NeuroMetrix, Inc.
Form S-1/A
October 20, 2016

As filed with the Securities and Exchange Commission on October 20, 2016

Registration No. 333-207566

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

AMENDMENT NO. 2 TO
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

NEUROMETRIX, INC.

(Exact name of registrant as specified in its charter)

Delaware	3841	04-3308180
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(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)

Shai N. Gozani, M.D., Ph.D.
Chief Executive Officer
NeuroMetrix, Inc.
1000 Winter Street
Waltham, Massachusetts 02451
(781) 890-9989

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Megan N. Gates, Esq.
Garrett M. Winslow, Esq.
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
One Financial Center
Boston, MA 02111
Telephone: (617) 542-6000
Fax: (617) 542-2241

Shai N. Gozani, M.D., Ph.D.
Chief Executive Officer
NeuroMetrix, Inc.
1000 Winter Street
Waltham, Massachusetts 02451
(781) 890-9989

Robert Charron, Esq.
Ellenoff Grossman & Schole LLP
1345 Avenue of the Americas
New York, NY 10105-0302
Telephone: (212) 370-1300
Fax: (212) 370-7889

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: o

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. o

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. o

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. o

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 o	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company x

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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 E Convertible Preferred Stock, par value $0.001		
(ii) Warrants to purchase Common Stock[3]		
Common Stock issuable upon conversion of Series E 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	$ 1,738.50 [4]

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

(2) Pursuant to Rule 416 under the Securities Act, the securities being registered hereunder include such indeterminable 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) The registrant previously paid a filing fee of $1,510.50. In light of the recent revision of the filing fee rate that became effective on October 1, 2016, the registrant has paid an additional $228.00 with respect to this offering.

(5) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

(6) 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 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 October 20, 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 E Convertible Preferred Stock and Warrants

(shares of Common Stock underlying the Series E 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 E 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 E convertible preferred stock do not generally have any voting rights but are convertible into shares of common stock. The shares of Series E 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 E convertible preferred stock and upon the exercise of the 2016 warrants being offered by this prospectus.

For a more detailed description of the Series E convertible preferred stock, see the section entitled Description of Securities We Are Offering Series E Convertible Preferred Stock beginning on page 60. 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 55 of this prospectus.

We refer to the Series E convertible preferred stock issued hereunder, the 2016 warrants and the shares of common stock issued hereunder and issuable upon conversion of the Series E 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 October 19, 2016 was $1.49 per share. We do not intend to list the Series E 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[1]	$	$	$
Proceeds to NeuroMetrix, before expenses	$	$	$

(1) We have agreed to reimburse the placement agent for certain of its expenses and to issue common stock purchase warrants to the placement agent. See Plan of Distribution on page 63 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 a commercial stage, innovation driven healthcare company combining bioelectrical and digital medicine to address chronic health conditions including chronic pain, sleep disorders, and diabetes. 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 and a half 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 third quarter of 2016, approximately 45,000 Quell devices plus electrodes and accessories were shipped to customers. Quell revenues for the year ended December 31, 2015 and for the nine months ended September 30, 2016 were approximately $2.1 million and $4.9 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 retail merchandisers including Target, CVS and Walgreens, and via health care professionals such as pain management physician practices and podiatry practices. Distribution is supported by television promotion 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. In June 2016, we filed with the European Medicines Agency for regulatory approval to market Quell in the European Union and, assuming we receive such approval, we plan to initiate marketing during 2017.

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 nine months ended September 30, 2016 were approximately $1.7 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 both patient quality of life and cost of care. Also, the diagnosis and documentation of

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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 2014; in China where we have received regulatory approval and are working with Omron Healthcare toward commercial launch in late 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 is 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. To date, product returns have averaged 28%. 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 available via e-commerce on our product website (quellrelief.com) and on Amazon, via direct response television including QVC, via retail merchandisers including Target, CVS and Walgreens, and via select health care professionals. Distribution is supported by television promotion designed to expand product awareness. Following commercial launch through the third quarter of 2016 approximately 45,000 devices and accessories were shipped to customers with a total invoiced

value of $10.2 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 10,300 devices through September 30, 2016. We believe that the launch of Quell and contraction of the DME distribution channel due to Medicare competitive bidding will significantly 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 2.4 million patient studies have been performed using our NC-stat technology and there have been approximately 7.0 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 3,200 devices had been placed with customers through September 30, 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 2.4 million patient studies have been performed using our NC stat technology and there have been approximately 7.0 million nerve tests, including 1.3 million sural nerve tests. As of September 30, 2016, we had an installed base of approximately 400 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 nine months ended September 30, 2016 were approximately $1.6 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 September 30, 2016 we had an accumulated deficit of $175.7 million and held cash and cash equivalents of $7.6 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 end 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 first quarter of 2018 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 E 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 E 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 E convertible preferred stock has been converted. In addition, holders of Series E convertible preferred stock will be prohibited from converting Series E 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 E 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 E 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 E 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

5,318,273 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 E 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 E 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 5,318,273 shares of common stock outstanding as of September 30, 2016, and, as of that date, excludes the following:

10,892,929 shares of common stock issuable upon the conversion, at the option of the holder, of 500 shares of Series B convertible preferred stock and 19,639 shares of Series D convertible preferred stock (see Description of Capital Stock Preferred Stock);

28,206,975 shares of common stock issuable upon the exercise of warrants outstanding as of September 30, 2016, at a weighted average exercise price of $2.76 per share;

731,472 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2016, at a weighted average exercise price of $4.59 per share;

27,316 shares of common stock available for future issuance under our 2004 Stock Option and Incentive Plan as of September 30, 2016;

50,000 shares of common stock available for future issuance under our 2009 Non-Qualified Inducement Stock Plan as of September 30, 2016;

115,585 shares of common stock available for future issuance under our 2010 Employee Stock Purchase Plan as of September 30, 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.

(2) Assumes only Class A Units are sold in this offering. To the extent we sell any Class B Units, the same aggregate number of common stock equivalents resulting from this offering would be convertible under the Series E 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 nine months ended September 30, 2016 and 2015 and our balance sheet data as of September 30, 2016 were derived from our unaudited interim financial statements included in our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 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 September 30, 2016, both of which are incorporated by reference into this prospectus.

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	Nine Months Ended September 30,		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	$8,312	$4,562	$7,300	$5,513	$5,279	$7,575	$10,397
Cost of revenues	5,087	2,351	3,951	2,569	2,194	3,589	4,722
Gross Profit	3,225	2,211	3,349	2,944	3,085	3,986	5,675
Net loss[1]	$(12,099)	$(6,478)	$(9,187)	$(7,766)	$(8,019)	$(10,008)	$(9,981)
Deemed dividends[2]	(19,846)	(3,551)	(11,883)	(2,956)	(767)		
Net loss applicable to common stockholders	$(31,945)	$(10,029)	$(21,070)	$(10,722)	$(8,786)	$(10,008)	$(9,981)
Net loss per common share, basic and diluted[2]	$(7.01)	$(1.02)	$(7.75)	$(6.15)	$(12.28)	$(20.86)	$(62.14)

(1) Includes warrants income (expense) of $4,083,606, $1,050,095, and $(289,657) for the years ended December 31, 2015, 2014 and 2013, respectively. For nine months ended September 30, 2016 and 2015, warrant income was $227,873 and $3,473,804, respectively.

(2) Deemed dividends attributable to preferred shareholders and returns of capital to common shareholders associated with equity offerings.

(3) Per common share amounts have been adjusted for all periods prior to the first quarter of 2013 to reflect a 1-for-6 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.

	September 30,	As of December 31,				
	2016	2015	2014	2013	2012	2011
	(In thousands)	(In thousands)				
Balance sheet data:						
Cash, cash equivalents, and short-term investments	$ 7,568	12,463	$ 9,222	$ 9,196	$ 8,699	$ 10,290
Working capital[1]	7,006	11,956	8,392	8,919	8,567	10,482
Total assets	11,349	16,100	11,402	10,797	10,877	14,221
Total liabilities	3,639	3,537	8,015	3,602	2,077	3,132
Total stockholders equity	7,710	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 September 30, 2016 and for each of the four quarters in the years ended December 31, 2015 and 2014. 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)	$(4,096)	$(3,908)	$
Deemed Dividends[1]		(19,846)		
Net loss applicable to common stockholders	$(4,095)	$(23,942)	$(3,908)	$
Net loss per common share, basic and diluted[2]	$(1.00)	$(5.37)	$(0.76)	$
2015:				
Net loss	$(2,071)	$(1,203)	$(3,204)	$(2,709)
Deemed Dividends[1]		(3,551)		(8,332)
Net loss applicable to common stockholders	$(2,071)	$(4,754)	$(3,204)	$(11,041)
Net loss per common share, basic and diluted[2]	$(1.00)	$(2.07)	$(1.06)	$(3.19)
2014:				
Net loss	$(1,225)	$(2,171)	$(1,462)	$(2,909)
Deemed Dividends[1]		(2,956)		
Net loss applicable to common stockholders	$(1,225)	$(5,126)	$(1,462)	$(2,909)
Net loss per common share, basic and diluted[2]	$(0.83)	$(3.42)	$(0.74)	$(1.44)

(1) Deemed dividends attributable to preferred shareholders and returns of capital to common shareholders associated with equity offerings.

(2) 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 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 nine months ended September 30, 2016 and the years ended December 31, 2015, 2014, 2013, were approximately $12.1 million, $9.2 million, $7.8 million, and $8.0 million, respectively. At September 30, 2016, we had an accumulated deficit of $175.7 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 $7.6 million as of September 30, 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 end 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 further 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 first quarter of 2018 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 45,000 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 online marketing efforts, direct response television, retail merchandisers and health care professional channels;
unfavorable results from the retail initiative resulting in loss of current retail mass merchandisers;
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, China and Mexico;
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

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increase the number of customers that purchase our products, or if we are unable to charge the necessary prices, our financial condition and results of operations will be materially and adversely affected.

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

Widespread adoption of our 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.

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 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

We are subject to extensive regulation by the FDA which couldrestrict the sales and marketing of the Quell SENSU

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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 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 conduction testing. Katecho, Inc. manufactures biosensors for use with our DPNCheck devices and manufactures electrodes for Quell and SENSUS. Sunburst EMS, Inc. and MC Assembly manufacture electronic boards and other components of our 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

Sunburst EMS, 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

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

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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 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 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

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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;
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 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.

The patent rights we rely upon to protect the intellectualproperty underlying our products may not be adequate, whi

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

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

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

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

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

We rely on patents to protect a portion of our intellectual property and our competitive position. Patent law relating to the scope of claims in the technology fields in which we operate is still evolving and, consequently, patent positions in the medical device industry are generally uncertain. In order to protect or enforce our patent rights, we may initiate patent litigation against third parties, such as infringement suits or interference proceedings. Litigation may be necessary to:

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

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

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

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

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were made against us and we could not develop non-infringing technology or license the infringed or similar technology on a timely and cost-effective basis, our revenues may decrease substantially and we could be exposed to significant liability.

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

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

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

There are a number of federal and state laws protecting the confidentiality of individually identifiable patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services promulgated patient privacy rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. These privacy rules protect medical records and

other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. 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

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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 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.

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 43 full-time employees as of September 30, 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.

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

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

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

Our success depends on the successful development, regulatory clearance or approval (if required), introduction and commercialization of new generations of products, treatment systems, and enhancements to and/or simplification of existing products. Quell and DPNCheck must keep pace with, among other things, the products of our competitors. We are making significant investments in long-term growth initiatives. Such initiatives require significant capital commitments, involvement of senior management and other investments on our part, which we may be unable to recover. Our timeline for the development of new products or enhancements may not be achieved and price and profitability targets may not prove feasible. Commercialization of new products may prove challenging, and we may be required to invest more time and money than expected to successfully introduce them. Once introduced, new products may adversely impact orders and sales of our existing products, or make them less desirable or even obsolete. Compliance with regulations, competitive alternatives, and shifting market preferences may also impact the successful implementation of new products or enhancements.

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

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

meet our product development plan and launch timelines.

Even if customers accept new products or product enhancements, the revenues from these products may not be sufficient to offset the significant costs associated with making them available to customers.

Failure to successfully develop, obtain regulatory approval or clearance for, manufacture or introduce new products or to complete these processes in a timely and efficient manner could result in delays that could affect our ability to attract and retain customers, or could cause customers to delay or cancel orders, causing our backlog, revenues and operating results to suffer.

If we are unable to develop new products or enhance existingproducts, we may be unable to attract or retain custor

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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 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.

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

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

If future clinical studies or other articles are published, orphysician associations or other organizations anduncepos

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

Foreign markets represented approximately 19% and 19% of our revenues in 2015 and 2014, respectively, and 11% of our revenues for the nine months ended September 30, 2016. We are working to expand market penetration, particularly in Asia. Any such expansion will subject us to the possibility of new business risks, including:

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

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

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

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

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

In addition, we are required to meet certain financial covenants customary with this type of credit facility, including maintaining a minimum specified tangible net worth. The credit facility also contains other customary covenants, which we may not be able to comply with in the future. Our failure to comply with these covenants may result in the declaration of an event of default and could cause us to be unable to borrow under the credit facility. In addition to preventing additional borrowings under the credit facility, an event of

Our loan and security agreement with a bank, which we refer toas our credit facility, contains financial and operating

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default, if not cured or waived, may result in the acceleration of the maturity of indebtedness outstanding under the credit facility at the time of the default, which would require us to pay all amounts outstanding. If an event of default occurs, we may not be able to cure it within any applicable cure period, if at all. If the maturity of our indebtedness is accelerated, we may not have sufficient funds available for repayment or we may not have the ability to borrow or obtain sufficient funds to replace the accelerated indebtedness on terms acceptable to us, or at all. We have not borrowed any funds under this agreement; however, as of September 30, 2016, $499,481 of the amounts available under the agreement are restricted to support letters of credit issued in favor of our landlords and a materials component supplier.

Risks Relating to Owning Our Securities

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

Until we are profitable, we will need significant additional funds to develop our business and sustain our operations. We sold shares of convertible preferred stock and warrants in June 2016, and any additional sales of shares of our common stock or other securities exercisable into our common stock are likely to have a dilutive effect on some or all of our then existing stockholders. Resales of newly issued shares in the open market could also have the effect of lowering our stock price, thereby increasing the number of shares we may need to issue in the future to raise the same dollar amount and consequently further diluting our outstanding shares.

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

If our stock price declines, we may be unable to raise additional capital. A sustained inability to raise capital could force us to go out of business. Significant declines in the price of our common stock could also impair our ability to attract and retain qualified employees, reduce the liquidity of our common stock and result in the delisting of our common stock from The NASDAQ Stock Market LLC, or NASDAQ.

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

The trading price of our common stock has been highly volatile. For the five year period ended September 30, 2016, our stock price has fluctuated from a low of $1.35 to a high of $49.20, as adjusted for stock splits during that time. The market price for our common stock will be affected by a number of factors, including:

the denial or delay of regulatory clearances or approvals for our products under development or receipt of regulatory approval of competing products;
our ability to accomplish clinical, regulatory and other product development and commercialization milestones and to do so in accordance with our timing estimates;
changes in policies affecting third-party coverage and reimbursement in the United States and other countries;
changes in government regulations and standards affecting the medical device industry and our products;
ability of our products to achieve market success;

the performance of third-party contract manufacturers and component suppliers;
actual or anticipated variations in our results of operations or those of our competitors;
announcements of new products, technological innovations or product advancements by us or our competitors;
developments with respect to patents and other intellectual property rights;

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sales of common stock or other securities by us or our stockholders in the future;

additions or departures of key scientific or management personnel;

disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

trading volume of our common stock;

changes in earnings estimates or recommendations by securities analysts, failure to obtain or maintain analyst coverage of our common stock or our failure to achieve analyst earnings estimates;

public statements by analysts or clinicians regarding their perceptions of our clinical results or the effectiveness of our products;

decreases in market valuations of medical device companies; and

general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors.

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

There can be no assurance that we will be able to comply with the continued listing standards of The NASDAQ Capital Market.

We cannot assure you that we will be able to comply with the standards that we are required to meet in order to maintain a listing of our common stock on The NASDAQ Capital Market. In 2015, we received two notices from the Listing Qualifications Department of the NASDAQ Stock Market, and we regained compliance with respect to both of these notices before the end of fiscal 2015. If we fail to continue to meet all applicable NASDAQ Capital Market requirements in the future and NASDAQ determines to delist our common stock, the delisting could substantially decrease trading in our common stock and adversely affect the market liquidity of our common stock; adversely affect our ability to obtain financing on acceptable terms, if at all, for the continuation of our operations; and harm our business. Additionally, the market price of our common stock may decline further and stockholders may lose some or all of their investment.

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

The low trading volume of our common stock may adversely affect the price of our shares.

Although our common stock is listed on The NASDAQ Capital Market, our common stock has experienced low trading volume. The 50 day average trading volume through September 30, 2016 as reported by NASDAQ was approximately 85,000 shares. Limited trading volume may subject our common stock to greater price volatility and may make it difficult for investors to sell shares at a price that is attractive to them.

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

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

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authorize the issuance of preferred stock which can be created and issued by the Board of Directors without prior stockholder approval, with rights senior to those of our common stock;

provide for a classified Board of Directors, with each director serving a staggered three-year term;

prohibit our stockholders from filling board vacancies, calling special stockholder meetings, or taking action by written consent;

provide for the removal of a director only with cause and by the affirmative vote of the holders of 75% or more of the shares then entitled to vote at an election of our directors; and

require advance written notice of stockholder proposals and director nominations.

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

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

We do not intend to pay cash dividends.

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

Risks Related To This Offering

The offering may not be fully subscribed, and, even if the offering is fully subscribed, we will need additional capital in the future. If additional capital is not available, we may not be able to continue to operate our business pursuant to our business plan or we may have to discontinue our operations entirely.

The Placement Agent in this offering will offer the securities on a best-efforts basis, meaning that we may raise substantially less than the total maximum offering amounts. We will not provide any refund to investors if less than all of the securities are sold. We have incurred losses in each year since our inception. Our net cash used in operating activities for the year ended December 31, 2015 was $13.1 million which represents a $5.4 million increase in the net cash used from $7.7 million for the year ended December 31, 2014. If we continue to use cash at this rate we will need significant additional financing, which we may seek to raise through, among other things, public and private equity offerings and debt financing. Any equity financings will likely be dilutive to existing stockholders, and any debt

financings will likely involve covenants restricting our business activities. Additional financing may not be available on acceptable terms, or at all.

We have broad discretion in the use of the proceeds of this offering and may apply the proceeds in ways with which you do not agree.

Substantially all of our net proceeds from this offering will be used, as determined by management in its sole discretion, to continue commercialization of our Quell product, and for working capital and other general corporate purposes. Our management will have broad discretion over the use and investment of the net

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proceeds of this offering. The failure of our management to apply these funds effectively could harm our business. You will not have the opportunity, as part of your investment decision, to assess whether our proceeds are being used appropriately. Pending application of our proceeds, they may be placed in investments that do not produce income or that lose value.

There must be a current prospectus and state registration or exemption in order for you to exercise the 2016 warrants.

The 2016 warrants issued in this offering will be immediately exercisable and will expire five years from the date on which such 2016 warrants become exercisable. Purchasers of the warrants in this offering will be able to exercise the warrants only if a current prospectus relating to the common stock underlying the warrants is then in effect and only if such securities are qualified for sale or exempt from qualification under the applicable securities laws of the states in which the various holders of warrants reside. Although we will attempt to maintain the effectiveness of a current prospectus covering the common stock underlying the warrants and maintain the registration or exemption of such common stock under the securities laws of the states in which we initially sell the common stock and warrants in this offering, there can be no assurance that we will be able to do so. We will be unable to issue common stock to those persons desiring to exercise their warrants if a current prospectus covering the common stock issuable upon the exercise of the warrants is not kept effective or if such shares are neither qualified nor exempt from qualification in the states in which the holders of the warrants reside.

If the registration statement covering the shares issuable upon exercise of the warrants is no longer effective, the warrants may only be exercised on a cashless basis and will be issued with restrictive legends unless such shares are eligible for sale under Rule 144 of the Securities Act.

Holders of our warrants will have no rights as a common stockholder until they acquire our common stock, but will be subject to all changes made with respect thereto.

Until you acquire shares of our common stock upon exercise of your warrants, you will have no rights with respect to our common stock. You will have rights with respect to our common stock only if you receive our common stock upon exercise of the warrants and only as of the date when you become a record owner of the shares of our common stock upon such exercise. For example, if a proposed amendment to our charter or bylaws requires stockholder approval and the record date for determining the stockholders of record entitled to vote on the amendment occurs prior to the date that you are deemed to be the owner of the shares of our common stock due upon exercise of your warrants, you will not be entitled to vote on the amendment, although you will be subject to any changes in the powers, preferences or special rights of our common stock.

There is no public market for the Series E convertible preferred stock or the warrants to purchase common stock being offered by us in this offering.

There is no established public trading market for the Series E convertible preferred stock or the warrants to purchase common stock being offered in this offering, and we do not expect a market to develop. In addition, we do not intend

to apply to list the Series E convertible preferred stock or the warrants to purchase common stock on any national securities exchange or other nationally recognized trading system, including The NASDAQ Capital Market. Without an active market, the liquidity of the Series E convertible preferred stock and the warrants may be limited.

Purchasers will experience immediate dilution in the value per share of common stock as a result of this offering.

Investors in this offering will experience immediate dilution in their net tangible book value per share to the extent of the difference between the public offering price per share of common stock and the adjusted net tangible book value per share after giving effect to the offering. Our net tangible book value as of September 30, 2016 was approximately $7.7 million, or $1.45 per share of our common stock based on 5,318,273 shares outstanding. Assuming that we issue $15,000,000 of Class A Units in this offering at an assumed offering price of $ per share, the closing price of our common stock on the NASDAQ Capital Market on , 2016, and after deducting placement agent s fees and estimated offering expenses payable by us, our adjusted net tangible book value as of September 30, 2016, would have been

There is no public market for the Series E convertible preferredstock or the warrants to purchase commonstock bei

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approximately $ million, or $ per share of our common stock. This calculation excludes the proceeds, if any, from the exercise of the warrants issued in this offering. This amount represents an increase in net tangible book value of $ per share to our existing stockholders and an immediate dilution in net tangible book value of $ per share to investors in this offering. To the extent that

any of our outstanding options or warrants, including the warrants issued in this offering, are exercised,
any outstanding preferred stock is converted,
we grant additional options under our stock option plans or
we issue additional common stock, warrants or preferred stock,

there may be further dilution to purchasers in this offering. See the section entitled Dilution below.

Purchasers will experience immediate dilution in the value pershare of common stock as a result of this offering.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. Forward-looking statements relate to future events or our future financial performance. We generally identify forward-looking statements by terminology such as may, will, should, expects, plans, anticipates, could, intends, target, projects, contemplates, believes, estimates, p strategy, goal or continue or the negative of these terms or other similar words, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements regarding our or our management s expectations, hopes, beliefs, intentions or strategies regarding the future, such as our estimates regarding anticipated operating losses, future revenues and projected expenses; our expectations for commercialization of our Quell products; our liquidity and our expectations regarding our needs for and ability to raise additional capital; our ability to manage our expenses effectively and raise the funds needed to continue our business; our belief that there are unmet needs for the management of chronic pain and in the diagnosis and treatment of diabetic neuropathy; our expectations surrounding Quell and DPNCheck; our expected timing and our plans to develop and commercialize our products; our ability to meet our proposed timelines for the commercial availability of our products; the success and timing of our studies; our ability to obtain and maintain regulatory approval of our existing products and any future products we may develop; regulatory and legislative developments in the United States and foreign countries; the performance of our third-party manufacturers; our ability to obtain and maintain intellectual property protection for our products; the successful development of our sales and marketing capabilities; the size and growth of the potential markets for our products and our ability to serve those markets; our plan to make Quell more broadly available through retail distribution; our belief that there are significant opportunities to market Quell outside the United States; our estimate of our customer returns of our products; the rate and degree of market acceptance of any future products; our reliance on key scientific management or personnel; the payment and reimbursement methods used by private or governmental third-party payers; and other factors discussed elsewhere in this prospectus or any document incorporated by reference herein or therein. The forward-looking statements contained in this prospectus are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in the section titled Risk Factors. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary from those projected in these forward-looking statements. The forward-looking statements made in this prospectus relate only to events as of the date on which the statements are made. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. Risk Factors and Business, as well as other sections in this prospectus or incorporated by reference into this prospectus, discuss some of the factors that could contribute to these differences.

This prospectus also contains market data related to our business and industry. These market data include projections that are based on a number of assumptions. While we believe these assumptions to be reasonable and sound as of the date of this prospectus, if these assumptions turn out to be incorrect, actual results may differ from the projections based on these assumptions. As a result, our markets may not grow at the rates projected by these data, or at all. The failure of these markets to grow at these projected rates may have a material adverse effect on our business, results of operations, financial condition and the market price of our common stock.

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USE OF PROCEEDS

We estimate that the net proceeds to us from this offering will be approximately $ million, from the sale of $15.0 million of the securities offered by us in this offering, after deducting estimated Placement Agent s fees and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds of this offering to support the United States commercialization program for Quell, product development, clinical studies and for general corporate purposes. Quell is our OTC wearable device for pain relief which was launched in the second quarter of 2015. It utilizes our proprietary non-invasive neuro-stimulation technology to provide relief from chronic intractable pain, particularly nerve pain due to diabetes and lower back problems.

Specifically, we plan to use the net proceeds from this offering as follows:

Advertising and Promotion. Quell promotional efforts are essential to expanding product awareness leading to device placements and growth of our installed base of users. Continuous users drive the sales of replacement electrodes and other consumables which are essential to our business model. Quell promotion includes television advertising, including direct response television (DRTV), social media advertisements on Google, Facebook, Yahoo and others; public relations outreach to on-line and traditional print media; and cultivation of thought leaders, chronic pain-focused organizations, and discussion forums. We anticipate that approximately $ million of the net proceeds will be used to fund advertising and promotion.

Product Innovation. We believe that Quell is unique among products currently available for managing chronic pain. Our competitive position is strong. Innovation will be essential to sustaining competitive advantage and expanding our intellectual property position. Our product development strategy is focused on the annual delivery of new features that enhance usability and biometric tracking. These include form factor changes, electrode improvements and expanding digital health integration. We anticipate that approximately $ million of the net proceeds will be used for product development.

Cost of Goods Sold (COGS) Improvement. We have identified specific opportunities to reduce Quell COGS with both near-term and longer-term initiatives underway. Lower COGS would improve gross margins, thereby providing pricing flexibility, which may be necessary to expand Quell adoption. COGS initiatives require investment in engineering design and equipment in addition to manufacturing process improvements. We anticipate that approximately $ million of the net proceeds will be used for product COGS improvements.

Clinical Studies. Quell is an FDA-cleared Class 2 medical device. We expect that an expanding body of evidence from clinical studies will build Quell credibility among health care professionals and support our marketing efforts. We plan small-scale clinical studies to assess efficacy in key pain indications, reduction in prescription opioid use, and improvements in sleep, among others. We anticipate that approximately $ million of the net proceeds will be used for clinical studies.

General Corporate Purposes. The remaining proceeds, and any proceeds we receive from the exercise of the 2016 warrants, will be used for working capital purposes.

The expected use of net proceeds from this offering represents our current intentions based upon our present plans and business conditions. The amounts and timing of our actual expenditures depend on numerous factors, including the level of Quell sales as well as sales of our current products, changes we may make to the business that affect ongoing operating expenses, changes we may make in our business strategy, regulatory developments affecting our existing products, changes in our research and development spending plans, and other items affecting our forecasted level of expenditures and use of cash resources. Depending on the outcome of these factors, our plans and priorities may change, and we may apply the net proceeds from this offering differently than we currently anticipate. Changes in any

of these factors could mean that we delay or refocus the pursuit of any aspect of our commercialization plans for Quell in ways that we cannot currently predict. As a result, our management will retain broad discretion over the allocation of the net proceeds of this offering. Investors will be relying on the judgment of our management regarding the application of the proceeds of this offering.

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Pending specific utilization of the net proceeds described above, we intend to invest the net proceeds in United States government securities and other short term, investment grade, interest bearing securities.

PRICE RANGE OF OUR COMMON STOCK

Our common stock is traded on The NASDAQ Capital Market under the symbol NURO . The price range per share reflected in the table below is the high and low sales prices of our common stock as reported by NASDAQ (rounded to the nearest penny) for the periods presented. Market values have been adjusted to reflect a 1-for-4 reverse split of our common stock effected on December 1, 2015.

	High	Low
Fiscal Year 2016		
First Quarter	$ 2.35	$ 1.35
Second Quarter	$ 2.36	$ 1.51
Third Quarter	$ 1.80	$ 1.36
Fourth Quarter (through October 19, 2016)	$ 1.60	$ 1.40
Fiscal Year 2015		
First Quarter	$ 8.20	$ 6.40
Second Quarter	$ 6.80	$ 3.36
Third Quarter	$ 4.96	$ 2.84
Fourth Quarter	$ 3.72	$ 1.88
Fiscal Year 2014		
First Quarter	$ 12.56	$ 8.68
Second Quarter	$ 10.44	$ 6.68
Third Quarter	$ 12.60	$ 6.28
Fourth Quarter	$ 8.04	$ 6.08

As of September 30, 2016, there were approximately 81 stockholders of record of our common stock. Because many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock. We currently intend to retain any future earnings to finance the growth and development of our business. Therefore, we do not anticipate declaring or paying any cash dividends in the foreseeable future. Any future determination as to the declaration and payment of dividends, if any, will be at the discretion of our Board of Directors and will depend on then existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our Board of Directors may deem relevant. Our credit agreement also restricts our ability to pay dividends. Holders of the Series E convertible preferred stock will not be entitled to receive any dividends, unless and until specifically declared by our Board of Directors.

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CAPITALIZATION

The following table describes our capitalization and cash and cash equivalents as of September 30, 2016, on (A) an actual basis and (B) an as adjusted basis to reflect the sale of $15,000,000 of Units (assuming for this purpose, a sale of only Class A Units) offered hereby and the net proceeds of $ after deducting Placement Agent s fees and estimated offering expenses by us. The as adjusted information presented is illustrative only and will change based on the actual offering price and other terms of this offering determined at pricing. You should read this capitalization table together with Use of Proceeds, the financial statements and related notes that are 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 contained in our Annual Report on Form 10-K for the year ended December 31, 2015 and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, both of which are incorporated by reference into this prospectus.

	As of September 30, 2016	
	Actual	As adjusted
Cash and cash equivalents	$7,568	$
Common stock warrant liability	$52	$
Stockholders equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized, actual, as adjusted, and as adjusted, converted no shares issued and outstanding, actual, as adjusted, and as adjusted, converted		
Convertible preferred stock, $0.001 par value; 193,181 shares designated actual, and shares designated, as adjusted; and 20,500 shares issued and outstanding, actual, and shares issued and outstanding, as adjusted		
Common stock, $0.0001 par value; 100,000,000 shares authorized, 5,318,273 shares issued and outstanding; as adjusted, and shares issued and outstanding, as adjusted		
Additional paid-in capital	183,374	
Accumulated deficit	(175,664)	
Total stockholders equity	7,710	
Total capitalization	$7,762	$

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The preceding table excludes an aggregate of 10,892,929 shares of common stock issuable upon the conversion of (i) 500 shares of Series B convertible preferred stock and (ii) 19,639 shares of Series D convertible preferred stock; 28,206,975 shares of common stock issuable upon the exercise of warrants outstanding as of September 30, 2016, at a weighted average exercise price of $2.76 per share; 731,472 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2016, at a weighted average exercise price of $4.59 per share; 27,316 shares of common stock available for future issuance under our 2004 Stock Option and Incentive Plan; 50,000 shares of common stock available for future issuance under our 2009 Non-Qualified Inducement Stock Plan; and 115,585 shares of our common stock available for future issuance under our 2010 Employee Stock Purchase Plan. The preceding table also excludes shares of common stock issuable upon the exercise of warrants, including warrants to be issued to the Placement Agent, to be sold in this offering.

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DILUTION

If you invest in our common stock, your ownership interest will be diluted to the extent of the difference between the amount per share paid by purchasers of shares of our common stock in this offering and the pro forma net tangible book value per share of our common stock immediately after the closing of this offering.

Our net tangible book value is the amount of our total tangible assets less our total liabilities. Net tangible book value per share is our net tangible book value divided by the number of shares of common stock outstanding as of September 30, 2016. Our net tangible book value as of September 30, 2016 was $7.7 million, or $1.45 per share, based on 5,318,273 shares of our common stock outstanding as of September 30, 2016.

The information below assumes only Class A Units are sold in this offering. To the extent we sell any Class B Units, the same aggregate number of common stock equivalents resulting from this offering would be convertible under the Series E convertible preferred stock issued as part of the Class B Units.

After giving effect to the sale of $15,000,000 Units by us in this offering at an assumed public offering price of $ per Unit, the closing price of our common stock on the NASDAQ Capital Market on October , 2016, and after deducting estimated Placement Agent s fees and commissions and estimated offering expenses payable by us, our pro forma net tangible book value as of September 30, 2016 would have been approximately $ million, or $ per share of common stock. This calculation excludes the proceeds, if any, from the exercise of warrants issued in this offering. This represents an immediate increase in pro forma net tangible book value of $ per share to our existing stockholders and an immediate dilution of $ per share to investors purchasing shares of common stock in this offering.

The following table illustrates this dilution on a per share basis:

Public offering price per Unit		$
Net tangible book value per share at September 30, 2016	$ 1.45	
Increase to net tangible book value per share attributable to investors purchasing our common stock in this offering	$	
Pro forma net tangible book value per share as of September 30, 2016, after giving effect to the offering		$
Dilution of pro forma net tangible book value per share to investors purchasing our common stock in this offering		$

The information above is based on 5,318,273 shares outstanding as of September 30, 2016 and excludes:

10,892,929 shares of common stock issuable upon the conversion of (i) 500 shares of Series B convertible preferred stock and (ii) 19,639 shares of Series D convertible preferred stock;
28,206,975 shares of common stock issuable upon the exercise of warrants outstanding as of September 30, 2016, at a weighted average exercise price of $2.76 per share;
731,472 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2016, at a weighted average exercise price of $4.59 per share;
27,316 shares of common stock available for future issuance under our 2004 Stock Option and Incentive Plan;
50,000 shares of common stock available for future issuance under our 2009 Non-qualified Inducement Stock Plan; and
115,585 shares of our common stock available for future issuance under our 2010 Employee Stock Purchase Plan.

To the extent that any of these outstanding options are exercised, or warrants, including the warrants issued in this offering, are exercised or we issue additional shares under our equity incentive plans, there will be further dilution to new investors. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

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BUSINESS

Overview

NeuroMetrix is a commercial stage, innovation driven healthcare company combining bioelectrical and digital medicine to address chronic health conditions including chronic pain, sleep disorders, and diabetes. 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.

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

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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 third quarter of 2016, approximately 45,000 Quell devices plus electrodes and accessories were shipped to customers. Quell revenues for the year ended December 31, 2015 and for the nine months ended September 30, 2016 were approximately $2.1 million and $4.9 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 retail merchandisers including Target, CVS and Walgreens, and via health care professionals such as pain management physician practices and podiatry practices. Distribution is supported by television promotion 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. In June 2016, we filed with the European Medicines Agency for regulatory approval to market Quell in the European Union and, assuming we receive such approval, we plan to initiate marketing during 2017.

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 nine months ended September 30, 2016 were approximately $1.7 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 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 2014; in China where we

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have received regulatory approval and are working with Omron Healthcare toward commercial launch late 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 is 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. To date, product returns have averaged 28%. 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 retail merchandisers including Target, CVS and Walgreens, and via select health care professionals. Distribution is supported by television promotion designed to expand product awareness. Following commercial launch through the third quarter of 2016 approximately 45,000 devices and accessories were shipped to customers with a total invoiced value of $10.2 million prior to the impact of product returns.

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

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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 10,300 devices through September 30, 2016. We believe that the launch of Quell and contraction of the DME distribution channel due to Medicare competitive bidding will significantly 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.

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 2.4 million patient studies have been performed using our NC-stat technology and there have been approximately 7.0 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 3,200 devices had been placed with customers through September 30, 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 2.4 million patient studies have been performed using our NC stat technology and there have been approximately 7.0 million nerve tests, including 1.3 million sural nerve tests. As of September 30, 2016, we had an installed base of approximately 400 active customers using our ADVANCE System.

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The following chart summarizes our previously marketed products and currently marketed products.

Product	Time on Market	Technology	Primary Clinical Indications	No. Patients Tested/Treated
Quell	Q2 2015 present	Transcutaneous Electrical Nerve Stimulation	Relief for chronic, intractable pain	> 45,000
SENSUS	Q1 2013 present	Transcutaneous Electrical Nerve Stimulation	Relief for chronic, intractable pain	> 10,000
DPNCheck	Q4 2011 present	Nerve Conduction	Diagnosis and evaluation of peripheral neuropathies, such as DPN	> 595,000
ADVANCE	Q2 2008 present	Nerve Conduction	Diagnosis and evaluation of CTS, low back pain, peripheral neuropathies (including DPN)	> 1,850,000 (ADVANCE and NC-stat combined)
NC-stat	Q2 1999 Q3 2010	Nerve Conduction	Diagnosis and evaluation of CTS, low back pain, peripheral neuropathies (including DPN)	

Customers

Customers for our therapeutic products, Quell and SENSUS, include consumers, patients, retail merchandisers, health care professionals (physicians and clinics), and durable medical equipment (DME) suppliers in the United States. Customers for our diagnostic products, DPNCheck and ADVANCE, include physicians, clinics, hospitals, managed care organizations, and independent distributors in the United States and abroad. Through September 30, 2016, approximately 45,000 Quell devices were shipped. SENSUS was launched in 2013 and is sold to DME suppliers who, in turn, distribute the product along with consumables directly to patients. SENSUS customers purchased approximately 10,300 devices since launch. DPNCheck shipments commenced in 2011 and approximately 3,200 devices had been placed with customers through September 30, 2016. These customers include managed care organizations, retail health businesses, endocrinologists, podiatrists and primary care physicians. As of September 30, 2016, we had an installed base of approximately 400 active customers using our ADVANCE System. These customers include primary care, internal medicine, orthopedic and hand surgeons, pain medicine physicians, neurologists, physical medicine and rehabilitation, or PM&R, physicians, and neurosurgeons. At September 30, 2016, one customer accounted for 11% of accounts receivable and for the nine months ended September 30, 2016, one customer accounted for 11% of revenue.

Geographic Information

Substantially all of our assets, revenues, and expenses for 2015, 2014, 2013, and for the nine months ended September 30, 2016, were located at or derived from operations in the United States. In addition, we have had sales through distributors in Europe, Asia, the Middle East and various regions. During the nine months ended September 30, 2016, and for the years ended December 31, 2015, 2014 and 2013, international revenues accounted for approximately 11%, 19%, 19%, and 16%, respectively, of our total revenues.

Sales, Marketing, and Distribution

Quell was launched in the second quarter of 2015. It 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 retail merchandisers including Target, CVS and Walgreens, and via health care professionals such as pain management physician practices and podiatry practices. Distribution is supported by television promotion designed to expand product awareness. We believe there are significant opportunities to market Quell outside

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of the United States, particularly in Western Europe, Japan and China. We have filed for regulatory approval to market Quell in the European Union and, assuming we receive such approval, we plan to initiate marketing during 2017.

SENSUS is sold through a combination of national and regional DME suppliers whose sales representatives call on endocrinologists, podiatrists, and primary care physicians that are challenged with trying to manage chronic pain in their patients, including patients with painful diabetic neuropathy. The efforts of DME suppliers are coordinated from our corporate office.

Our U.S. sales efforts for DPNCheck focuses on Medicare Advantage providers who assume financial responsibility and the associated risks for the health care costs of their patients. We believe that DPNCheck presents an attractive clinical case with early detection of neuropathy allowing for earlier clinical intervention to help mitigate the effects of neuropathy on both patient quality of life and cost of care. Also, the diagnosis and documentation of neuropathy provided by DPNCheck helps clarify the patient health profile which, in turn, may have a direct, positive effect on the Medicare Advantage premium received by the provider. We believe that attractive growth opportunities exist outside the United States, including Japan where DPNCheck is sold by our distribution partner Omron Healthcare; in China where we recently received regulatory approval and are working with Omron Healthcare toward commercial launch in late 2016; and in Mexico where our distributor Scienta Farma initiated sales in the fourth quarter of 2015.

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

Quell sales and marketing efforts are led by our Senior Vice President, Consumer. Sales and marketing support for DPNCheck, ADVANCE and SENSUS are provided by our Senior Vice President, Commercial Operations and other staff in our corporate office.

We invest in technical, clinical, and business practices training for our commercial employees including sales and marketing and customer services staff. Promotion and sales of medical devices are highly regulated not only by the FDA, but also by the U.S. Centers for Medicare and Medicaid Services, or CMS, and the Office of Inspector General, or OIG, and, outside the United States, by other international bodies, and are subject to federal and state fraud and abuse enforcement activities. See FDA and other Governmental Regulation below.

Manufacturing and Supply

We perform final assembly and servicing of our Quell, SENSUS and DPNCheck devices at our manufacturing facility in Massachusetts. The ADVANCE device, which is no longer in production, but for which we continue to sell accessories was previously manufactured by an outside manufacturer and is now serviced by us. Outside suppliers provide us the subassemblies and components that we use in manufacturing Quell, SENSUS and DPNCheck, as well as our consumable biosensor/electrodes. We maintain alternative suppliers for some but not all of the subassemblies and key components and are expanding our list of alternative suppliers. Consumable biosensor/electrodes are manufactured to our specifications by single, long standing suppliers. In outsourcing, we target companies that meet FDA, International Organization for Standardization, or ISO, and other quality standards supported by internal policies and procedures. Supplier performance is maintained and managed through a corrective action program ensuring all product requirements are met or exceeded. Following the receipt of products or product components from our third-party manufacturers, we conduct the necessary inspection, final assembly, packaging, and labeling at our corporate headquarters facility. We believe these manufacturing relationships minimize our capital investment,

provide us with manufacturing expertise, and help control costs.

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

MC Assembly, Inc., a contract manufacturer, initiated manufacture during 2016 of sub-assemblies for Quell at a facility in Massachusetts.

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Polymer Flexible Circuits, Inc. or Parlex, has been manufacturing electrodes for us since 1999. In 2006 we entered into a manufacturing agreement with Parlex for the manufacture and supply of our requirements of nerve specific electrodes for resale in the United States. Under the agreement, Parlex agreed not to manufacture electrodes to be used to measure nerve conduction for any other company during the term of the agreement and, in some cases, for a period of one year thereafter. This agreement will continue indefinitely until terminated by either party upon not less than 18 months prior written notice to the other party. Parlex manufactures our electrodes at a facility in Massachusetts and also has the ability to perform certain manufacturing steps for our electrodes at a second site located in the United Kingdom.

Katecho, Inc., a full service original equipment manufacturer, or OEM, specializing in medical and cosmetic devices, manufactures biosensors for use with our DPNCheck device and electrodes for use with our SENSUS and Quell devices under normal commercial terms contained in our purchase orders. Katecho manufactures electrodes at its facility in Iowa.

We and our third-party manufacturers are registered with the FDA and subject to compliance with FDA quality system regulations. We are also ISO registered and undergo frequent quality system audits by European agencies. Our ADVANCE System and DPNCheck are cleared for marketing within the United States, Canada, and the European Union. DPNCheck is also cleared for marketing in Japan, China and Mexico. Our neuro-stimulation systems for chronic pain, Quell and SENSUS, are cleared for marketing in the United States and Canada. Our facility is subject to periodic inspections by regulatory authorities, and may undergo compliance inspections conducted by the FDA and corresponding state agencies. As a registered device manufacturer, we will undergo regularly scheduled FDA quality system inspections. However, additional FDA inspections may occur if deemed necessary by the FDA.

Research and Development

We believe that we have research and development (R&D) capability that is unique to the industry with nearly two decades of experience in developing diagnostic and therapeutic devices involving the stimulation and measurement of nerve signals for clinical purposes. This group has extensive experience in neurophysiology, biomedical instrumentation, signal processing, biomedical sensors, and information systems. Our R&D team works closely with our marketing group and customers to design products that are focused on improving clinical outcomes. The team consists of ten people including one who holds an M.D. degree and three who hold Ph.D. degrees. It includes the extensive involvement of our founder and Chief Executive Officer who holds both M.D. and Ph.D. degrees and who also coordinates the clinical programs that we support.

R&D efforts currently encompass the following areas:

Quell Innovation. Quell utilizes our proprietary wearable intensive nerve stimulation (WINS) technology to provide relief from chronic pain which can encompass lower back problems, fibromyalgia, arthritis, painful diabetic neuropathy and others. Quell is unique among OTC neuro-stimulation products in its clinical indications, technology, personalization and digital health features. Our R&D efforts to date have provided us first-to-market competitive advantage. We anticipate that success will attract competition and that we must continually innovate to maintain a leadership position. Our product development strategy is focused on the annual delivery of new features that enhance usability and biometric tracking. These include form factor changes, electrode improvements and expanding digital health integration. We intend to strengthen our intellectual property position with the development of additional know-how and a growing body of patent applications.

Cost of Goods Sold (COGS) Improvement. We have identified specific opportunities to reduce Quell COGS, with both near-term and longer-term initiatives underway. Lower COGS would improve gross margins, thereby providing

pricing flexibility, which may be necessary to expand Quell adoption. These COGS initiatives involve R&D support as well as investment in engineering design and equipment.

Support for DPNCheck. DPNCheck is our quantitative nerve conduction test for peripheral neuropathies including DPN. Its usage is growing in the Medicare Advantage market in the United

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States and in Japan. DPNCheck recently received regulatory approval in China and we are working with Omron Healthcare toward commercial launch in late 2016. The characteristics of new markets often require device modification for local acceptance which, in turn, involves our R&D team. We are collaborating with Omron Healthcare in Asia for DPNCheck and anticipate continuing engineering support requirements.

Support clinical studies for our wearable technology. Quell is an FDA-cleared Class 2 medical device. We expect that an expanding body of evidence from clinical studies will continue to build Quell credibility among health care professionals and support our marketing efforts. As an example, in 2015 we completed an independent post-market clinical study for Quell. Results were positive with 81% of subjects reporting an improvement in their chronic pain and overall health, and 67% reporting a reduction in their use of pain medications while using Quell. This was directly relevant to Quell marketing and reinforced the need to continue to build the clinical foundation for Quell. We have underway small-scale clinical studies to assess efficacy in key pain indications, reduction in prescription opioid use in cancer patients, and improvements in sleep, among others. Also, we are exploring new clinical indications such as restless leg syndrome.

R&D expenses were approximately $3.9 million, $4.1 million, and $3.4 million for 2015, 2014, and 2013, respectively. R&D expenses for the nine months ended September 30, 2016 were approximately $3.5 million.

Clinical Program

Our clinical program operates under the direction of our Chief Executive Officer. This may from time-to-time be comprised of internal, collaborative, and external clinical studies. Internal clinical studies are designed and implemented directly by us for the purposes of product design and early clinical validation. Collaborative studies are conducted together with leading researchers around the world to provide clinical validation and to explore the clinical utility of our products. External studies are entirely independent of us, although in many cases the researchers request unrestricted grants for financial and/or material support, such as for devices and consumables. External studies may examine the clinical performance and utility of our products or our products may be used as outcomes measures.

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

During the third quarter of 2015 we completed an external pilot study with a leading researcher at the Massachusetts General Hospital employing our wearable technology for restless leg syndrome, or RLS. The results indicated a meaningful reduction in RLS symptoms and as a result, we will consider a study in a larger RLS population. Also during the third quarter of 2015 we completed an external study managed by Ipsos-Vantis of our wearable technology for chronic pain among subjects with several diseases accompanied by chronic pain. The results indicated a statistically significant improvement in chronic pain and a reduction in use of pain medications. The encouraging results have led us to planning further studies during 2016 with the goal of expanding the clinical foundation for our wearable technology for chronic pain.

Competition

We believe there is no direct competition to our wearable neuro-stimulation devices, Quell and SENSUS, for the treatment of chronic pain. The most common approach to chronic pain is pain medication. This includes over-the-counter drugs (such as Advil and Motrin), and prescription drugs including anti-convulsants (such as Lyrica and Neurontin) and anti-depressants (such as Cymbalta and Elavil). Topical creams may also be used (such as Zostrix and Bengay). With severe pain, narcotic 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.

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Reflecting the difficulty in treating chronic pain, inadequate relief leads many pain sufferers to turn to the over-the-counter market for supplements or alternatives to prescription pain medications. These include non-prescription medications, topical creams, lotions, electrical stimulators, dietary products, braces, sleeves, pads and other items. In total they account for over $4 billion in annual spending in the United States on pain relief products.

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; however, both 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. We believe that Quell and SENSUS clinical and market claims covering chronic pain and sleep, technical characteristics of high power and automation, and the digital health integration characteristics (Quell), place our products in a unique neuro-stimulation category. There are numerous manufacturers of transcutaneous electrical nerve stimulation devices including widely marketed over-the-counter TENS such as Sanofi s IcyHotSmartRelief, Omron PM3030 and Homedics RapidRelief.

We believe that DPNCheck is currently the only objective and standardized test for DPN widely available at the point-of-care. The American Diabetes Association, or ADA, and other organizations recommend at least annual evaluation of all people with diabetes for DPN. Due to cost and availability, this screen is typically performed with a simple (5.07/10g) monofilament. This subjective method identifies late stage neuropathy where intervention is generally limited to foot care. Experts in the field have indicated that there is an unmet need for a practical, objective, and sensitive test for diabetic neuropathy that can be widely deployed in the regular care of all people with diabetes. Monofilaments (5.07/10g) are a commodity sold by a number of medical supply companies.

There are several companies that sell neurodiagnostic devices that compete with our ADVANCE System. These companies include Cadwell Laboratories, Inc. and Natus Medical Incorporated. Natus Medical Incorporated has substantially greater financial resources than we do. Natus Medical Incorporated and Cadwell Laboratories, Inc. have established reputations as having effective worldwide distribution channels for medical instruments to neurologists and PM&R physicians.

Intellectual Property

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

Patents

As of September 30, 2016, we had 43 issued U.S. patents, three issued foreign patents, and 34 patent applications, including 15 U.S. applications, and 18 foreign applications. Our wearable therapeutic products have one issued U.S. utility patent and three issued design patents plus 26 utility and design patent applications. For our DPNCheck diagnostic device, three utility patents were issued that cover the core technology and there are seven additional utility patent applications.

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. In particular, seven of our issued U.S. utility patents

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covering various aspects of the legacy neurodiagnostic products will expire on the same date in 2017. Although the patent protection for material aspects of these products covered by the 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.

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

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

Trademarks

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

Third-Party Reimbursement

Procedures performed with our neurodiagnostic medical devices including ADVANCE and DPNCheck may be paid for by third-party payers, including government health programs, such as Medicare, and private insurance and managed care organizations. The 2016 Physicians Fee Schedule published by CMS includes CPT 95905 for nerve conduction studies performed with pre-configured electrode arrays such as are used with the DPNCheck device and the ADVANCE System.

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

In the United States, some insured individuals are receiving their medical care through managed care programs which monitor and often require pre-approval of the services that a member will receive. Some managed care programs are paying their providers on a per capita basis a predetermined annual payment per member which puts the providers at financial risk for the services provided to their members. This is generally the case under Medicare Advantage where contracting insurers receive a monthly capitated fee from CMS to provide all necessary medical care to participating members. These capitated fees are adjusted under CMS s risk-adjustment model which uses health status indicators, or risk scores, to ensure the adequacy of payment. Members with higher risk codes generally require more healthcare resources than those with lower risk codes. In turn, the insurer fully absorbs the risk of patient health care costs. Insurers may share a portion of the risk

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with provider organizations such as independent practice associations (IPAs) with whom they contract to provide medical services to their members. Proper assessment of each member s health status and accurate coding helps to assure that insurers receive capitation fees consistent with the cost of treating these members. Nerve conduction testing can provide valuable, early identification of neuropathy leading to clinical interventions that can reduce health care costs. Also, these tests provide valuable input regarding each member s health risk status which can result in more appropriate capitated payments from CMS. We believe that the clinical and economic proposition for DPNCheck is attractive to Medicare Advantage insurers and risk bearing provider organizations. We are focusing our sales effort for DPNCheck on the Medicare Advantage managed care market segment.

We believe that the SENSUS pain management therapeutic system is considered a durable medical equipment (DME) benefit and is reimbursed for chronic pain by Medicare and many commercial insurers under HCPCS code EO730 for the device and under HCPCS code A4595 for the consumable electrodes. These pre-existing codes apply to DME benefits employing transcutaneous electrical nerve stimulation equipment. We expect that Quell will generally not be reimbursed by third party payers.

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

Our success in selling DPNCheck, SENSUS and ADVANCE will depend upon, among other things, our customers receiving, and our potential customers' expectation that they will receive sufficient reimbursement or patient capitated premium adjustments from third-party payers for procedures or therapies using these products. See Risk Factors, *If health care providers are unable to obtain sufficient reimbursement or other financial incentives from third-party health care payers related to the use of our products other than Quell, the adoption of our products and our future product sales will be materially adversely affected.*

FDA and Other Governmental Regulation

FDA Regulation

Our products are medical devices subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act, or FDCA, and the regulations promulgated thereunder, as well as by other regulatory bodies in the United States and abroad. The FDA classifies medical devices into one of three classes on the basis of the amount of risk associated with the medical device and the controls deemed necessary to reasonably ensure their safety and effectiveness:

Class I, requiring general controls, including labeling, device listing, reporting and, for some products, adherence to good manufacturing practices through the FDA s quality system regulations and pre-market notification;
Class II, requiring general controls and special controls, which may include performance standards and post-market surveillance; and
Class III, requiring general controls and pre-market approval, or PMA, which may include post-approval conditions and post-market surveillance.

Before being introduced into the market, our products must obtain market clearance or approval through the 510(k) pre-market notification process, the *de novo* review process or the PMA process, unless they qualify for an exemption from these processes. See Risk Factors, *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.*

510(k) Pre-Market Notification Process

To obtain 510(k) clearance, we must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to a legally marketed Class I or II medical device or to a Class III device marketed prior to May 28, 1976 for which the FDA has not required the submission of a PMA application. In some cases, we may be required to perform clinical trials to support a claim of substantial equivalence. If clinical trials are required, we must submit an application for an investigational device exemption, or IDE,

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which must be cleared by the FDA prior to the start of a clinical investigation, unless the device and clinical investigation are considered non-significant risk by the FDA or are exempt from the IDE requirements. It generally takes three months from the date of the pre-market notification submission to obtain a final 510(k) decision, but it can be significantly longer.

After a medical device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires the submission of a new 510(k) clearance or could require *de novo* classification or PMA. The FDA allows each company to make this determination, but the FDA can review the decision. If the FDA disagrees with a company s decision not to seek FDA authorization, the FDA may require the company to seek 510(k) clearance or PMA. The FDA also can require the company to cease marketing and/or recall the medical device in question until its regulatory status is resolved.

De Novo Review Process

If a previously unclassified new medical device does not qualify for the 510(k) pre-market notification process because there is no predicate device to which it is substantially equivalent, and if the device may be adequately regulated through general controls or special controls, the device may be eligible for *de novo* classification through what is called the *de novo* review process. In order to use the de novo review process, a company must receive a letter from the FDA stating that, because the device has been found not substantially equivalent to a legally marketed Class I or II medical device or to a Class III device marketed prior to May 28, 1976 for which the FDA has not required the submission of a PMA application, it has been placed into Class III. After receiving this letter, the company, within 30 days, must submit to the FDA a request for a risk based down classification of the device from Class III to Class I or II based on the device s moderate or low risk profile which meets the definition of a Class I or Class II medical device. The FDA then has 60 days in which to decide whether to down classify the device. If the FDA agrees that a lower classification is warranted, it will issue a new regulation describing the device type and, for a Class II device, publish a Special Controls guidance document. The Special Controls guidance document specifies the scope of the device type and the recommendations for submission of subsequent devices for the same intended use. If a product is classified as Class II through the *de novo* review process, then that device may serve as a predicate device for subsequent 510(k) pre-market notifications.

PMA Process

If a medical device does not qualify for the 510(k) pre-market notification process and is not eligible for clearance through the *de novo* review process, a company must submit a PMA application. The PMA requires more extensive pre-filing testing than is required in the 510(k) and is more costly, lengthy and uncertain. The FDA will decide within 45 days of receiving a PMA whether it is sufficiently complete to permit a substantive review and if the PMA is complete, the FDA will notify the applicant that the PMA has been filed. The PMA process can take one to three years or longer, from the time the PMA application is filed with the FDA. The PMA process requires the company to prove that the medical device is safe and effective for its intended purpose. A PMA typically includes extensive pre-clinical and clinical trial data, and information about the device, its design, manufacture, labeling and components. Before approving a PMA, the FDA generally also performs an on-site inspection of manufacturing facilities for the product to ensure compliance with the FDA s quality system regulation, or QSR.

If FDA approves the PMA, the approved indications may be more limited than those originally sought. In addition, FDA s approval order may include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution and post-market study requirements. Failure to comply with the post-approval conditions can result in adverse enforcement or administrative actions, including the withdrawal of the approval. Approval of a new PMA application

or a PMA supplement may be required in the event of modifications to the device, including to its labeling, intended use or indication, or its manufacturing process that affect safety and effectiveness.

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Post-Approval Obligations

After a device is placed on the market, numerous regulatory requirements continue to apply. These include:

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

Regulatory Approvals and Clearances

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

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

As transcutaneous electrical nerve stimulators, the SENSUS and Quell pain therapy devices are Class II medical devices which received 510(k) clearance from the FDA in August 2012 and July 2014, respectively. In November 2012, the FDA provided 510(k) clearance for the disposable electrode used in conjunction with the SENSUS device, and in July 2013, the FDA provided 510(k) clearance for the use of SENSUS during sleep. The intended use of the SENSUS pain management therapeutic system is the symptomatic relief and management of chronic pain. In July 2014, our Quell device received 510(k) clearance for over-the-counter use and in November 2014, our Quell disposable electrode received 510(k) clearance for over-the-counter use. In January 2016, a number of new features were added to Quell and received 510(k) clearance, most notably use with an optional mobile app that contains several convenience features. The intended use of the Quell pain management therapeutic system is the symptomatic relief and management of chronic pain. The Quell device may also be used during nighttime sleep.

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Manufacturing Facilities

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

U.S. Anti-Kickback and False Claims Laws

In the United States, the federal Anti-Kickback Statute, as well as numerous state anti-kickback laws, prohibit the offer, payment, solicitation or receipt of kickbacks, bribes or other remuneration, whether direct or indirect, overt or covert, in cash or in kind, intended, among other things, to induce the purchase or recommendation of healthcare products and services. While the federal law applies only to products and services for which payment may be made by a federal healthcare program, the state laws may apply regardless of whether any public healthcare funds are involved. Violations of these laws can lead to severe civil and criminal penalties, including exclusion from participation in federal healthcare programs. These laws are potentially applicable to manufacturers of medical devices, such as us, and to hospitals, physicians and other potential purchasers of our products.

Also, the federal False Claims Act, as well as many state false claims statutes, provides civil and criminal penalties for presenting, or causing to be presented, to third-party payers for reimbursement, claims that are false or fraudulent, or which are for items or services that were not provided as claimed. Under the federal False Claims Act, in addition to actions initiated by federal law enforcement authorities, the statute authorizes qui tam actions to be brought on behalf of the federal government by a private party in certain circumstances and, if successful, that private party can share in any monetary recovery. Any challenge by federal or state enforcement officials or others under these laws, could have a material adverse effect on our business, financial condition, and results of operations.

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

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Medicare fiscal intermediaries assumed coverage for CPT 95905 for at least 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 nine months ended September 30, 2016 were approximately $1.6 million. We currently manage this business to optimize cash flow.

Employees

As of September 30, 2016, we had a total of 43 full-time employees. Of these employees, 10 were in research and development, 15 in sales and marketing, 10 in production/distribution, and eight in general and administrative services. One employee holds both M.D. and Ph.D. degrees, one employee holds an M.D. degree and two additional employees hold Ph.D. degrees. Our employees are not represented by a labor union and are not subject to a collective bargaining agreement. We have never experienced a work stoppage. We believe that we have good relations with our employees.

Properties

Our headquarters and engineering activities are located in an approximately 12,000 square foot leased facility in Waltham, Massachusetts and our manufacturing and fulfillment activities are located in a 6,000 square foot leased facility in Woburn, Massachusetts. We believe these facilities will be adequate for our needs during the foreseeable future.

Legal Proceedings

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

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PRINCIPAL AND MANAGEMENT STOCKHOLDERS

The following table sets forth certain information concerning beneficial ownership as of September 30, 2016, except as noted below, of our common stock by:

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

The number of common shares beneficially owned by each stockholder is determined under rules issued by the SEC regarding the beneficial ownership of securities. This information is not necessarily indicative of beneficial ownership for any other purpose. Under these rules, beneficial ownership of common stock includes (1) any shares as to which the person or entity has sole or shared voting power or investment power and (2) any shares as to which the person or entity has the right to acquire beneficial ownership within 60 days after September 30, 2016, including any shares that could be purchased by the exercise of options or warrants on or within 60 days after September 30, 2016. Each stockholder s percentage ownership is based on 5,318,273 shares of our common stock outstanding as of September 30, 2016 plus the number of shares of common stock that may be acquired by such stockholder upon exercise of options or warrants that are exercisable on or within 60 days after September 30, 2016.

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

Name and Address[1] of Beneficial Owner	Amount and Nature of Beneficial Ownership			Percent of Class of Total	Percent of Class of Total After the Offering
	Common Stock	Options[2]	Total		
Directors and Executive Officers					
Shai N. Gozani, M.D., Ph.D.	141,909	84,632	226,541	4.2 %	
Thomas T. Higgins	70,309	36,240	106,549	2.0 %	
Francis X. McGillin	37,886	28,125	66,011	1.2 %	
Allen Hinkle, M.D.	209	1,420	1,629	*	
David E. Goodman, M.D.	209	1,420	1,629	*	
Timothy R. Surgenor	1,834	1,420	3,254	*	
Nancy E. Katz	209	1,420	1,629	*	
David Van Avermaete		3,052	3,052	*	
All Current Directors and Executive Officers as a group (8 persons)	252,565	157,729	410,294	7.5 %	

Name and Address[1] of Beneficial Owner	Amount and Nature of Beneficial Ownership		Percent of Class of Total	Percent of Class
	Options[2]	Total		

	Common Stock			of Total After the Offering
Beneficial Owner of 5% or More Other than Directors or Executive Officers				
Sabby Management, LLC[3]	590,263	590,263	9.99	%

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

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

(2) Includes all options and/or warrants that are exercisable on or within 60 days from September 30, 2016 by the beneficial owner, except as otherwise noted.

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(3) Reflects shares of common stock issuable upon the exercise of warrants beneficially owned by Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. The amount does not include 25,910,321 shares of common stock issuable upon exercise of warrants issued to Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. in 2012, 2013, 2014, 2015 and 2016 and an aggregate of 10,880,554 shares of common stock issuable upon the conversion of 19,639 shares of Series D convertible preferred stock issued to Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd., some of which are subject to a 9.99% or 4.99% beneficial ownership limitation and related warrant exercise restriction. Sabby Management, LLC and Hal Mintz do not directly own shares of common stock, but are deemed to have beneficial ownership over these shares of common stock because Sabby Management, LLC is the investment manager for both Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. and Hal Mintz is the manager of Sabby Management, LLC. The address for the reporting persons is 10 Mountainview Road, Suite 205, Upper Saddle River, New Jersey 07458.

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TRANSACTIONS WITH RELATED PERSONS

Except as otherwise set forth below, we did not engage in any related person transactions during the years ended December 31, 2015, 2014 and 2013 and for the nine months ended September 30, 2016. Pursuant to our audit committee charter currently in effect, the audit committee is responsible for reviewing and approving, prior to our entry into any such transaction, all transactions in which we are a participant and in which any parties related to us has or will have a direct or indirect material interest.

Offerings of Convertible Preferred Stock and Warrants; Repurchases of Convertible Preferred Stock and Forfeiture of Warrants

In June 2016, we completed a private equity offering, or the June 2016 Offering, with Sabby Management, LLC and its affiliates, or Sabby, a principal stockholder, providing for the issuance of (i) 21,300 shares of Series D convertible preferred stock at a price of $1,000 per share, and (ii) warrants to purchase up to 11,800,554 shares of our common stock, at an exercise price of $1.69 per share for an aggregate purchase price of $21.3 million. We used $13.8 million of the proceeds from this offering to repurchase all of our outstanding Series C convertible preferred stock, which were issued in the December 2015 Offering, as described below. The June 2016 Offering resulted in approximately $6.7 million in net proceeds after deducting placement agent fees and expenses and the repurchase of $13.8 million of Series C convertible preferred stock. Each share of Series D convertible preferred stock has a stated value of $1,000 and is convertible, at any time at the option of the holder thereof, into a number of shares of our common stock determined by dividing the stated value by the initial conversion price of $1.805, subject to a 4.99% beneficial ownership limitation. As of September 30, 2016, there were 19,639 shares of Series D convertible preferred stock outstanding that were convertible into 10,880,554 shares of common stock.

In December 2015, we completed a private equity offering, or the December 2015 Offering, with Sabby, providing for the issuance of (i) 13,800 shares of Series C convertible preferred stock at a price of $1,000 per share, and (ii) warrants to purchase up to 10,823,528 shares of our common stock, at an exercise price of $2.30 per share, for an aggregate purchase price of $13.8 million. We used $6.3 million of the proceeds from this offering to repurchase 63,000 shares of Series B convertible preferred stock, which were issued in the May 2015 Offering, as described below. The December 2015 Offering resulted in approximately $6.7 million in net proceeds after deducting placement agent fees and expenses and the repurchase of $6.3 million of Series B convertible preferred stock. Each share of Series C convertible preferred stock has a stated value of $1,000 and is convertible, at any time at the option of the holder thereof, into a number of shares of our common stock determined by dividing the stated value by the initial conversion price of $2.55, subject to a 4.99% beneficial ownership limitation. All outstanding shares of Series C convertible preferred stock were repurchased in connection with the June 2016 Offering.

In May 2015, we completed an underwritten public offering, or the 2015 May Offering, of (i) 147,000 shares of Series B convertible preferred stock at a price of $100 per share, which is the stated value, and (ii) five year warrants to purchase up to 3,638,250 shares of common stock with an exercise price of $5.00 per share. As part of the 2015 May Offering, Sabby agreed to purchase 122,000 units at the public offering price of $100 per unit. Simultaneous with the closing of the 2015 May Offering, we repurchased from Sabby the then outstanding 3,206.357 shares of the Series A-4 convertible preferred stock for an aggregate purchase price of $3.2 million, which we refer to as the Repurchase. Additionally, as part of the Repurchase, Sabby agreed to forfeit warrants to purchase 392,936 shares of our common stock that were issued in connection with the original issuance of the Series A-4 convertible preferred stock, which warrants had an exercise price of $8.16. 63,000 shares of Series B convertible preferred stock were repurchased in connection with the December 2015 Offering. As of September 30, 2016, there were 500 shares of Series B convertible preferred stock outstanding that were convertible into 12,375 shares of common stock.

During June 2014 and June 2013, we and entities affiliated with Sabby entered into securities purchase agreements for two equity offerings that were similar in structure and in terms. The purchase agreement entered into in June 2014, or the 2014 Offering provided for the issuance of (i) 166,150 shares of common stock at a price of $8.16 per share, (ii) 2,621.859 shares of Series A-3 convertible preferred stock at a price of $1,000 per share, (iii) 4,022.357 shares of Series A-4 convertible preferred stock at a price of $1,000 per share, and (iv) five year warrants to purchase up to 980,393 shares of common stock with an exercise price of $8.16 per share. The 2014 offering resulted in approximately $8.0 million in gross proceeds, before deducting expenses.

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The purchase agreement entered into in June 2013, or the 2013 Offering, provided for the issuance of (i) 62,037 shares of common stock at a price of $8.38 per share, (ii) 1,066.254 shares of Series A-1 convertible preferred stock at a price of $1,000 per share, (iii) 3,370.510 shares of Series A-2 convertible preferred stock at a price of $1,000 per share, and (iv) five year warrants to purchase up to 591,484 shares of common stock with an exercise price of $8.00 per share. The 2013 Offering resulted in approximately $5.0 million in gross proceeds, before deducting placement agent fees and other expenses.

In these private equity offerings, each share of preferred stock has or had a stated value of $1,000 and is convertible at the option of the holder into the number of shares of common stock determined by dividing the stated value by the conversion price which is subject to adjustment as provided in each Certificate of Designation for the preferred stock. The preferred stock has no dividend rights, liquidation preference or other preferences over common stock and has no voting rights except as provided in its respective Certificate of Designation and as required by law.

As of December 31, 2015, all of the shares of Series A-1 convertible preferred stock, Series A-2 convertible preferred stock, Series A-3 convertible preferred stock and Series A-4 convertible preferred stock have either been converted into shares of common stock or repurchased by us and retired.

Common share amounts and exercise prices per share in the discussion above have been adjusted to reflect the 1-for-4 reverse split of our common stock completed on December 1, 2015.

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DESCRIPTION OF CAPITAL STOCK

The following description of our securities is intended as a summary only and is qualified in its entirety by reference to our amended and restated certificate of incorporation and amended and restated bylaws, which are filed as exhibits to the registration statement of which the prospectus forms a part, and to the applicable provisions of the Delaware General Corporation Law. We refer in this section to our amended and restated certificate of incorporation as our certificate of incorporation, and we refer to our amended and restated bylaws as our bylaws.

Authorized Capitalization

Our authorized capital stock consists of 100,000,000 shares of common stock, $0.0001 par value per share, and 5,000,000 shares of preferred stock, par value $0.001 per share, in one or more series. Of such preferred stock, 193,181 shares have been designated as convertible preferred stock, par value $0.001 per share. Prior to the completion of this offering, we will file a certificate of designation designating shares of preferred stock as Series E convertible preferred stock. As of September 30, 2016, we had outstanding 5,318,273 shares of our common stock, 19,639 shares of our Series D convertible preferred stock that were convertible into 10,880,554 shares of common stock, 500 shares of our Series B convertible preferred stock that were convertible into 12,375 shares of common stock and no shares of our Series A-1, A-2, A-3, A-4 or C convertible preferred stock. At that date, we also had an aggregate of 731,472 shares of common stock reserved for issuance upon exercise of outstanding stock options granted under our stock incentive plans, and an aggregate of 28,206,975 shares of common stock reserved for issuance upon the exercise of outstanding warrants to purchase common stock, excluding warrants to be issued pursuant to this offering.

On December 1, 2015, we amended our certificate of incorporation to effect a 1-for-4 reverse stock split of our common stock, or the Reverse Stock Split. As a result of the Reverse Stock Split, every four shares of our pre-reverse split common stock were combined and reclassified into one share of our common stock. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who otherwise would have been entitled to receive a fractional share in connection with the Reverse Stock Split received a cash payment in lieu thereof. The par value and other terms of the common stock were not affected by the Reverse Stock Split.

Common Stock

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

Subject to the preferential rights of any other class or series of stock, all shares of our common stock have equal dividend, distribution, liquidation and other rights, and have no preference, appraisal or exchange rights, except for any appraisal rights provided by Delaware law. Furthermore, holders of our common stock have no conversion, sinking fund or redemption rights, or preemptive rights to subscribe for any of our securities. Our certificate of

incorporation and bylaws do not restrict the ability of a holder of our common stock to transfer his or her shares of our common stock.

In the event of our liquidation or dissolution, holders of our common stock are entitled to share ratably in all assets remaining after payment of all debts and other liabilities, subject to the prior rights of any outstanding preferred stock. Holders of our common stock have no preemptive, subscription, redemption or conversion rights. All shares of our common stock will, when issued, be duly authorized, fully paid and nonassessable. The shares to be issued by us in this offering, and the shares to be issued by us upon exercise of the warrants to be issued in this offering in accordance with the terms of the warrants, will be when issued and paid for, validly issued, fully paid and nonassessable.

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In 2015, we received two notices from the Listing Qualifications Department of the NASDAQ Stock Market relating to the Company s failure to maintain certain listing requirements, including requirements relating to the minimum stockholder s equity amount and the minimum closing bid price, and we regained compliance with respect to both these notices before the end of fiscal year 2015. If we fail to continue to meet all applicable NASDAQ Capital Market requirements in the future and NASDAQ determines to delist our common stock, the delisting could substantially decrease trading in our common stock and adversely affect the market liquidity of our common stock. See Risk Factors , *There can be no assurance that we will be able to comply with the continued listing standards of The NASDAQ Capital Market*.

Preferred Stock

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

On June 8, 2016 we issued units consisting of (i) 21,300 shares of Series D convertible preferred stock at a price of $1,000 per share, and (ii) warrants to purchase up to 11,800,554 shares of common stock with an exercise price of $1.69 per share. Each share of Series D convertible preferred stock had a stated value of $1,000 and is convertible at the option of the holder into the number of shares of common stock determined by dividing the stated value by the initial conversion price of $1.805, which is subject to adjustment as provided in the Certificate of Designation for the Series D c