NeuroMetrix, Inc.
Form 10-K
January 24, 2019

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

FORM 10-K

(Mark One)

ý 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

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission File Number 001-33351

NEUROMETRIX, INC.
(Exact name of registrant as specified in its charter)

Delaware	04-3308180
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

1000 Winter Street, Waltham, Massachusetts	02451
(Address of Principal Executive Offices)	(Zip Code)

(781) 890-9989
(Registrant's Telephone Number, Including Area Code)

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

Title of each class	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

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

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

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 ý No o

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 ý No o

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. ý

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 x	Emerging growth company o
o	o	o		

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

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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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 expres 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.

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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

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Corporate Information

NeuroMetrix was founded in June 1996 by our President and Chief Executive Officer, Shai N. Gozani, M.D., Ph.D. We 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 and 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.
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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,			
	2018	2017	Change	% Change
	(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,			
	2018	2017	Change	% Change
	(in thousands)			
Cost of revenues	$8,707.1			