 shares of Series F Preferred Stock in exchange for the repurchase and retirement of 4,184,483 warrants to purchase common stock valued by an independent party at \$3,622,219.

Also in 2017, the Company completed a private equity offering (the "Q1 2017 Offering") with the Investor and issued (i) 7,000 shares of Series E convertible preferred stock (the "Series E Preferred Stock") at a price of \$1,000 per share, and (ii) warrants to purchase up to 1,250,000 shares of common stock, par value \$0.0001 per share (the "Common Stock"), at an exercise price of \$5.60 per share. As a part of this offering, the Company reset (i) the conversion price of 19,458.90 shares of Series D convertible preferred stock that were held by the Investor to \$5.60 per share, and (ii) the exercise price of warrants to purchase up to 2,934,484 shares of Common Stock that were held by the Investor to \$5.60 per share. The Q1 2017 Offering resulted in gross proceeds of 7.0 million, and after deducting fees and expenses, net proceeds were \$6.3 million.

Each share of Series D Preferred Stock, Series E Preferred Stock, and Series F Preferred Stock (collectively the "Preferred Stock") have a stated value of \$1,000 and is convertible at the option of the holder into the number of shares of Common Stock determined by dividing the stated value by the conversion price of \$2.63, which is subject to adjustment as provided in the Certificate of Designation for the Preferred Stock. The 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 for the Preferred Stock and as required by law.

The Q3 2017 Offering and the Q1 2017 Offering were accounted for as extinguishments of the Investor's equity holdings in recognition of the revisions of certain preexisting equity instruments and the significant transfer of value in excess of the funding received by the Company. Under the extinguishment model, a deemed dividend was recognized within additional paid in capital which represented the fair value of issued Preferred Stock plus the incremental fair value of repricing the Preferred Stock held by the Investor, less the fair value of the consideration transferred, less the carrying value of the outstanding Preferred Stock, and warrants to purchase Common Stock. The amount of the deemed dividend totaled \$2.8 million and \$4.0 million for the Q3 2017 Offering and the Q1 2017 Offering, respectively.

The Company determined that equity classification was appropriate for the warrants issued in the Q1 2017 Offering, following guidance in the Derivatives and Hedging topic of the Codification. In making this equity classification determination, the Company noted the warrants may only be settled in shares of common stock and had no requirements to be settled in registered shares when exercised. The fair value of the five year warrants was estimated to be \$3.5 million on the offering date using a Black-Scholes model with the following assumptions: stock price of \$4.96, exercise price of \$5.60, expected volatility of 70.2%, risk free interest rate of 2.04%, expected term of 5 years, and no dividends.

During 2017, 3,149.72 shares of the Series D Preferred Stock were converted into a total of 859,077 shares of common stock, and 2,693.95 shares of the Series F Preferred Stock were converted into a total of 974,163 shares of common stock.

2018 activity

In 2018, 300.00 shares of the Series B Preferred Stock were converted into a total of 928 shares of Common Stock. As of December 31, 2018, 200.00 shares of Series B Preferred Stock remained outstanding. In 2018, 3,739.3 shares of the Series E Preferred Stock were converted into a total of 1,421,787 shares of Common Stock. As of December 31, 2018, 3,260.70 shares of Series E Preferred Stock remained outstanding. In 2018, 7,927.05 shares of the Series F Preferred Stock were converted into a total of 3,014,087 shares of Common Stock. As of December 31, 2018, zero shares of Series F Preferred Stock remained outstanding.

Notes to Financial Statements

12. Stockholder's Equity - (continued)*Other equity activity*

In 2018, the Company issued shares of fully vested common stock in partial settlement of management incentive compensation. The 2018 issuance totaled 214,791 shares with a value of \$294,264 reflecting the \$1.37 closing price of the Company's common stock as reported on the Nasdaq Capital Market on April 12, 2018.

In 2017, the Company issued 24,380 shares of fully vested common stock in exchange for 201,327 equity-classified warrants. The fair value of the warrants was estimated to be \$45,102 on the exchange date using date using a Black-Scholes model with the following assumptions: stock price of \$1.85, exercise price of \$15.19, expected volatility of 70.0%, risk free interest rate of 2.0%, expected term of 3.8 years, and no dividends.

As of December 31, 2018, the Company had 100,000,000 shares of common stock authorized and 7,380,463 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, 2018, the Company has reserved authorized shares of common stock for future issuance as follows:

Warrants	459,375
Outstanding stock options	494,101
Possible future issuance under inducement plan	12,500
Possible future issuance under stock option plans	390,045
Possible future issuance under employee stock purchase plan	127,775
Total	1,483,796

13. Management Retention and Incentive Plan

The Company has adopted the Management Retention and Incentive Plan (the "Plan"), under which 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. The Plan is structured to work in conjunction with, and not replace, the Company's other incentive programs and is designed to provide market-based incentives which will be reduced over time by any future equity grants to participants.

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, 2018					
Allowance for Doubtful Accounts	\$ 25,000	3,447	—	(3,447)	\$ 25,000
Deferred Tax Asset Valuation Allowance	35,331,314	269,241	—	(559,255) ⁽¹⁾	35,041,300
December 31, 2017					
Allowance for Doubtful Accounts	\$ 25,000	8,374	—	(8,374)	\$ 25,000
Deferred Tax Asset Valuation Allowance	49,274,154	3,175,637	—	(17,118,477) ⁽¹⁾	35,331,314

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

**AMENDMENT NO. 11 TO
SHAREHOLDER RIGHTS AGREEMENT**

This Amendment No. 11 to Shareholder Rights Agreement (the “**Amendment**”), dated as of January 21, 2019, 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 thirteenth 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. 11 to Shareholder Rights Agreement as of the date first stated above.

NEUROMETRIX, INC.

By: /S/ Thomas T. Higgins

Name: Thomas T. Higgins

Title: Senior Vice President, Chief
Financial Officer, Treasurer and
Principal Accounting Officer

AMERICAN STOCK TRANSFER & TRUST COMPANY, LLC

By: /S/ Michael A. Nespoli

Name: Michael A. Nespoli

Title: Executive Director

**AMENDMENT NO. 1
TO
DEVELOPMENT AND SERVICES AGREEMENT**

THIS AMENDMENT NO. 1 TO DEVELOPMENT AND SERVICES AGREEMENT (this “**Amendment No. 1**”) is made and entered into as of December 3, 2018 (the “**Amendment No. 1 Effective Date**”), by and between NeuroMetrix, Inc., a Delaware corporation (“**NeuroMetrix**”) and GSK Consumer Healthcare S.A. (formally known as Novartis Consumer Health S.A.), a *société anonyme* organized under the laws of Switzerland (“**GSK**”). NeuroMetrix and GSK are sometimes referred to herein individually as “**Party**” and collectively as “**Parties.**”

RECITALS

WHEREAS, NeuroMetrix and GSK are Parties to that certain Development and Services Agreement, effective as of January 12, 2018 (the “**Original Agreement**” and together with this Amendment No. 1, the “**Agreement**”) pursuant to which, among other things, GSK agreed to pay to NeuroMetrix certain milestone payments within [***] of the achievement of such milestone events;

WHEREAS, the Parties desire to amend the Original Agreement, including with respect to certain milestone events and corresponding milestone payments, and certain other provisions as more fully set forth herein; and

WHEREAS, pursuant to Section 12.11 of the Original Agreement, the Original Agreement may be amended from time to time by an instrument in writing signed on behalf of each of the Parties.

NOW, THEREFORE, in consideration of the foregoing, and the mutual promises contained herein, the receipt and sufficiency of which are hereby acknowledged, intending to be legally bound, the Parties hereto hereby agree as follows:

1. The following new definitions are hereby added to Article 1 of the Original Agreement, in appropriate alphabetical and numerical order, and the Section numbers of Article 1 of the Original Agreement are hereby updated to reflect the addition of such defined terms:

“**CE Marking**” means the certification and marking required by the EU Medical Devices Directive for marketing and sales of medical devices in the European Union.

Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

“**Design History File**” means a compilation of records which describes the design history of a finished device.

“**Technical File**” means the documentation which is used to show compliance of a medical device with the requirements of a specific Regulatory Authority.

2. Section 3.9.2 of the Original Agreement is hereby amended and restated as follows:

“GSK may pay to NeuroMetrix a milestone payment (including as a pre-payment before such payment is due or pursuant to the cure provisions set forth in Section 11.2.6) (a) under Sections 6.1.1(viii) or 6.1.1(ix) with respect to [***] or (b) under Section 6.1.1(x) with respect to [***] in which case GSK’s diligence obligations pursuant to Section 3.9.1 shall be deemed permanently fulfilled with respect to [***] as applicable.”

3. Section 6.1.1 of the Original Agreement is hereby amended and restated as follows:

“**Development and Regulatory Milestones.** In partial consideration of the rights granted by NeuroMetrix to GSK hereunder and subject to the terms and conditions of this Agreement, including the last sentence of this Section 6.1.1 and any right of GSK to offset amounts due from NeuroMetrix to GSK pursuant to Article 10, GSK shall pay to NeuroMetrix a milestone payment within [***] days after the achievement of each of the following milestones, calculated as follows:

- (i) receipt by GSK (a) of a [***], and (b) written confirmation by [***] that it has validated its ability to [***];
- (ii) delivery to GSK of [***] fully verified Prototypes meeting the [***] and incorporating [***];
- (iii) execution of this Amendment No. 1 by each of the Parties hereto, two million Dollars (\$2,000,000) (for purposes of this Section 6.1.1(iii) only, GSK shall pay to NeuroMetrix the milestone payment within [***] after the Amendment No. 1 Effective Date);
- (iv) provided that NeuroMetrix uses good faith efforts (as determined by GSK in its sole discretion) to assist GSK in finalizing the [***], the earlier to occur of (a) the submission by GSK of the [***], or (b) [***];
- (v) receipt of the [***];
- (vi) the earlier to occur of (a) completion (as determined by GSK in its sole discretion) of the [***] (as agreed to in the Development Plan for Calendar Year [***] Development activities (as the same may be amended from time to time in accordance with the provisions of this Agreement)), or (b) submission by GSK of [***];

Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

- (vii) Completion and validation of the manufacturing transfer (as determined by GSK in its sole discretion), [***];
- (viii) First Commercial Sale by GSK, its Affiliate or licensee, of a Device meeting the [***];
- (ix) First Commercial Sale by GSK, its Affiliate or licensee, of a Device meeting the [***]; and
- (x) First Commercial Sale by GSK, its Affiliate or licensee, of a Device meeting the [***].

Each milestone payment in this Section 6.1.1 shall be payable only upon the first achievement of such milestone and no amounts shall be due for subsequent or repeated achievements of such milestone, whether for the same or a different Device. For the avoidance of doubt, no milestone payment shall be paid by GSK for the First Commercial Sale by GSK, its Affiliates or its licensee of a Device meeting the [***]. The maximum aggregate amount payable by GSK pursuant to this Section 6.1.1 is [***].”

4. The Parties acknowledge and agree that as of the Amendment No. 1 Effective Date, the milestones set forth in Sections 6.1.1(i) and 6.1.1(ii) of the Agreement have been achieved, and GSK has paid the corresponding milestone amounts to NeuroMetrix in full satisfaction of GSK’s obligations set forth in such Sections 6.1.1(i) and 6.1.1(ii).

5. Section 11.4.1(iii) of the Original Agreement is hereby amended and restated as follows:

(iii) In the event of a termination of this Agreement by GSK pursuant to Section 11.2.2, (a) the rights and licenses granted by GSK to NeuroMetrix under Section 2.1.1 through Section 2.1.3 shall become irrevocable, (b) the rights and licenses granted by NeuroMetrix to GSK under Section 2.2 shall become irrevocable, (c) Section 3.9.1 (including GSK’s obligations thereunder) shall survive (provided that clause (a) of the proviso of Section 3.9.1 shall be of no effect), (d) GSK’s obligation to make the milestone payments set forth in Sections 6.1.1(i), 6.1.1(ii), 6.1.1(iii), 6.1.1(iv), 6.1.1(v), 6.1.1(vi) and 6.1.1(vii) shall immediately terminate; and (e) GSK’s obligation to make the milestone payments set forth in Sections 6.1.1(viii), 6.1.1 (ix) and 6.1.1(x) shall survive such termination; provided that (1) the applicable milestone amounts payable by GSK under Sections 6.1.1(viii), 6.1.1(ix) or 6.1.1(x), as applicable, shall be discounted by [***]), and (2) after reducing the amount payable pursuant to the foregoing clause (1), GSK may deduct from its milestone payment the [***].”

6. Section 11.4.2 of the Original Agreement is hereby amended and restated as follows:

Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

“Termination for Failure to Agree Upon a Development Plan. In the event of a termination of this Agreement by either Party pursuant to Section 11.2.5, (a) the rights and licenses granted by GSK to NeuroMetrix under Section 2.1.1 through Section 2.1.3 shall become irrevocable, (b) the rights and licenses granted by NeuroMetrix to GSK under Section 2.2 shall become irrevocable, (c) Section 3.9.1 (including GSK’s obligations thereunder) shall survive (provided that clause (a) of the proviso of Section 3.9.1 shall be of no effect), (d) GSK’s obligation to make the milestone payments set forth in Sections 6.1.1(i), 6.1.1(ii), 6.1.1(iii), 6.1.1(iv), 6.1.1(v), 6.1.1(vi) and 6.1.1(vii) shall immediately terminate; and (e) GSK’s obligation to make the milestone payments set forth in Sections 6.1.1(viii), 6.1.1(ix) and 6.1.1(x) shall survive such termination.”

7. Section 11.4.3 of the Original Agreement is hereby amended and restated as follows:

“Termination by NeuroMetrix for Material Breach. In the event of a termination of this Agreement by NeuroMetrix pursuant to Section 11.2.1, (a) the rights and licenses granted by GSK to NeuroMetrix under Section 2.1.1 through Section 2.1.3 shall become irrevocable, (b) the rights and licenses granted by NeuroMetrix to GSK under Section 2.2 shall become irrevocable, (c) Section 3.9.1 (including GSK’s obligations thereunder) shall survive (provided that clause (a) of the proviso of Section 3.9.1 shall be of no effect), (d) GSK’s obligation to make the milestone payments set forth in Sections 6.1.1(i), 6.1.1(ii), 6.1.1(iii), 6.1.1(iv), 6.1.1(v), 6.1.1(vi) and 6.1.1(vii) shall immediately terminate; (e) GSK’s obligation to make the milestone payments set forth in Sections 6.1.1(viii), 6.1.1(ix) and 6.1.1(x) shall survive such termination; and (f) the Restricted Period with respect to NeuroMetrix’s obligations under Section 3.10.1 shall be deemed to be terminated and the restrictions on NeuroMetrix under Section 3.10.1 shall be of no further effect.”

8. Section 11.4.5 of the Original Agreement is hereby amended and restated as follows:

“Expiration of the Term. Upon the later of (i) expiration of the Initial Term as provided in Section 11.1 or (ii) the conclusion (without early termination) of each Renewal Term, as applicable, (a) the rights and licenses granted by GSK to NeuroMetrix under Section 2.1.1 through Section 2.1.3 shall become irrevocable, (b) the rights and licenses granted by NeuroMetrix to GSK under Section 2.2 shall become irrevocable, (c) Section 3.9.1 (including GSK’s obligations thereunder) shall survive (provided that clause (a) of the proviso of Section 3.9.1 shall be of no effect), (d) GSK’s obligation to make the milestone payments set forth in Sections 6.1.1(i), 6.1.1(ii), 6.1.1(iii), 6.1.1(iv), 6.1.1(v), 6.1.1(vi) and 6.1.1(vii) shall immediately terminate; and (e) GSK’s obligation to make the milestone payments set forth in Sections 6.1.1(viii), 6.1.1(ix) and 6.1.1(x) shall survive such termination.”

9. **Miscellaneous.**

a. **No Other Modifications; Defined Terms.** This Amendment No. 1 is intended to be a written instrument meeting the requirements of Section 12.11 of the Original

Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Agreement. Except as otherwise provided in this Amendment No. 1, the Original Agreement shall remain in full force and effect, and is ratified and confirmed in all respects. This Amendment No. 1 shall not, by implication or otherwise, limit, impair, constitute a waiver of or otherwise affect any rights or remedies of either Party under the Original Agreement, or alter, modify, amend or in any way affect any of the other terms, obligations or covenants contained therein. Capitalized terms used but not otherwise defined in this Amendment No. 1 shall have the meanings set forth in the Original Agreement.

b. **No Amendment.** This Amendment No. 1 may not be amended or terminated except by an instrument in writing signed on behalf of each of the Parties in accordance with Section 12.11 of the Original Agreement.

c. **Counterparts.** This Amendment No. 1 may be executed in one or more of counterparts (including by facsimile or electronic transmission in .pdf, .tiff or any similar format), each of which shall be considered one and the same agreement and shall become effective when one or more counterparts have been signed by each of the Parties and delivered to the other Party.

d. **Entire Agreement.** Other than the Transaction Agreements (as defined in the Asset Purchase Agreement), the Confidentiality Agreements, and other related agreements, this Amendment No. 1 and the Original Agreement contain the entire agreement between the Parties with respect to the subject matter hereof.

e. **Governing Law.** This Amendment No. 1 shall be governed by, and construed in accordance with, the applicable laws of the State of New York, regardless of the applicable laws that might otherwise govern under applicable principles of conflicts of applicable laws thereof.

[Signatures on following page]

Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

IN WITNESS WHEREOF, the Parties hereto have caused their respective duly authorized representatives to execute this Amendment No. 1 as of the Amendment No. 1 Effective Date.

GSK CONSUMER HEALTHCARE S.A. NEUROMETRIX, INC.

By: By:

— —

Name: Name:

Title: Title:

By:

—

Name:

Title:

Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

[Signature page to Amendment No. 1 to Development and Services Agreement]

TENTH MODIFICATION TO LOAN AND SECURITY AGREEMENT

This Tenth Modification to Loan and Security Agreement (this "Modification") dated January 14, 2019, is entered into by and between **Neurometrix, Inc.**, a Delaware corporation ("Borrower"), and **Comerica Bank** ("Bank").

RECITALS

Bank and Borrower previously entered into a Loan and Security Agreement dated March 5, 2010, as amended by the following:

the First Modification to Loan and Security Agreement dated March 1, 2011,
the Second Modification to Loan and Security Agreement dated February 15, 2012,
the Third Modification to Loan and Security Agreement dated April 19, 2012,
the Fourth Modification to Loan and Security Agreement dated January 28, 2013,
the Fifth Modification to Loan and Security Agreement dated January 31, 2014,
the Sixth Modification to Loan and Security Agreement dated January 23, 2015,
the Seventh Modification to Loan and Security Agreement dated January 14, 2016,
the Eighth Modification to Loan and Security Agreement dated December 29, 2016, and
the Ninth Modification to Loan and Security Agreement dated January 17, 2018 (collectively "**Agreement**").

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as set forth below.

AGREEMENT

1. Incorporation by Reference. The Recitals and the documents referred to therein are incorporated herein by this reference. Except as otherwise noted, the terms not defined herein shall have the meanings set forth in the Agreement.

2. Modification to the Agreement. Subject to the satisfaction of the conditions precedent as set forth in Section 3 hereof, the Agreement is hereby modified as set forth below.

(a) The following defined term, which is set forth in Exhibit A of the Agreement, is given the following amended definition:

'Revolving Maturity Date' means **April 15, 2019**."

3. Legal Effect.

(a) Except as expressly set forth herein, the execution, delivery, and performance of this Modification shall not operate as a waiver of, or as an amendment of, any right, power, or remedy of Bank under the Agreement, as in effect prior to the date hereof. Borrower ratifies and reaffirms the continuing effectiveness of all promissory notes, guaranties, security agreements, environmental agreements, and all other instruments, documents and agreements entered into in connection with the Agreement.

(b) Borrower represents and warrants that the representations and warranties contained in the Agreement are true and correct as of the date of this Modification, and that no Event of Default has occurred and is continuing.

(c) The effectiveness of this Modification and each of the documents, instruments and agreements entered into in connection with this Modification is conditioned upon receipt by Bank of:

- (i) this Modification and any other documents which Bank may require to carry out the terms hereof; and
- (ii) payment of any Bank expenses incurred through the date of this Modification.

4. No Other Changes. Except as specifically provided in this Modification, it does not vary the terms and provisions of any of the Loan Documents. This Modification shall not impair the rights, remedies, and security given in and by the Loan Documents. The terms of this Modification shall control any conflict between its terms and those of the Agreement.

5. Integration. This is an integrated Modification and supersedes all prior negotiations and agreements regarding the subject matter hereof. All amendments hereto must be in writing and signed by the parties.

6. Counterparts. This Modification may be executed in one or more counterparts, each of which shall be deemed an original but all of which taken together shall constitute one and the same Agreement, and shall become effective when one or more counterparts have been signed by each of the parties hereto and delivered to the other party.

[end of Modification; signature page follows]

IN WITNESS WHEREOF, the parties have agreed to this Tenth Modification to Loan and Security Agreement as of the date first set forth above.

BANK:

Comerica Bank

By: 
Bryan W. Kana
Its: Vice President

BORROWER:

NeuroMetrix, Inc., a Delaware corporation

By: 
Printed Name: THOMAS J. HIGGINS
Its: CEO

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 and 333-226245) and on Form S-3 (Nos. 333-150087, 333-162303, 333-189392, 333-197405, 333-199359, 333-208923, 333-209528, 333-211919, 333-215792 and 333-219783) of our report dated January 24, 2019 relating to the financial statements and schedule of NeuroMetrix, Inc, which appears in the Company's Annual Report on Form 10-K for the year ended December 31, 2018. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ Moody, Famiglietti, & Andronico, LLP

Moody, Famiglietti, & Andronico, LLP
Tewksbury, Massachusetts
January 24, 2019

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 24, 2019

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

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

Chairman, President and Chief Executive Officer

CERTIFICATION

I, Thomas T. Higgins, certify that:

1. I have reviewed this 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 24, 2019

/s/ THOMAS T. HIGGINS

Thomas T. Higgins

Senior Vice President, Chief Financial Officer and Treasurer

CERTIFICATION

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

The Annual Report for the year ended December 31, 2018 (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 24, 2019

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

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

Chairman, President and Chief Executive Officer

Date: January 24, 2019

/s/ THOMAS T. HIGGINS

Thomas T. Higgins

Senior Vice President, Chief Financial Officer and Treasurer