

NeuroMetrix, Inc.
Form S-1/A
May 13, 2016

As filed with the Securities and Exchange Commission on May 13, 2016

Registration No. 333-207566

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

**AMENDMENT NO. 1 TO
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

NEUROMETRIX, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

3841
(Primary Standard Industrial
Classification Code Number)

04-3308180
(I.R.S. Employer
Identification No.)

**1000 Winter Street
Waltham, Massachusetts 02451
(781) 890-9989**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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 and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer
(Do not check if a smaller reporting company)

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CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price ⁽¹⁾	Amount of Registration Fee ⁽⁵⁾
Class A Units consisting of:		
(i) Common Stock, par value \$0.0001 ⁽²⁾		
(ii) Warrants to purchase Common Stock ⁽³⁾		
Class B units consisting of:		
(i) Series D Convertible Preferred Stock, par value \$0.001		
(ii) Warrants to purchase Common Stock ⁽³⁾		
Common Stock issuable upon conversion of Series D Convertible Preferred Stock ⁽²⁾⁽⁶⁾		
Placement agent's warrants to purchase Common Stock ⁽³⁾		
Common Stock issuable upon exercise of warrants to purchase Common Stock ⁽²⁾		
Total	\$ 15,000,000	\$ 1,510.50 ⁽⁴⁾

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the U.S. Securities Act of 1933, as amended (the Securities Act).

Pursuant to Rule 416 under the Securities Act, the securities being registered hereunder include such (2) indeterminate number of additional shares of common stock as may be issued after the date hereof as a result of stock splits, stock dividends or similar transactions.

(3) No additional registration fee is payable pursuant to Rule 457(g) under the Securities Act.
(4) \$1,510.50 previously paid.

(5) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price. Pursuant to a shareholder rights agreement, dated as of March 7, 2007, between the Company and American Stock Transfer & Trust Company, as amended, each share of common stock has an attached right to purchase our Series (6) A Junior Cumulative Preferred Stock, which rights are not currently exercisable, on the terms set forth in the rights agreement.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is declared effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

**Subject to Completion, Dated May 13, 2016
PRELIMINARY PROSPECTUS**

**Up to \$15,000,000 of Class A Units consisting of
Common Stock and Warrants and Class B Units
consisting of Series D Convertible Preferred Stock and
Warrants**

**(shares of Common Stock underlying the Series D
Convertible Preferred Stock and Warrants)**

We are offering up to \$15,000,000 of Class A Units (consisting of one share of our common stock and a warrant to purchase shares of our common stock at an exercise price per full share of common stock equal to % of the public offering price of the Class A Units (each, a 2016 warrant)). Each 2016 warrant will be immediately exercisable and will expire five years from the date on which such 2016 warrants become exercisable. The shares of common stock and 2016 warrants that form part of a Class A Unit are immediately separable and will be issued separately in this offering.

We are also offering to those purchasers, if any, whose purchase of Class A Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering, the opportunity, in lieu of purchasing Class A Units, to purchase Class B Units. Each Class B Unit will consist of one share of our Series D convertible preferred stock, with a stated value of \$1,000 per share and convertible into shares of our common stock at the public offering price of the Class A Units, together with the equivalent number of 2016 warrants as would have been issued to such purchaser if they had purchased Class A Units based on the public offering price. The shares of Series D convertible preferred stock do not generally have any voting rights but are convertible into shares of common stock. The shares of Series D convertible preferred stock and 2016 warrants are immediately separable and will be issued separately in this offering. We are also offering the shares of common stock that are issuable from time to time upon conversion of the Series D convertible preferred stock and upon the exercise of the 2016 warrants being offered by this prospectus.

For a more detailed description of the Series D convertible preferred stock, see the section entitled Description of Securities We Are Offering Series D Convertible Preferred Stock beginning on page 59. For a more detailed description of the 2016 warrants, see the section entitled Description of Securities We Are Offering Warrants to Purchase Common Stock beginning on page 60 of this prospectus. For a more detailed description of our common

stock, see the section entitled **Description of Capital Stock – Common Stock** beginning on page 54 of this prospectus.

We refer to the Series D convertible preferred stock issued hereunder, the 2016 warrants and the shares of common stock issued hereunder and issuable upon conversion of the Series D convertible preferred stock and upon exercise of the 2016 warrants, collectively, as the securities.

Our common stock is listed on The NASDAQ Capital Market under the symbol **NURO**. The last reported sale price of our common stock on The NASDAQ Capital Market on May 12, 2016 was \$1.64 per share. We do not intend to list the Series D convertible preferred stock or the 2016 warrants to be sold in this offering on The NASDAQ Capital Market or any other national securities exchange or any other nationally recognized trading system.

Investing in our securities involves a high degree of risk. See Risk Factors beginning on page 13.

	Per Class A Unit	Per Class B Unit	Total
Public offering price	\$	\$	\$
Placement agent's fees ⁽⁴⁾	\$	\$	\$
Proceeds to NeuroMetrix, before expenses	\$	\$	\$

We have agreed to reimburse the placement agent for certain of its expenses and to issue common stock purchase (1) warrants to the placement agent. See **Plan of Distribution** on page 62 of this prospectus for a description of the compensation payable to the placement agent.

We have engaged H.C. Wainwright & Co., LLC (**Wainwright** or the **Placement Agent**) to act as our exclusive placement agent in connection with this offering. Wainwright is not purchasing or selling the securities offered by us, and is not required to sell any specific number or dollar amount of securities, but will use its reasonable best efforts to arrange for the sale of the securities offered. We have agreed to pay Wainwright a cash commission fee equal to % of the aggregate gross proceeds to us from the sale of the securities in the offering, plus additional compensation as set forth under **Plan of Distribution** . Wainwright may engage one or more sub-agents or selected dealers in connection with this offering. We estimate total expenses of this offering, excluding the Placement Agent's fees, will be approximately \$. Because there is no minimum offering amount required as a condition to closing this offering, the actual public offering amount, Placement Agent's fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above. This offering will terminate on , 2016, unless the offering is fully subscribed before that date or we decide to terminate the offering prior to that date. In either event, the offering may be closed without further notice to you.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

Delivery of the shares will take place on or about , 2016.

Sole Book-Running Manager

Rodman & Renshaw
a unit of H.C. Wainwright & Co.

The date of this prospectus is , 2016.

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You should rely only on the information contained or incorporated by reference in this prospectus and any free-writing prospectus prepared by or on behalf of us or to which we have referred you. We have not authorized anyone to provide you with additional or different information. We are offering to sell, and are seeking offers to buy these securities only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our securities. Our business, financial status, results of operations, and prospects may have changed since that date.

No action is being taken in any jurisdiction outside the United States to permit a public offering of our securities or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable to that jurisdiction.

Registered Trademarks and Trademark Applications: NEUROMETRIX , NC-STAT , SENSUS , DPNCheck OptiTherapy and Quell are the subject of either a trademark registration or application for registration in the United States. Other brands, names and trademarks contained in this prospectus are the property of their respective owners. Solely for convenience, the trademarks, service marks and trade names referred to in this prospectus are without the ® and ™ symbols, but such references are not intended to indicate, in any way, that the owner thereof will not assert, to the fullest extent under applicable law, such owner's rights to these trademarks, service marks and trade names. This prospectus contains additional trade names, trademarks and service marks of other companies, which, to our knowledge, are the property of their respective owners.

We obtained industry and market data used throughout and incorporated by reference into this prospectus through our research, surveys and studies conducted by third parties and industry and general publications. We have not independently verified market and industry data from third-party sources.

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PROSPECTUS SUMMARY

This summary highlights selected information contained in greater detail elsewhere in this prospectus or incorporated by reference into this prospectus. This summary may not contain all of the information that you should consider before investing in the securities. You should carefully read the entire prospectus, including Risk Factors beginning on page 13 and the financial statements and related notes and other documents incorporated by reference into this prospectus, before making an investment decision. As used in this prospectus, references to we, our, Company, us and NeuroMetrix refer to NeuroMetrix, Inc. unless the context requires otherwise.

Our Business An Overview

NeuroMetrix is an innovative health-care company that develops wearable medical technology and point-of-care tests that help patients and physicians better manage chronic pain, nerve diseases, and sleep disorders. Our business is fully integrated with in-house capabilities spanning product 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 selected overseas markets, and are cleared by the U.S. Food and Drug Administration, or FDA, and regulators in foreign jurisdictions where appropriate. We have two principal product lines:

Wearable neuro-stimulation therapeutic devices

Point-of-care neuropathy diagnostic tests

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 also have an experienced management team and Board of Directors.

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 in contrast to acute pain which is a normal bodily response to injury or trauma. Chronic pain conditions include painful diabetic neuropathy, or PDN, arthritis, fibromyalgia, sciatica, musculoskeletal 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 is widespread. It affects over 100 million adults in the United States and more than 1.5 billion people worldwide. The global market for pain management drugs and devices alone was valued at \$35 billion in 2012. 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 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 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, we believe that inadequate relief leads 25% to 50% of 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 total they account for over \$4 billion in annual spending in the United States on pain relief products.

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High frequency 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 deep brain stimulation and through implantable spinal cord stimulation, both of which require surgery and have attendant risks. Non-invasive approaches to neuro-stimulation (transcutaneous electrical nerve stimulation, or TENS) have achieved limited efficacy in practice due to device limitations, ineffective dosing and low patient compliance.

Our Strategy

There are large and important unmet medical needs in chronic pain treatment. Prescription pain medications and over-the-counter therapies are often inadequate and can lead to other health issues. We believe that controlled, personalized, neuro-stimulation to suppress pain provides an important complement to pain medications. As a medical device company with unique experience in designing devices to manage and alter peripheral nerve function, we believe we are well positioned to make neuro-stimulation widely available to chronic pain sufferers. We have direct experience with neuro-stimulation through our prescription SENSUS wearable pain management device which has been on the market for the past three years and Quell, our over-the-counter, or OTC, wearable device for pain relief which was launched in the second quarter of 2015 and builds upon the core SENSUS neuro-stimulation technology.

Our primary objective is revenue growth. We expect this to be led by the successful market adoption of Quell. We also expect an important contribution to revenue from DPNCheck, our rapid, accurate diagnostic test for diabetic peripheral neuropathy.

Our key business strategies include:

Driving Commercial Adoption of Key Proprietary Products.

Quell, our OTC wearable device for pain relief, was made commercially available in the United States during the second quarter of 2015. Following commercial launch through the end of the first quarter of 2016, approximately 22,000 Quell devices plus electrodes and accessories were shipped to consumers. Quell revenues for the year ended December 31, 2015 and for the quarter ended March 31, 2016 were approximately \$2.1 million and \$1.2 million, respectively. Quell utilizes OptiTherapy, our proprietary non-invasive neuro-stimulation technology to provide relief from chronic intractable pain, such as nerve pain due to diabetes, fibromyalgia, arthritic pain, and lower back and leg pain. This advanced wearable 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 intractable pain without a doctor's prescription. Users of the device have the option of using their smartphones to control pain therapy and to track sleep and therapy parameters. Quell is distributed in North America via e-commerce, including the Company's website (www.quellrelief.com) and Amazon, via direct response television including QVC, via specialty catalogs such as Hammacher Schlemmer, and via health care professionals such as pain management physician practices and podiatry practices. Recently, we initiated retail distribution in Target stores and expect to make Quell available in select chain drug stores starting in the second quarter of 2016. The retail distribution initiative is supported by television promotion designed to expand product awareness. We believe there are significant opportunities to market Quell outside of the United States, particularly in Western Europe, Japan and China; however, we do not intend to approach those markets until we have established a solid presence in the United States.

DPNCheck, our diagnostic test for peripheral neuropathies, was made commercially available in the fourth quarter of 2011. DPNCheck revenues for the years ended December 31, 2015 and 2014 were approximately \$2.3 million and \$1.8 million, respectively. DPNCheck revenues for the first quarter of 2016 were approximately \$0.5 million. Our US 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

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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. We believe that attractive growth opportunities exist outside the United States, including Japan where we launched DPNCheck with our distribution partner Omron Healthcare in the third quarter of 2014; in China where we recently received regulatory approval and are working with Omron Healthcare toward commercial launch in the second half of 2016; and in Mexico where our distributor Scienta Farma received regulatory approval and initiated sales in the fourth quarter of 2015.

Maintaining a High Level of Research and Development Productivity. Our research and development, or R&D, team successfully delivered Quell, an FDA cleared, technologically sophisticated, smart phone integrated product with electrodes and other accessories. We believe that there are no comparable products on the market. Our R&D team is now charged with maintaining and expanding this Quell competitive technological advantage, addressing opportunities to reduce Quell cost of goods sold, and enhancing our intellectual property position, through continuing innovation. We expect innovation to take the form of device and software enhancements to improve the user experience, expanded smart phone applications, and new electrode features to optimize therapy. Technological innovation will continue to be one of our top priorities.

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 goal for these devices is to build an installed base of active customer accounts and distributors that regularly order aftermarket products to meet their needs. We successfully implemented this model when we started our business with the NC-stat system and applied it to subsequent product generations including the ADVANCE system. Our recently developed products, Quell, SENSUS and DPNCheck, conform to this model.

Marketed Products

Quell

Quell is a wearable device for relief of chronic intractable pain, such as nerve pain due to diabetes and lower back problems. It incorporates our OptiTherapy technology, 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 carried in a neoprene band that is worn on the upper calf and (2) an electrode that attaches to the device and is the interface between the device and the skin. 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 intractable pain and will be available OTC. Users of the device have the option of using their smartphones to control pain therapy and to track sleep and therapy parameters. The device was made commercially available in June 2015. In an independent post-market clinical study of Quell initiated by NeuroMetrix, 81% of subjects reported an improvement in management of 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. We estimate, over time, we will see product returns in the range of 20% to 25%, as indicated by the results of the post-market clinical study. Quell is currently available via e-commerce on our product website (quellrelief.com) and on Amazon, via direct response television including QVC, via specialty catalogs, and via select health care professionals. Recently we initiated retail distribution in Target stores and expect to make Quell available in select chain drug stores starting in the second quarter of 2016. The retail distribution initiative is supported by

television promotion designed to expand product awareness. Following commercial launch through the first quarter of 2016 approximately 22,000 devices and accessories were shipped to consumers with a total invoiced value of \$4.8 million prior to the impact of product returns.

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SENSUS

The SENSUS pain therapy device, the technological predecessor to Quell, is a prescription neuro-stimulation device based on TENS for relief of chronic, intractable pain. SENSUS, which was commercially launched in the first quarter of 2013, is a convenient and wearable device that offers physicians and their patients a non-narcotic pain relief option as a complement to medications. SENSUS is comprised of: (1) an electronic device with a strap that is worn on the upper calf and (2) an electrode which attaches to the device. We provide prescribing physicians with PC-based software that links to the device via a USB connection, thereby allowing them to download a record of the patient's use of the device. The SENSUS device and electrodes were cleared by the FDA for commercial distribution. When medically indicated and supported by proper documentation, TENS devices are generally reimbursed by Medicare and many commercial insurance companies under the DME benefit. SENSUS customers have purchased approximately 10,000 devices through March 31, 2016. We believe that the launch of Quell and contraction of the DME distribution channel due to Medicare competitive bidding will reduce future opportunities for SENSUS sales. Accordingly, we believe SENSUS will have a limited impact on future revenues.

DPNCheck

DPNCheck is a fast, accurate, and quantitative nerve conduction test that is used to evaluate systemic neuropathies such as diabetic peripheral neuropathy, or DPN. It is designed to be used by primary care physicians, endocrinologists, podiatrists and other clinicians at the point-of-care to objectively detect, stage, and monitor 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. This PC software allows physicians to generate reports and manage their sural nerve conduction data.

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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 which costs less than the original device, has the same functionality with respect to sural nerve testing. More than 1.8 million patient studies have been performed using our NC-stat technology and there have been approximately 6.8 million nerve tests. It 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. DPNCheck shipments commenced in late 2011 and approximately 2,900 devices had been placed with customers through March 31, 2016.

ADVANCE System

Our legacy neurodiagnostics business is based on the ADVANCE NCS/EMG System, or 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 needles, and (3) a communication hub that enables the physician's office to network their device to their personal computers and our servers for data archiving, report generation, and other network services. The ADVANCE System is most commonly 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. More than 1.8 million patient studies have been performed using our NC stat technology and there have been approximately 6.3 million nerve tests, including 700,000 sural nerve tests. As of March 31, 2016, we had an installed base of approximately 450 active customers using our ADVANCE System.

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Legacy Neurodiagnostics Business

We were founded in 1996 as a science-based health care company. Our focus had been 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. 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, or CDC, 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.

Following launch of NC-stat in 1999, we experienced rapid revenue growth, which led to our initial public offering in 2004. The health market, particularly the physician office segment, embraced the opportunity to perform nerve conduction tests which previously had always required referral to specialists. Point-of-care nerve testing was seen to provide a combination of improved patient care and patient convenience. The success of point-of-care nerve testing, a market which we created, was met with resistance in some sectors of the medical community, particularly by neurologists and physical medicine and rehabilitation physicians, both of which had traditionally provided nerve testing services. As a consequence of successful lobbying by these specialists, physicians using our technology experienced increased denials of coverage by third party payers resulting in their discontinuing usage and our difficulty in accruing new customer accounts. In late 2009 CMS included in the Physician Fee Schedule a new Category I CPT Code, CPT 95905, for nerve conduction studies performed using preconfigured electrode such as those employed with our products. During 2010 most Medicare fiscal intermediaries assumed coverage for CPT 95905 for some clinical indications; however, the health care environment was such that we were unable to secure broad coverage among private payers which is essential to the success of our ADVANCE System product. This experience was reflected in our revenues for the legacy Neurodiagnostics business, which peaked in 2006 at \$55.3 million. We reported revenue for our legacy Neurodiagnostics business of \$2.3 million, \$2.8 million and \$3.8 million in 2015, 2014 and 2013, respectively. Revenues for our legacy Neurodiagnostics business for the quarter ended March 31, 2016 were approximately \$0.6 million. We currently manage this business to optimize cash flow.

Risks Affecting Us

Our business is subject to numerous risks, as discussed more fully in the section entitled "Risk Factors" immediately following this prospectus summary. At March 31, 2016 we had an accumulated deficit of \$167.7 million and held cash and cash equivalents of \$8.7 million. We believe that these resources, the cash to be generated from expected product sales and, assuming we sell the securities registered under this registration statement, the net proceeds from this offering will be sufficient to meet our projected operating

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requirements through the third quarter of 2017. However, the amount of our future product sales is difficult to predict, especially in light of the limited nature of the recent commercialization of Quell, and actual sales may not be in line with our forecasts. We continue to face significant challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected. Accordingly, we will need to raise additional funds along with the securities registered under this registration statement to support our operating and capital needs for the fourth quarter of 2017 and beyond. However, we may not be able to secure such financing in a timely manner or on favorable terms, if at all. 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.

Our Corporate Information

Our President and Chief Executive Officer, Shai N. Gozani, M.D., Ph.D. founded NeuroMetrix in June 1996. We are incorporated in Delaware. Our common stock is listed on The NASDAQ Capital Market under the ticker symbol NURO. Our principal offices are now located at 1000 Winter Street, Waltham, Massachusetts 02451. Our telephone number is (781) 890-9989. Our web site is www.neurometrix.com. We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this document. Our web site address is included in this document as an inactive textual reference only. The NeuroMetrix name and logo and the names of products and services offered by NeuroMetrix are trademarks, registered trademarks, service marks or registered service marks of NeuroMetrix.

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The Offering

*The following summary contains basic information about the offering and the securities we are offering and is not intended to be complete. It does not contain all the information that is important to you. For a more complete understanding of the common stock, Series D convertible preferred stock and the 2016 Warrants, please refer to the sections titled *Description of Capital Stock* and *Description of Securities We Are Offering**

Class A Units offered by us

We are offering up to \$15,000,000 of Class A Units. Each Class A Unit will consist of one share of our common stock and a warrant to purchase shares of our common stock at an exercise price per full share of common stock equal to % of the public offering price of the Class A Units (each, a 2016 warrant). The Class A Units will not be certificated and the share of common stock and warrants part of such unit are immediately separable and will be issued separately in this offering.

This prospectus also relates to the offering of shares of our common stock issuable upon the exercise of the 2016 warrants that are part of the Class A Units.

Assuming we sell all \$15,000,000 of Class A Units (and no Class B Units) being offered in this offering at a public offering price of \$, the reported closing price of our common stock on , 2016, we would issue in this offering an aggregate of shares of our common stock and 2016 warrants to purchase shares of our common stock.

Class B Units offered by us

We are also offering to those purchasers, if any, whose purchase of Class A Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering, the opportunity, in lieu of purchasing Class A Units, to purchase Class B Units. Each Class B Unit will consist of one share of our Series D convertible preferred stock, with a stated value of \$1,000 and convertible into shares of our common stock at the public offering price of the Class A Units, together with the equivalent number of 2016 warrants as would have been issued to such purchaser if they had purchased Class A Units based on the public offering price.

Ownership of the Class B Units alone will not increase the purchaser's beneficial ownership percentage of common stock unless and until a portion or all of such Series D convertible preferred stock has been converted. In addition, holders of Series D convertible preferred stock will be prohibited from converting Series D convertible preferred stock if, as a result of such conversion, the holder, together with its affiliates and certain related parties, and any persons acting as a group together with such holder or any such affiliate, would beneficially own more than 4.99% of the total number of shares of our outstanding common stock.

However, any holder may decrease or increase such ownership percentage to any other percentage, provided that any increase in such percentage shall not be effective until 61 days after such notice to us. Exceeding 4.99% ownership in shares of our

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outstanding common stock will trigger certain SEC filing requirements by such holder, including the submission of a Schedule 13G or Schedule 13D, as applicable, while such ownership percentage remains above 4.99%, and Forms 3 and 4, while such ownership percentage remains above 9.99%.

Shares of Series D convertible preferred stock do not generally have any voting rights but are convertible into shares of common stock. The Class B Units will not be certificated and the shares of Series D convertible preferred stock and 2016 warrants that are part of such unit are immediately separable and will be issued separately in this offering.

This prospectus also relates to the offering of shares of our common stock issuable upon conversion of the Series D convertible preferred stock and the 2016 warrants part of the Class B Units.

2016 Warrants

Each 2016 warrant included in the Units will have an exercise price per full share of common stock equal to % of the public offering price of the Class A Units, will be immediately exercisable and will expire five years from the date on which such 2016 warrants become exercisable.

There is no established public trading market for the warrants, and we do not expect a market to develop. In addition, we do not intend to apply for a listing of the 2016 warrants on any national securities exchange.

Common stock outstanding before this offering

4,389,899 shares

Common stock to be outstanding immediately after this offering

shares⁽¹⁾⁽²⁾

Use of proceeds

We intend to use the net proceeds of this offering to fund the commercialization of Quell in the United States and for general corporate purposes. Pending these uses, we intend to invest our net proceeds from this offering primarily in investment-grade, interest bearing instruments. See Use of Proceeds on page 31.

Risk factors

See Risk Factors beginning on page 13 and the other information included in this prospectus for a discussion of factors you should read and carefully consider before deciding whether to invest in the securities offered by this prospectus.

NASDAQ Capital Market Symbol

NURO

No market for the Units or Series D convertible preferred stock or warrants

The units will not be certificated, and the securities that are part of such units are immediately separable and will be issued separately in this offering. There is no established public trading market for the Series D convertible preferred stock or the 2016 warrants to be issued in this offering, and we do not intend to apply to list such securities on any securities exchange or automated quotation system.

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(1) The number of shares of our common stock that will be outstanding immediately after this offering is based on 4,389,899 shares of common stock outstanding as of March 31, 2016, and, as of that date, excludes the following: 5,424,139 shares of common stock issuable upon the conversion, at the option of the holder, of 500 shares of Series B convertible preferred stock and 13,800 shares of Series C convertible preferred stock (see Description of Capital Stock Preferred Stock); 15,816,393 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2016, at a weighted average exercise price of \$3.57 per share; 211,127 shares of common stock issuable upon the exercise of options outstanding as of March 31, 2016, at a weighted average exercise price of \$13.25 per share; 97,661 shares of common stock available for future issuance under our 2004 Stock Option and Incentive Plan as of March 31, 2016; 50,000 shares of common stock available for future issuance under our 2009 Non-Qualified Inducement Stock Plan as of March 31, 2016; 19,792 shares of common stock available for future issuance under our 2010 Employee Stock Purchase Plan as of March 31, 2016; and shares of common stock issuable upon the exercise of the warrants, including warrants to be issued to the Placement Agent, to be sold in this offering.

Assumes only Class A Units are sold in this offering. To the extent we sell any Class B Units, the same aggregate (2) number of common stock equivalents resulting from this offering would be convertible under the Series D convertible preferred stock issued as part of the Class B Units.

Unless otherwise noted, all information in this prospectus reflects a 1-for-4 reverse stock split of our common stock that was effected on December 1, 2015.

Selected Financial Data

The following tables summarize our financial data for the periods presented. The summary statement of operations data and balance sheet data for each of the years ended December 31, 2015, 2014, 2013, 2012, and 2011, have been derived from our audited financial statements. The audited financial statements for the years ended December 31, 2015, 2014, and 2013, and the report thereon, were included in our Annual Report on Form 10-K for the year ended December 31, 2015, which is incorporated by reference into this prospectus. Our statement of operations data for the three months ended March 31, 2016 and 2015 and our balance sheet data as of March 31, 2016 were derived from our unaudited interim financial statements included in our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2016, which is incorporated by reference in this prospectus. Our historical results are not necessarily indicative of the results to be expected for any future periods.

You should read this data together with the financial statements and related notes incorporated by reference into this prospectus, as well as Management's Discussion and Analysis of Financial Condition and Results of Operations and the other financial information in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 and the Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, both of which are incorporated by reference into this prospectus.

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	Three Months Ended March 31,		Years Ended December 31,				
	2016	2015	2015	2014	2013	2012	2011
	(In thousands, except per share data)		(In thousands, except per share data)				
Statement of operations data:							
Revenues	\$2,275	\$1,283	\$7,300	\$5,513	\$5,279	\$7,575	\$10,397
Cost of revenues	1,482	637	3,951	2,569	2,194	3,589	4,722
Gross Profit	793	646	3,349	2,944	3,085	3,986	5,675
Net loss ⁽¹⁾	\$(4,095)	\$(2,071)	\$(9,187)	\$(7,766)	\$(8,019)	\$(10,008)	\$(9,981)
Net loss per common share, basic and diluted ⁽²⁾	\$(1.00)	\$1.00	(7.75)	(6.15)	(12.28)	(20.86)	(62.14)

Includes warrants income (expense) of \$4,083,606, \$1,050,095, and \$(289,657) for the years ended December 31, (1)2015, 2014 and 2013, respectively. For three months ended March 31, 2016 and 2015, warrant income was \$94,316 and \$1,186,302, respectively.

Per common share amounts have been adjusted for all periods prior to the first quarter of 2013 to reflect a 1-for-6 (2)reverse split of our common stock completed on February 15, 2013, and for all periods prior to the fourth quarter of 2015 to reflect a 1-for-4 reverse split of our common stock completed on December 1, 2015.

	March 31,	As of December 31,				
	2016	2015	2014	2013	2012	2011
	(In thousands)	(In thousands)				
Balance sheet data:						
Cash, cash equivalents, and short-term investments	\$ 8,740	12,463	\$ 9,222	\$ 9,196	\$ 8,699	\$ 10,290
Working capital ⁽¹⁾	8,194	11,956	8,392	8,919	8,567	10,482
Total assets	12,308	16,034	11,402	10,797	10,877	14,221
Total liabilities	3,456	3,471	8,015	3,602	2,077	3,132
Total stockholders equity	8,852	12,563	3,387	7,195	8,800	11,089

(1) We define working capital as current assets less current liabilities.

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The following table represents certain unaudited quarterly information for each of the quarters in the interim period ended March 31, 2016 and for each of the four quarters in the years ended December 31, 2015, 2014, and 2013. This information has been prepared on the same basis as the audited financial statements incorporated by reference into this prospectus and includes all the adjustments necessary for a fair statement of the unaudited quarterly results of operations (in thousands, except per share data).

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2016:				
Net loss	\$ (4,095)			
Basic and diluted net loss per share	\$ (1.00)	\$	\$	
2015:				
Net loss	\$ (2,071)	\$ (1,203)	\$ (3,204)	\$ (2,709)
Basic and diluted net loss per share ⁽¹⁾	\$ (1.00)	\$ (2.07)	\$ (1.06)	\$ (3.19)
2014:				
Net loss	\$ (1,225)	\$ (2,171)	\$ (1,462)	\$ (2,909)
Basic and diluted net loss per share ⁽¹⁾	\$ (0.83)	\$ (3.42)	\$ (0.74)	\$ (1.44)
2013:				
Net loss	\$ (2,253)	\$ (1,346)	\$ (716)	\$ (3,704)
Basic and diluted net loss per share ⁽¹⁾	\$ (4.24)	\$ (3.68)	\$ (1.05)	\$ (3.47)

⁽¹⁾ Per common share amounts have been adjusted for all periods prior to the fourth quarter of 2015 to reflect a 1-for-4 reverse split of our common stock completed on December 1, 2015.

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RISK FACTORS

*Investing in our securities involves a high degree of risk. You should carefully consider the following risk factors and all other information contained in or incorporated by reference into this prospectus before purchasing our securities. The risks and uncertainties described below and in our other filings with the SEC are not the only ones we face. If any of the following risks were to occur, our business, financial condition or results of operations could be materially and adversely affected. In these circumstances, the market price of our securities could decline, and you may lose some or all of your investment. Please also read carefully the section below titled *Special Note Regarding Forward-Looking Statements*.*

Risks Related to Our Business

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

We have incurred significant cumulative net losses since our inception. Our net losses for the three months ended March 31, 2016 and the years ended December 31, 2015, 2014, 2013, were approximately \$4.1 million, \$9.2 million, \$7.8 million, and \$8.0 million, respectively. At March 31, 2016, we had an accumulated deficit of \$167.7 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 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 \$8.7 million as of March 31, 2016. We believe that these resources, and the cash to be generated from future product sales and, assuming we sell all of the securities registered under this registration statement, the net proceeds from this offering will be sufficient to meet our projected operating requirements through the third quarter of 2017. However, the amount of our future product sales is difficult to predict, especially in light of the limited nature of the recent commercialization of Quell, and actual sales may not be in line with our forecasts.

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 aim to successfully commercialize Quell and DPNCheck and the operations of our business and will be dependent on funding our operations through additional 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. These circumstances raise substantial doubt about our ability to continue as a going concern. As a result of this uncertainty and the substantial doubt about our ability to continue as a going concern as of December 31, 2015, the report of our independent registered public accounting firm in our Annual Report on Form 10-K for the year ended December 31, 2015 includes a going concern explanatory paragraph. Management's plans include increasing revenue through the commercialization of Quell and DPNCheck. However, no assurance can be given at this time as to whether we will be able to achieve these objectives. 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 affecting our existing products and delays in the FDA approval process for products under development; (e) changes in our research and development spending plans; and (f) other items affecting our forecasted level of expenditures and use of cash resources.

Accordingly, we will need to raise additional funds, even if we issue all of the securities registered under this registration statement to support our future operating and capital needs for the fourth quarter of 2017 and beyond. We may attempt to obtain additional

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funding through 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 commercialization 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 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 approximately 22,000 Quell devices since then. Additionally, DPNCheck, which was launched in 2011, is a quantitative nerve conduction test for systemic neuropathies, such as DPN. We also have other product candidates and product enhancements in our development pipeline. 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. 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 create market demand for Quell through a direct sales force, through online marketing efforts, direct response television and other retail channels;

manufacturing issues with Quell or our other products;

inability to increase adoption of DPNCheck within the Medicare Advantage market;

unfavorable market response to DPNCheck in Japan and other Asia markets;

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' reluctance to alter their existing practices and adopt the use of our devices.

If we are unable to expand exposure and penetrate the market for Quell and/or 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 anticipate that as revenue from our legacy neurodiagnostics business, the ADVANCE System, continues to decrease, we will rely more heavily on revenue from sales of Quell, our OTC wearable device. As a result, we will continue to incur operating losses until such time as sales of Quell and other products or product candidates reach a mature level and we are able to generate sufficient revenue from their sale to meet our operating expenses. There can be no assurance that customers will adopt our technology and products, or that prospective customers will agree to pay for our products. In the event that we are not able to significantly increase the number of customers that purchase our products, or if we are unable to charge the necessary prices, our financial condition and results of operations will be materially and adversely affected.

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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, if managed care organizations do not receive improved capitated payments due to more accurate patient risk assessment using our products, and if DME suppliers are not adequately reimbursed for supplying our therapeutic 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 those 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.

Healthcare reform legislation could adversely affect our future revenues.

Our future revenues from SENSUS will be impacted by the CMS Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program. Under this program, Medicare will no longer reimburse suppliers for certain products and services, including transcutaneous electrical nerve stimulation (TENS), based on the Medicare fee schedule amount. Instead CMS will provide reimbursement for those products and services based on a competitive bidding process. Our SENSUS pain management system is presently classified within TENS. The DMEPOS Competitive Bidding Program will likely require us to sell SENSUS devices and related consumables subject to Medicare reimbursement at significantly lower prices which would have a material adverse effect on SENSUS profitability. In those regions of the country where DMEPOS Competitive Bidding was implemented in January 2014, low Medicare pricing is restricting our ability to sell SENSUS. As the DMEPOS program is expanded to other regions, a similar effect will likely be seen.

We are subject to extensive regulation by the FDA which could restrict the sales and marketing of the Quell, SENSUS 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

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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, including any issues arising from the not substantially equivalent letter described above, 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 the program will be modified and what effect the modified review process will have on our ability to bring our product candidates to market.

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

We rely on third-party manufacturers to manufacture components of our Quell, DPNCheck and SENSUS systems, 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

We depend on several single source manufacturers to produce components of our products. Any material adverse

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 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 Parlex Polymer Flexible Circuits, Inc. for the manufacture of the ADVANCE electrodes for nerve

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conduction testing. Katecho, Inc. manufactures biosensors for use with our DPNCheck devices and manufactures electrodes for Quell and SENSUS, and Sunburst EMS, Inc. manufactures electronic boards and other components of our Quell, DPNCheck and SENSUS 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 new products, including Quell, during the initial production ramp-up phase. If any materially adverse changes in our relationships with these manufacturers occur, our ability to supply our customers will be severely limited until we are able to engage an alternate manufacturer 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 as we expand our markets, 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 within the United States and internationally, 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

If our manufacturers are unable to supply us with an adequate supply of product components as we expand our ma

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.

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

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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 maintaining or increasing our gross margins on product sales which we may not be able to achieve.

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

- lower than expected manufacturing yields of high cost components leading to increased manufacturing costs;
- low production volume which will result in high levels of overhead cost per unit of production;
- the timing of revenue recognition and revenue deferrals;
- increased material or labor costs;
- increased service or warranty costs or the failure to reduce service or warranty costs;
- increased price competition;
- variation in the margins across products in a particular period; and
- how well we execute on our strategic and operating plans.

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

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

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

- the pending patent applications we have filed or to which we have exclusive rights may not result in issued patents or may take longer than we expect to result in issued patents;
- the claims of any patents that are issued may not provide meaningful protection;

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

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 begin to expire in 2017. Although the patent protection for material aspects of these products covered by the

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claims of the patents will be lost at that time, we have additional patents and patent applications directed to other novel inventions that will have patent terms extending beyond 2017. 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. 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.

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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

Claims that our products infringe on the proprietary rights of others could adversely affect our ability to sell our prod

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

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use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. Although we do not believe that we are subject to the HIPAA rules, the exact scope of these rules has not been clearly established. 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. As sales and use of our products increase, 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 are found to have violated laws protecting the confidentiality of patient health information, we could be subject to

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 General Manager Consumer. 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.

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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 full-time employees as of March 31, 2016, 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.

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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;
- 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

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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 likely be faced with competition from other companies that decide and are able to enter the market. 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

We currently compete, and may in the future need to compete, against other medical device and consum46compar

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

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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.