

NeuroMetrix, Inc.  
Form S-1/A  
May 22, 2015

As filed with the Securities and Exchange Commission on May 22, 2015

**Registration No. 333-188133**

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

**AMENDMENT NO. 13 TO  
FORM S-1  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

**NEUROMETRIX, INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

3841  
(Primary Standard Industrial  
Classification Code Number)

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

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

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

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

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Title of each class of securities to be registered	Proposed maximum aggregate offering price <sup>(1)</sup>	Amount of registration fee
145,000 Units consisting of:		
(i) 145,000 shares of Series B Convertible Preferred Stock, \$0.001 par value	\$ 14,500,000.00	\$ 1,684.90
(ii) 12,180,000 Warrants to purchase up to 12,180,000 shares of Common Stock, \$0.0001 par value <sup>(2)(5)</sup>	\$	\$
12,180,000 shares of Common Stock issuable upon conversion of the Series B Convertible Preferred Stock <sup>(3)(4)(5)(6)</sup>	\$	\$
12,180,000 shares of Common Stock issuable upon exercise of Warrants to purchase Common Stock <sup>(3)(4)</sup>	\$ 16,077,600.00	\$ 1,868.22
Warrants to be issued to the Underwriter <sup>(2)</sup>	\$	\$
304,500 shares of Common Stock issuable upon exercise of Warrants issued to the Underwriter <sup>(3)(5)</sup>	\$ 456,750.00	\$ 53.07
Total	\$ 31,034,350.00	\$ 3,606.19 <sup>(8)</sup>

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

(2) No registration fee required pursuant to Rule 457(g) under the Securities Act.

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

(4) We have calculated the securities included in this registration statement by assuming that each share of Series B Preferred Stock is convertible into 84 shares of Common Stock (rounded up to the nearest whole share) at an assumed conversion price of \$1.20 per share of Common Stock, which was 100% of the closing price of our Common Stock on The NASDAQ Capital Market on May 21, 2015 of \$1.20 per share, and that each Warrant is exercisable for one share of Common Stock at an assumed exercise price per share of \$1.32, which is 110% of the closing price of our Common Stock on The NASDAQ Capital Market on May 21, 2015 of \$1.20 per share.

(5) 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.

(6) No additional consideration is payable upon conversion of the Series B Convertible Preferred Stock. We have calculated the securities included in this registration statement by assuming that each Warrant issued to the Underwriter is exercisable for one share of Common Stock at an assumed exercise price per share of \$1.50, which is 125% of the closing price of our Common Stock on The NASDAQ Capital Market on May 21, 2015 of \$1.20 per share.

(8) Amount previously paid.

**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**

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**pursuant to said Section 8(a), may determine.**

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

**Subject to Completion, Dated May 22, 2015**

**145,000 Shares of Series B convertible preferred stock  
(and up to 12,180,000 Shares of Common Stock  
Underlying the Series B convertible preferred stock)  
12,180,000 Warrants to Purchase up to 12,180,000  
Shares of Common Stock  
(and up to 12,180,000 Shares of Common Stock  
Issuable Upon Exercise of the Warrants)**

We are offering 145,000 units to purchasers in this offering, with each unit consisting of (1) one share of Series B convertible preferred stock which is convertible into that number of shares of our common stock equal to \$100 divided by the conversion price of the Series B convertible preferred stock (rounded up to the nearest whole share) and (2) 84 warrants exercisable for an aggregate of 84 shares of our common stock, which amount of warrants and shares of common stock underlying the warrants both equal 100% of the number of shares of our common stock issuable upon conversion of one share of Series B convertible preferred stock at the conversion price (rounded up to the nearest whole share), at an exercise price per share equal to \$ , which is 110% of the closing price of our common stock on The NASDAQ Capital Market on the date of the underwriting agreement or the date immediately prior to such date. Each warrant will be immediately exercisable for one share of our common stock. This prospectus also covers up to 12,180,000 shares of common stock issuable upon conversion of the Series B convertible preferred stock and up to 12,180,000 shares of common stock issuable upon exercise of the warrants.

The units will be sold for a purchase price equal to \$100 per unit. Units will not be issued or certificated. The shares of Series B convertible preferred stock and the warrants are immediately separable and will be issued separately. Subject to certain ownership limitations, the Series B convertible preferred stock is convertible at any time at the option of the holder into shares of our common stock at a conversion price per share equal to \$ , which is 100% of the closing price of our common stock on The NASDAQ Capital Market on the date of the underwriting agreement or the date immediately prior to such date, as permitted by NASDAQ. Subject to certain ownership limitations, the warrants are immediately exercisable and expire on the fifth anniversary of the date of issuance.

For a more detailed description of the Series B convertible preferred stock, see the section entitled Description of Securities Series B Convertible Preferred Stock Sold as Part of the Units in this Offering beginning on page 64. For a more detailed description of the warrants, see the section entitled Description of Securities Warrants Sold as Part of the Units in this Offering beginning on page 65 of this prospectus. For a more detailed description of our common stock, see the section entitled Description of Securities Common Stock beginning on page 63 of this prospectus. We

145,000 Shares of Series B convertible preferred stock (and up to 12,180,000 Shares of Common Stock Underlying

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

Our common stock is listed on The NASDAQ Capital Market under the symbol NURO. The last reported sale price of our common stock on The NASDAQ Capital Market on May 21, 2015 was \$1.20 per share. We do not intend to list the Series B convertible preferred stock to be sold in this offering on The NASDAQ Capital Market or any other national securities exchange or any other nationally recognized trading system. The warrants to be sold in this offering have been approved for listing on The NASDAQ Capital Market under the symbol NUROW. None of our other warrants are listed or traded on a national securities exchange or market.

**Investing in our common stock and warrants involves risks. See Risk Factors beginning on page 13.**

	Per Unit	Total
Offering price	\$ 100.00	\$
Underwriter discounts and commissions <sup>(1)</sup>	\$	\$
Offering proceeds, before expenses, to NeuroMetrix	\$	\$

(1) See Underwriting for additional compensation details.

The above summary of offering proceeds to us does not give effect to any exercise of the warrants being issued in this offering.

**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.**

An existing principal stockholder and its affiliates have indicated an interest in purchasing units in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriter could determine to sell or not sell units to this principal stockholder, and this principal stockholder could determine to purchase or not purchase units in this offering.

This is a firm commitment underwriting. The underwriter expects to deliver the shares of common stock and warrants to purchasers on or about \_\_\_\_\_, 2015.

*Sole Book-Running Manager*

**Maxim Group LLC**

**The date of this prospectus is \_\_\_\_\_, 2015.**

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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. Neither we nor the underwriter have 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.

**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 common stock and the warrants. 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, us and NeuroMetrix refer to NeuroMetrix, Inc. unless the context requires otherwise.*

### Our Business An Overview

NeuroMetrix is an innovative health-care company that develops wearable medical technology and point-of-care tests that help patients and physicians better manage chronic pain, nerve diseases, and sleep disorders. Our business is fully integrated with in-house capabilities spanning product development, manufacturing, regulatory affairs and compliance, sales and marketing, and customer support. We derive revenues from the sale of medical devices and after-market consumable products and accessories. Our products are sold in the United States and selected overseas markets, and are cleared by the U.S. Food and Drug Administration, or FDA, and regulators in foreign jurisdictions where appropriate. We have two principal product lines:

Wearable neuro-stimulation therapeutic devices

Point-of-care neuropathy diagnostic tests

Our core expertise in biomedical engineering has been refined over nearly two decades of designing, building and marketing medical devices that stimulate nerves and analyze nerve response for diagnostic and therapeutic purposes. We created the market for point-of-care nerve testing and were first to market with sophisticated, wearable technology for management of chronic pain. We have an experienced management team and Board of Directors. Our Scientific Advisory Board includes internationally recognized experts in diabetes and pain.

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, 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. Within the US chronic pain population one of the largest segments is patients with neuropathic pain estimated at 25 million persons. A significant subset of these patients is persons with diabetes of which 16% to 25% suffer painful diabetic neuropathy, or PDN, estimated at 6 to 8 million patients. 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.

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Reflecting the difficulty in treating chronic pain, 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 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 two years.

Our primary objective for 2015 is revenue growth. We expect this to be led by the successful introduction and market adoption of a new over-the-counter analgesic category featuring Quell, our wearable device for pain relief which builds upon the core SENSUS neuro-stimulation technology. We also expect an important contribution to revenue growth from DPNCheck, our rapid, accurate diagnostic test for diabetic peripheral neuropathy, which we previously referred to as NC-stat DPNCheck.

Our key business strategies for 2015 include:

### ***Driving Commercial Adoption of Our Proprietary Products.***

**Quell**, our over-the-counter (OTC) wearable device for pain relief, was unveiled at the January 2015 Consumer Electronics Show (CES). Quell utilizes OptiTherapy™, our proprietary non-invasive neuro-stimulation technology to provide relief from chronic intractable pain, particularly nerve pain due to diabetes and lower back problems. 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 will also have the option of using their smartphones to automatically track and personalize their pain therapy. Response to Quell at CES and from independent market studies has been positive. We began making shipments to physicians and thought leaders in chronic pain in May 2015 and anticipate making Quell commercially available in the United States in June 2015. Our commercial launch plan involves two distribution channels: a professional channel using a direct sales force to target podiatrists, pain physicians, primary care physicians, and chiropractors who would resell the product, and a direct-to-consumer channel using online marketing and lead generation. During 2016 we plan to evaluate additional U.S. retail distribution opportunities. We believe there are significant opportunities to

market Quell outside of the United States, particularly in Western Europe, Japan and China; however, we do not intend to approach those markets until we have established a solid presence in the United States.

During March 2015 we initiated a month-long, Quell pre-order campaign on the crowdfunding platform Indiegogo. Our goal was to receive 500 preorders for the device and to obtain funding of approximately \$100,000. We received preorders for approximately 1,900 Quell devices, generating gross proceeds of approximately \$390,000.

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**SENSUS**, our prescription neuro-stimulation therapeutic device for relief of chronic pain, was launched in the first quarter of 2013 and provides the technological foundation for Quell. SENSUS revenues in 2014 and 2013 were approximately \$0.9 million and \$0.2 million, respectively. SENSUS is distributed through durable medical equipment (DME) suppliers who call on pain medicine physicians, neurologists, endocrinologists, podiatrists, and primary care physicians to create awareness among physicians who are challenged with trying to manage chronic pain in their patients. These physicians prescribe SENSUS to their patients who, in turn, have their prescriptions fulfilled by a DME. The DME is also responsible for billing and collection from third party payers such as Medicare and other insurers. This is a high cost distribution channel with tight margins. The DME channel is under pressure from Medicare's competitive bidding initiative. We believe that the U.S. growth opportunity for this prescription neuro-stimulation device is limited and that there are more attractive opportunities in the OTC market.

**DPNCheck**, our diagnostic test for peripheral neuropathies was made commercially available in the fourth quarter of 2011. DPNCheck revenues for 2014 and 2013 were approximately \$1.8 million and \$1.3 million, respectively. 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 opportunities are developing in Japan where we received regulatory approval and launched DPNCheck with Omron Healthcare in 2014; in China where we are working with Omron Healthcare on the regulatory process and anticipate commercial launch in 2016; in Mexico where our distributor Scienta Farma recently received regulatory approval and plans to launch in mid-2015; and in the Middle East.

***Maintaining a High Level of Research and Development Productivity.*** New products commercialized over the past three years made up nearly fifty percent of our 2014 revenues, and we expect them to comprise the majority of our revenues in 2015. During those three years, we brought to market DPNCheck and SENSUS. Our research and development team faces its greatest challenge of the past few years in completing development of the Quell device, smartphone application and electrode in time for commercial launch in June 2015. This is our top priority and we believe Quell has the potential to be the largest contributor to 2015 revenues of our marketed products, including SENSUS and DPNCheck.

## **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, SENSUS and DPNCheck, conform to this model. Quell and other products in our development pipeline are based on the device plus consumables business 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 a therapeutic stimulation intensity and compensate for nerve desensitization, and automated detection of user sleep and appropriate adjustment of stimulation level. Quell is comprised of (1) an electronic device carried in a neoprene band that is worn on the upper calf and (2) an electrode that attaches to the device and is the interface between the device and the skin. The device is lightweight and can be worn during the day while active, and at night while sleeping. It has been cleared by the FDA for treatment of chronic intractable pain and will be available OTC. Users of the

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device will have the option of using their smartphones to automatically track and personalize their pain therapy. The device was unveiled at the Consumer Electronics Show in January 2015. We began making shipments to physicians and thought leaders in chronic pain in May 2015 and anticipate making it commercially available in the United States in June 2015. Our commercial launch plan involves two distribution channels: a professional channel using a direct sales force to target podiatrists, pain physicians, primary care physicians, and chiropractors who would resell the product, and a direct-to-consumer channel using online marketing and lead generation.

During March 2015, we initiated a month-long, pre-order campaign for Quell on the crowdfunding platform Indiegogo. This campaign offered the opportunity to order Quell in advance of market launch and be one of the first to receive the product. The campaign was designed as a learning opportunity to test market interest in Quell and obtain feedback on design features. Our goal was to receive 500 preorders for the device and to obtain funding of approximately \$100,000. We received preorders for approximately 1,900 Quell devices, generating gross proceeds of approximately \$390,000. We anticipate that the Quell device will sell for a retail price ranging between \$200 and \$250 and that the electrodes will be sold pursuant to monthly subscription programs at approximately \$30 per month.

We anticipate that our gross margins on Quell products will be in the range of 50% to 75% and that our sales and promotional spending will be approximately \$200 to \$300 per new user.

## SENSUS

The SENSUS pain therapy device 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 2014, 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. We used our expertise in peripheral nerve stimulation in the development of SENSUS which incorporates several proprietary features for ease of patient use and physician reporting. The SENSUS device and electrodes were cleared by the FDA for commercial distribution. When medically indicated and supported by proper documentation, TENS are generally reimbursed by Medicare and many commercial insurance companies under the DME benefit.



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An evidence-based review by the American Academy of Neurology determined that TENS was a useful modality for managing pain associated with DPN. Our assessment of currently available TENS devices indicated that many do not meet the needs of patients due to limitations of the devices and their difficulty to use.

**DPNCheck**

DPNCheck is a fast, accurate, and quantitative nerve conduction test that is used to evaluate systemic neuropathies such as DPN. It is designed to be used by primary care physicians, endocrinologists, podiatrists and other clinicians at the point-of-care to objectively detect, stage, and monitor 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 and has the same clinical indications with respect to DPN. The modified device has the same functionality with respect to sural nerve testing as the original device; however, the cost of the electronic hand-held unit and the consumable biosensors has been reduced by approximately 50%. More than 1.8 million patient studies have been performed using our NC-stat technology and there have been approximately 6.3 million nerve tests, including nearly 700,000 sural 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.

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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 and invasive electromyography procedures. 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.

Historically, the ADVANCE System has been 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.

## **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



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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 at least some clinical indications; however, the health care environment has been such that we have been 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 \$2.8 million, \$3.8 million, and \$6.1 million in 2014, 2013 and 2012, respectively. We currently manage this business to optimize cash flow.

## **Risks Affecting Us**

Our business is subject to numerous risks, as discussed more fully in the section entitled "Risk Factors" immediately following this prospectus summary. At March 31, 2015 we had an accumulated deficit of \$156.5 million and held cash and cash equivalents of \$6.4 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 requirements through the second quarter of 2016. 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 to support our operating and capital needs for the third quarter of 2016 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. As of April 30, 2015, we were not in compliance with the minimum tangible net worth covenant of our Loan and Security Agreement with a bank. We have not borrowed any funds under this Agreement; however, \$451,731 of amounts available under the Agreement are restricted to support letters of credit issued in favor of our landlords. The Company will be restricted from borrowing under the Agreement, and may be required to provide cash collateral under the letters of credit, until the covenant default is cured or waived by the bank.

## **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. The warrants to be sold in this offering have been approved for listing on The NASDAQ Capital Market under the symbol NUROW. None of our other warrants are listed or traded on a national securities exchange or market. 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](http://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

### Securities offered

145,000 units, with each unit consisting of (i) one share of Series B convertible preferred stock which is convertible into that number of shares of our common stock equal to \$100 divided by the conversion price of the Series B convertible preferred (rounded up to the nearest whole share), which will equal 100% of the closing price of our common stock on The NASDAQ Capital Market on the date of the underwriting agreement or the date immediately prior to such date, and (ii) 84 warrants exercisable for an aggregate of 84 shares of our common stock, which amount of warrants and shares of common stock underlying the warrants both equal 100% of the number of shares of our common stock issuable upon conversion of one share of Series B convertible preferred stock at the conversion price (rounded up to the nearest whole share), at an exercise price per share equal to \$ , which is 110% of the closing price of our common stock on The NASDAQ Capital Market on the date of the underwriting agreement or the date immediately prior to such date, as permitted by NASDAQ rules.<sup>(1)</sup> Each warrant will be immediately exercisable for one share of our common stock. Units will not be issued or certificated. The shares of Series B convertible preferred stock and the warrants are immediately separable and will be issued separately.

### Offering price

\$100.00 per unit

### Description of Series B convertible preferred stock

Each unit includes one share of Series B convertible preferred stock. The Series B convertible preferred stock is subject to certain ownership limitations. See the section entitled "Description of Securities - Series B Convertible Preferred Stock Sold as Part of the Units in this Offering" beginning on page 64. This prospectus also relates to the offering of shares of common stock issuable upon conversion of the Series B convertible preferred stock.

### Shares of common stock underlying the Series B convertible preferred stock in the units

12,180,000<sup>(1)</sup>

### Description of warrants

Each unit includes 84 warrants to purchase an aggregate of 84 shares of our common stock. The actual number of warrants issued in one unit and shares of common stock underlying the warrants in one unit will both equal 100% of the number of shares of our common stock issuable upon conversion of one share of Series B convertible preferred stock at the actual conversion price (rounded up to the nearest whole share), which will equal 100% of the closing price of our common stock on The NASDAQ Capital Market on the date of the underwriting agreement or the date immediately prior to such date, as permitted by NASDAQ rules.<sup>(1)</sup> Each warrant will be immediately exercisable for one share of our common stock and will expire on the fifth anniversary of the date of issuance. The warrants will have an exercise price of \$ per share, which is 110% of the closing price of our common stock on The NASDAQ Capital Market on the date of the underwriting agreement or the date immediately prior to such date,

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as permitted by NASDAQ rules. This prospectus also relates to the offering of shares of common stock issuable upon exercise of the warrants.

Shares of common stock underlying the warrants in the units

12,180,000<sup>(1)</sup>

Common stock outstanding before this offering

8,519,151 shares

Common stock to be outstanding after this offering, including shares of common stock underlying shares of Series B convertible preferred stock in the units

20,699,151<sup>(2)</sup> shares, which does not include 12,180,000 shares of common stock issuable upon exercise of the warrants to be sold in this offering.

Limitations on beneficial ownership

Notwithstanding anything herein to the contrary, each purchaser will be able to convert the Series B convertible preferred stock or exercise the warrants only if, after such conversion or exercise, such holder would beneficially own less than 9.99% of the shares of common stock then outstanding (subject to the right of the holder to increase or decrease such beneficial ownership limitation upon not less than 61 days prior notice provided that such 61 day period cannot be waived).

Use of proceeds

We intend to use the net proceeds of this offering to fund the commercial launch of Quell in the United States, for general corporate purposes and to repurchase certain shares of our Series A-4 convertible preferred stock. See Use of Proceeds for additional information.

Risk factors

You should read the Risk Factors section of, and all of the other information set forth in, this prospectus to consider carefully before deciding whether to invest in the securities offered by this prospectus.

NASDAQ Capital Market common stock symbol

Our common stock is quoted and traded on The NASDAQ Capital Market under the symbol NURO.

NASDAQ Capital Market

warrant symbol

The warrants to be sold in this offering have been approved for listing on The NASDAQ Capital Market under the symbol NUROW. None of our other warrants are listed or traded on a national securities exchange or market.

No market for the units or Series B convertible preferred stock or warrants

The units will not be certificated and the securities 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 B convertible preferred stock issued in this offering, and we do not intend to apply to list such Series B convertible preferred stock any securities exchange or automated quotation system.

<sup>(1)</sup> Based on an assumed Series B convertible preferred stock conversion price of \$1.20 per share, which was 100% of the closing price of our common stock on The NASDAQ Capital Market on May 21, 2015.

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The actual conversion price per share of the Series B convertible preferred stock will equal 100% of the closing price of our common stock on The NASDAQ Capital Market on the date of the underwriting agreement or the date immediately prior to such date, as permitted by NASDAQ rules.

(2) Common stock to be outstanding after this offering assumes the Series B preferred stock sold in this offering is converted by the holder into 12,180,000 shares of common stock.

The number of shares of our common stock that will be outstanding immediately after this offering is based on 8,519,151 shares outstanding as of March 31, 2015, and excludes the following:

1,571,744 shares of common stock issuable upon the conversion, at the option of the holder, of 3,206.357 shares of Series A-4 convertible preferred stock (see Description of Securities Preferred Stock );

5,760,847 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2015, at a weighted average exercise price of \$2.70 per share;

809,257 shares of common stock issuable upon the exercise of options outstanding as of March 31, 2015, at a weighted average exercise price of \$4.95 per share;

454,614 shares of common stock available for future issuance under our 2004 Stock Option and Incentive Plan as of March 31, 2015 and an additional 850,000 shares of common stock available for future issuance under our 2004 Stock Option and Incentive Plan that were approved by our stockholders at our 2015 Annual Meeting of Stockholders held on May 5, 2015;

200,000 shares of common stock available for future issuance under our 2009 Non-qualified Inducement Stock Plan as of March 31, 2015;

140,947 shares of common stock available for future issuance under our 2010 Employee Stock Purchase Plan as of March 31, 2015; and

12,180,000 shares of common stock issuable upon the exercise of the warrants to be sold in this offering.

Sabby Management, LLC and its affiliates ( Sabby ), a principal stockholder, have indicated an interest in purchasing units in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriter could determine to sell or not sell units to Sabby, and Sabby could determine to purchase or not purchase units in this offering. Sabby beneficially owns approximately 9.99% of our outstanding shares of common stock. See Principal and Management Stockholders. Should Sabby choose to purchase units in this offering at the public offering price, we anticipate that simultaneous with the closing of this offering, we will repurchase from Sabby the remaining 3,206.357 shares of the Series A-4 convertible preferred stock for an aggregate purchase price of \$3.2 million (the Repurchase ). Approximately 490.196 shares of our common stock underlie each share of the Series A-4 convertible preferred stock. We only intend to repurchase the shares of Series A-4 convertible preferred stock to the extent that Sabby agrees to forfeit warrants to purchase 1,571,744 shares of our common stock that were issued in connection with the original issuance of the Series A-4 convertible preferred stock, which warrants have an exercise price of \$2.04. The anticipated Repurchase and the related warrant forfeiture will be contingent on Sabby s participation in this offering. We have not yet entered into an agreement governing the Repurchase and related warrant forfeiture but anticipate doing so prior to completion of this offering.

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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, 2014, 2013, 2012, 2011, and 2010, have been derived from our audited financial statements. The audited financial statements for the years ended December 31, 2014, 2013, and 2012, and the report thereon, were included in our Annual Report on Form 10-K for the year ended December 31, 2014, which is incorporated by reference into this prospectus. Our statement of operations data for the three months ended March 31, 2015 and 2014 and our balance sheet data as of March 31, 2015 were derived from our unaudited interim financial statements included in our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2015, which is incorporated by reference in this prospectus. The as adjusted balance sheet data gives effect to the sale of the units offered by this prospectus at an assumed aggregate offering amount of \$14.5 million, based on an offering price of \$100 per unit, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and after the repurchase of 3,206,357 shares of our Series A-4 convertible preferred stock for \$1,000 per share. The as adjusted balance sheet data presented below is illustrative only and will change based on the actual offering price and other terms of this offering determined at pricing. 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, 2014 and the Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, both of which are incorporated by reference into this prospectus.

	Quarters Ended		Years Ended				
	March 31,		December 31,				
	2015	2014	2014	2013	2012	2011	2010
	(In thousands, except per share data)						
Statement of operations data:							
Revenues	\$1,283	\$1,332	\$5,513	\$5,279	\$7,575	\$10,397	\$13,900
Cost of revenues	637	615	2,569	2,194	3,589	4,722	7,050
Gross profit	646	717	2,944	3,589	3,986	5,675	6,850
Net loss <sup>(1)</sup>	\$(2,071)	\$(1,225)	\$(7,766)	\$(8,019)	\$(10,008)	\$(9,981)	\$(16,891)
Net loss per common share, basic and diluted <sup>(2)</sup>	\$(0.25)	\$(0.21)	\$(1.54)	\$(3.07)	\$(5.22)	\$(15.53)	\$(26.41)

Includes warrants income (expense) of \$1,050,095, and \$(289,657) for the years ended December 31, 2014 and (1)2013, respectively. For quarters ended March 31, 2015 and 2014, warrant income was \$1,186,302 and \$514,600, respectively.

(2) 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.

March 31,	As of December 31,				
	2015	2014	2013	2012	2011



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(In thousands)

Balance sheet data:

Cash, cash equivalents, and short-term investments	6,403	\$ 9,222	\$ 9,196	\$ 8,699	\$ 10,290	\$ 16,987
Working capital <sup>(1)</sup>	4,904	8,392	8,919	8,567	10,482	19,020
Total assets	9,131	11,402	10,797	10,877	14,221	23,066
Total liabilities	7,449	8,015	3,602	2,077	3,132	2,867
Total stockholders' equity	1,682	3,387	7,195	8,800	11,089	20,199

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	As of March 31, 2015	
	Actual	As adjusted <sup>(2)</sup>
(In thousands)		
As adjusted balance sheet effects of this offering:		
Cash and cash equivalents	\$ 6,403	\$ 16,403
Working capital <sup>(1)</sup>	\$ 4,904	\$ 14,904
Total assets	\$ 9,131	\$ 19,131
Total liabilities	\$ 7,449	\$ 6,115
Total stockholders' equity	\$ 1,682	\$ 13,016

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

(2) Each increase of 10,000 units offered by us at \$100 per unit would increase each of our as adjusted cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately \$925,000. Similarly, each decrease of 10,000 units offered by us at \$100 per unit would decrease each of our as adjusted cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately \$925,000. 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.

The following table represents certain unaudited quarterly information for the quarter ended March 31, 2015 and for each of the four quarters in the years ended December 31, 2014, 2013, and 2012. 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
2015:				
Net loss	\$ (2,071)			
Basic and diluted net loss per share	\$ (0.25 )	\$		
2014:				
Net loss	\$ (1,225)	\$ (2,171)	\$ 1,462	\$ (2,909)
Basic and diluted net loss per share	\$ (0.21 )	\$ (0.85 )	\$ (0.19 )	\$ (0.36 )
2013:				
Net loss	\$ (2,253)	\$ (1,346)	\$ (716 )	\$ (3,704)
Basic and diluted net loss per share <sup>(1)</sup>	\$ (1.06 )	\$ (0.92 )	\$ (0.26 )	\$ (0.87 )
2012:				
Net loss	\$ (2,752)	\$ (2,772)	\$ (2,610)	\$ (1,873)
Basic and diluted net loss per share <sup>(1)</sup>	\$ (1.99 )	\$ (1.32 )	\$ (1.24 )	\$ (0.89 )

(1) 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.

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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.*

*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.*

### **Risks Related to Our Business**

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

We have incurred significant cumulative net losses since our inception. Our net losses for the three months ended March 31, 2015 and the years ended December 31, 2014, 2013, and 2012, were approximately \$2.1 million, \$7.8 million, \$8.0 million, and \$10.0 million, respectively. At March 31, 2015, we had an accumulated deficit of approximately \$156.5 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 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 \$6.4 million as of March 31, 2015. 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 requirements through the second quarter of 2016.

Our financial statements have been prepared assuming that we will continue as a going concern which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. We expect to incur further losses as we aim to successfully commercialize DPNCheck and Quell 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, 2014, the report of our independent registered public accounting firm in our Annual Report on Form 10-K for the year ended December 31, 2014 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 to support our operating and capital needs for the third quarter of 2016 and beyond. We may attempt to obtain additional funding through public or private financing, collaborative arrangements with strategic partners, or through additional credit lines or other debt financing sources 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

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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 our wearable devices 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 in our development pipeline, will be successful.**

We are focused on the potential launch and subsequent commercialization of Quell, our OTC wearable device for pain relief. Quell is based on our prescription product for pain relief, SENSUS, which has been on the market for two years. We have shipped over 7,000 SENSUS devices during that period. DPNCheck, which was launched in late 2011, is a fast, accurate, and quantitative nerve conduction test for systemic neuropathies, such as DPN. We have other product candidates in our development pipeline. Our future prospects are closely tied to our success with our wearable devices for chronic pain 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 complete development and launch Quell in 2015;
- inability to create market demand for Quell through a direct sales force and through online marketing efforts;
- manufacturing issues with Quell, SENSUS or our other products;
- reduced demand and loss of revenue for SENSUS as a result of customer preference for Quell;
- inability to increase adoption of DPNCheck within the Medicare Advantage market;
- unfavorable market response to DPNCheck in Japan and other Asia markets;
- unfavorable changes to current Medicare, Medicare Advantage and commercial payer payment policies;
- changes to payor policies under the Patient Protection and Affordable Care Act;
- unfavorable experiences by patients and physicians using Quell, SENSUS 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 DPNCheck and SENSUS, or to establish a market for Quell, our ability to increase our revenues will be limited and our business prospects will be 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, the adoption of our products and our future product sales will be**

**materially adversely affected.**

Widespread adoption of our SENSUS and 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

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toward payment would harm our ability to market and sell our products. Third-party payers include those governmental programs such as Medicare and Medicaid, private health insurers, workers' compensation programs and other organizations.

Future regulatory action by CMS or other governmental agencies or negative clinical results may diminish reimbursement payments to physicians for performing procedures using our products. Medicaid reimbursement differs from state to state, and some state Medicaid programs may not cover the procedures performed with our products or pay physicians an adequate amount for performing those procedures, if at all. Additionally, some private payers do not follow the Medicare guidelines and may reimburse for only a portion of these procedures or not at all. We are unable to predict what changes will be made in the reimbursement methods used by private or governmental third-party payers. Importantly, we cannot predict the effects that implementation of the Patient Protection and Affordable Care Act will have on CMS, commercial insurers, health care providers, and ultimately on our business.

**Healthcare reform legislation could adversely affect our future revenues.**

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

**We are subject to extensive regulation by the FDA which could restrict the sales and marketing of the Quell, SENSUS and DPNCheck devices and the ADVANCE System as well as other products for which we may seek FDA clearance or approval, and could cause us to incur significant costs.**

We sell medical devices that are subject to extensive regulation in the United States by the FDA with regard to manufacturing, labeling, sale, promotion, distribution, shipping and ongoing monitoring and follow-up. Before a new medical device, or a new use of or claim for an existing product, can be marketed in the United States, it must first be cleared or approved by the FDA. Medical devices may be marketed only for the indications for which they are approved or cleared. The regulatory review process can be expensive and lengthy. The FDA's process for granting 510(k) clearance typically takes approximately three to six months, but it can be significantly longer. The process for obtaining a pre-market approval, or PMA, is much more costly and onerous. By law, the time period designated for the FDA's review of a PMA is 180 days; however, this time is often extended and it is not uncommon for the PMA review process to take three years or longer from the time the application is filed with the FDA.

The FDA may remove our devices from the market or enjoin them from commercial distribution if safety or effectiveness problems develop. Further, we may not be able to obtain additional 510(k) clearances or pre-market approvals for new products or for modifications to, or additional indications for, our existing products 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



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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 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 DPNCheck, SENSUS and Quell systems, and to fully manufacture 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 SENSUS and Quell, and Sunburst EMS, Inc. manufactures electronic boards and other components of our DPNCheck, SENSUS and Quell products which we assemble at our Massachusetts facility to produce completed devices. Sunburst EMS, Inc. also manufactures our ADVANCE System monitors, docking stations, and communication hubs.

We depend on several single source manufacturers to produce our products. Any material adverse changes in our

We have experienced transient inventory shortages on new products during the initial production ramp-up phase. If any materially adverse changes in our relationships with these manufacturers occur, our ability to supply our customers will be severely limited until we are able to engage an alternate manufacturer or, if applicable, resolve any quality issues with our existing manufacturer. This situation could prevent us from delivering products to our customers in a timely manner, lead to decreased sales or increased costs, or harm our reputation with our customers.

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**If our manufacturers are unable to supply us with an adequate supply of products 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 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 the manufacturers of our products 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

If our manufacturers are unable to supply us with an adequate supply of products as we expand our markets, we could

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.**

The primary focus of our research and development department is development of our Quell device for chronic intractable pain and the planned initiation of commercial shipments of Quell in June 2015. We have other products in our R&D pipeline. We expect that advancing our pipeline products will require significant time and resources. We may not be successful in our commercialization efforts for any of the product candidates 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.

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**We currently rely on sales of the products that comprise the ADVANCE System to generate a meaningful portion of our revenues. Any factors that negatively impact our sales of these products could significantly reduce our ability to generate revenues.**

We launched the ADVANCE System, our general purpose nerve conduction testing system, in June 2008. For 2014 and 2013, 51% and 72%, respectively, of our total revenue was attributed to the ADVANCE System. We continue to derive a substantial portion of our revenues from sales of ADVANCE electrodes. We expect that sales of ADVANCE System products will constitute approximately 20% of our sales during 2015. Accordingly, our revenue in the short-term is dependent on our ability to sell ADVANCE electrodes. ADVANCE electrode sales may be negatively impacted by many factors, including:

changes in reimbursement rates or policies by third-party payers;  
manufacturing problems;  
claims that our products infringe on patent rights or other intellectual property rights owned by other parties;  
adverse regulatory or legal actions relating to our products; and  
clinical trial results relating to our products or our competitors' products.

If any of these events occurs, ADVANCE electrode sales could be significantly reduced.

**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 design patents begin to expire in 2015. We also 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 success of our business depends upon our ability to advance our pipeline products to commercialization.

**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;

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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,

We may need to initiate lawsuits to protect or enforce our patents and other intellectual property rights, which could

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

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

A federal law commonly known as the federal anti-kickback law, and several similar state laws, prohibit the payment of any remuneration that is intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of health care products or services. These laws constrain



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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 ADVANCE system and DPNCheck, SENSUS and Quell products may be susceptible to claims of injury because their use involves the electric stimulation of a patient's nerves. Although we maintain product liability insurance for

We are subject to federal and state laws prohibiting kickbacks and false or fraudulent claims, which, if violated, could

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.

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**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 45 employees as of March 31, 2015, 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

Our products are complex in design, and defects may not be discovered prior to shipment to customers, which could

and marketing personnel would materially harm our ability to compete effectively and grow our business.

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

Our future business and financial success will depend, in part, on our ability to effectively market our new products, such as Quell, SENSUS 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

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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.

**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 and other illnesses, we may 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.**

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 could endorse products or methods that compete with our products or otherwise announce positions that are unfavorable to our products. We have experienced this with the professional societies representing the neurology community. Any of these events may negatively affect our sales efforts and result in decreased revenues.

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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% of our revenues in 2014, compared to 16% of our revenues in 2013. 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.

As we expand into foreign markets, we will be affected by new business risks that may adversely impact our financial

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



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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. As of April 30, 2015, we were not in compliance with the minimum tangible net worth covenant of our Loan and Security Agreement with a bank. We have not borrowed any funds under this Agreement; however, \$451,731 of amounts available under the Agreement are restricted to support letters of credit issued in favor of our landlords. The Company will be restricted from borrowing under the Agreement, and may be required to provide cash collateral under the letters of credit, until the covenant default is cured or waived by the bank.

**If we choose to acquire or invest in new businesses, products or technologies, instead of developing them ourselves, these acquisitions or investments could disrupt our business and could result in the use of significant amounts of equity, cash or a combination of both.**

From time to time we may seek to acquire or invest in businesses, products or technologies, instead of developing them ourselves. Acquisitions and investments involve numerous risks, including:

- the inability to complete the acquisition or investment;
- disruption of our ongoing businesses and diversion of management attention;
- difficulties in integrating the acquired entities, products or technologies;
- difficulties in operating the acquired business profitably;
- the inability to achieve anticipated synergies, cost savings or growth;
- potential loss of key employees, particularly those of the acquired business;
- difficulties in transitioning and maintaining key customer, distributor and supplier relationships;
- risks associated with entering markets in which we have no or limited prior experience; and
- unanticipated costs.

In addition, any future acquisitions or investments may result in one or more of the following:

- issuances of dilutive equity securities, which may be sold at a discount to market price;
- the use of significant amounts of cash;
- the incurrence of debt;
- the assumption of significant liabilities;
- increased operating costs or reduced earnings;
- financing obtained on unfavorable terms;
- large one-time expenses; and

the creation of certain intangible assets, including goodwill, the write-down of which may result in significant charges to earnings.

Any of these factors could materially harm our stock price, our business, or our operating results.

## **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 our common stock and warrants in June 2014 and June 2013 and any additional sales of shares of our common stock or other securities exercisable into our common stock are likely to have

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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 March 31, 2015, our stock price has fluctuated from a low of \$1.47 to a high of \$68.41, as adjusted for stock splits. The market price for our common stock will be affected by a number of factors, including:

the denial or delay of regulatory clearances or approvals for our products under development or receipt of regulatory approval of competing products;

our ability to accomplish clinical, regulatory and other product development and commercialization milestones and to do so in accordance with our timing estimates;

changes in policies affecting third-party coverage and reimbursement in the United States and other countries;

changes in government regulations and standards affecting the medical device industry and our products;

ability of our products to achieve market success;

the performance of third-party contract manufacturers and component suppliers;

actual or anticipated variations in our results of operations or those of our competitors;

announcements of new products, technological innovations or product advancements by us or our competitors;

developments with respect to patents and other intellectual property rights;

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

additions or departures of key scientific or management personnel;

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

trading volume of our common stock;

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.



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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.

**If we fail to continue to meet all applicable NASDAQ Capital Market requirements and The NASDAQ Stock Market determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock, impair the value of your investment, and harm our business.**

Our common stock is currently listed on the NASDAQ Capital Market. In order to maintain that listing, we must satisfy minimum financial and other requirements. On April 30, 2015, we received a letter, which we refer to as the Notice, from The NASDAQ Stock Market or NASDAQ, indicating that, as of March 31, 2015 our reported stockholders' equity did not meet the \$2,500,000 minimum required to maintain continued listing, as set forth in NASDAQ Listing Rule 5550(b)(1). Under NASDAQ rules, we have 45 calendar days to submit a plan to regain compliance. If our plan is accepted, NASDAQ can grant an extension of up to 180 calendar days, or until October 27, 2015, to evidence compliance. If we fail to regain compliance, our common stock will be subject to delisting by NASDAQ.

If NASDAQ does not accept our plan, NASDAQ will notify us that our common stock is subject to delisting. At that time, we may appeal the delisting determination to a NASDAQ Hearings Panel.

While we intend to engage in efforts to regain compliance, and thus maintain our listing, there can be no assurance that we will be able to regain compliance during the applicable time periods set forth above. 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 March 31, 2015 as reported by NASDAQ was

If we fail to continue to meet all applicable NASDAQ Capital Market requirements and The NASDAQ Stock Market

approximately 60,000 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:

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;

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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**

**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 work toward 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 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.

**If an active, liquid trading market for our warrants does not develop, you may not be able to sell your warrants quickly or at or above the price you paid for it.**

The warrants issued in this offering will be immediately exercisable and expire on the fifth anniversary of the date of issuance. The warrants will have an initial exercise price per share equal to \$ , which is 110% of the closing price of our common stock on The NASDAQ Capital Market on the date of the underwriting agreement or the date immediately prior to such date, as permitted by NASDAQ rules. In the event that our common stock price does not exceed the exercise price of the warrants during the period when the warrants are exercisable, the warrants may not have any value.

There is no established trading market for the warrants to be sold in this offering, and the market for the warrants may be highly volatile or may decline regardless of our operating performance. The warrants offered in this offering have been approved for listing on The NASDAQ Capital Market under the symbol NUROW. However, an active public market for our warrants may not develop or be sustained. We cannot predict the extent to which investor interest in our company will lead to the development of an active trading market in our warrants or how liquid that market might become. If a market does not develop or is not sustained, it may be difficult for you to sell your warrants at the time you wish to sell them, at a price that is attractive to you, or at all.



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

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 the 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 of 1933, as amended.

**Holders of our warrants will have no rights as a common stockholder until they acquire our common stock.**

Until you acquire shares of our common stock upon exercise of your warrants, you will have no rights with respect to our common stock. Upon exercise of your warrants, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

**There is no public market for the Series B convertible preferred stock being offered by us in this offering.**

There is no established public trading market for the Series B convertible preferred 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 B convertible preferred 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 B convertible preferred stock may be limited.

**Purchasers will experience dilution in the value of their investment as a result of this offering and conversion of their class B convertible preferred stock into common stock and may experience additional dilution in the future.**

Purchasers in this offering who convert their Series B convertible preferred stock to common stock will experience dilution in their net tangible book value per share to the extent of the difference between the conversion price per share of common stock and the adjusted, as converted net tangible book value per share after giving effect to the offering. Our net tangible book value as of March 31, 2015 was approximately \$1.7 million, or \$0.20 per share of our

common stock. Assuming that we issue 145,000 units at a price of \$100 per unit, assuming the Series B convertible preferred stock sold in this offering has a conversion price of \$1.20 per share, which was 100% of the closing price of our common stock on The NASDAQ Capital Market on May 21, 2015, and assuming the conversion of all the shares of Series B convertible preferred stock sold in this offering, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us our as adjusted, converted net tangible book value as of March 31, 2015 would have been approximately \$13.0 million, or \$0.63 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 \$0.43 per share to our existing stockholders and an immediate dilution in net tangible book value of \$0.57 per share to investors in this offering who convert their Series B convertible preferred stock to common stock. If outstanding options and warrants to purchase our common stock are exercised, purchasers will experience additional dilution. See the section entitled Dilution below.

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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, 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 pricing and gross margins on our Quell products; our expected timing for the commercial launch of Quell; 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 in the diagnosis and treatment of diabetic neuropathy and our expectations surrounding SENSUS, Quell and NC-stat DPNCheck; 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; 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. 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.

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 any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events.

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 we will receive approximately \$10.0 million in net proceeds from the sale of the securities in this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and after the repurchase of all of the outstanding shares of our Series A-4 convertible preferred stock.

Simultaneous with the closing of this offering, we anticipate that we will repurchase certain shares of Series A-4 convertible preferred stock held by Sabby for an aggregate purchase price of \$3.2 million out of the gross proceeds of this offering. This repurchase is contingent on Sabby's participation in this offering.

The amount of net proceeds does not include the proceeds that we may receive in connection with any exercise of the warrants issued in this offering. Assuming all of the warrants issued in this offering were exercised in full for cash at an assumed exercise price of \$1.32 per share, which is 110% of the closing price of our common stock on The NASDAQ Capital Market on May 21, 2015, we estimate that we would receive additional net proceeds of approximately \$16.1 million. We cannot predict when or if the warrants will be exercised, however, and it is possible that the warrants may expire and never be exercised.

We intend to use the net proceeds of this offering to fund the commercial launch of Quell in the United States and for general corporate purposes. Quell is our over-the-counter (OTC) wearable device for pain relief and was unveiled at the January 2015 Consumer Electronics Show (CES). Quell 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:

**Direct Sales Force** we plan to hire, train, and deploy a sales force to call on physicians in selected urban areas in the United States. The hiring and training of this sales force began during the first quarter of 2015. Depending on the order flow we see during the anticipated commercial launch of Quell in June 2015, and on market penetration during the third quarter of 2015, we will evaluate the size and location of our sales representatives and likely expand the sales force during the fourth quarter of 2015. Approximately \$1.6 million of the net proceeds will be used to fund the direct sales force during 2015.

**Advertising and Promotion** we plan to generate demand for Quell with a direct-to-consumer, or DTC, promotional effort. We expect that this promotional effort will employ narrowly targeted social media advertisements in channels such as Google, Facebook, and Yahoo; public relations outreach to traditional print and on-line media; and cultivation of thought leaders, chronic pain-focused organizations, and discussion forums. Approximately \$1.6 million of the net proceeds will be used to fund advertising and promotion during 2015.

**Product Development** we plan to develop an Android smartphone application and to initiate development of a second generation Quell product, incorporating early consumer feedback and features not built into the launch model. Approximately \$1.3 million of the net proceeds will be used for product development.

**General Corporate Purposes** The remaining proceeds will be used to build working capital, primarily inventory and accounts receivable in support of Quell of approximately \$0.7 million, clinical studies in support of our proprietary neuro-stimulation technology of approximately \$0.3 million, and for general corporate purposes of approximately \$4.5 million.

Any proceeds we receive from the exercise of the warrants will be used for general corporate 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

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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.

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.

	High	Low
Fiscal Year 2015		
First Quarter	\$ 2.05	\$ 1.60
Second Quarter (through May 21, 2015)	\$ 1.70	\$ 1.12
Fiscal Year 2014		
First Quarter	\$ 3.14	\$ 2.17
Second Quarter	\$ 2.61	\$ 1.67
Third Quarter	\$ 3.15	\$ 1.57
Fourth Quarter	\$ 2.01	\$ 1.52
Fiscal Year 2013		
First Quarter	\$ 3.24	\$ 1.98
Second Quarter	\$ 3.14	\$ 1.84
Third Quarter	\$ 2.18	\$ 1.50
Fourth Quarter	\$ 4.25	\$ 1.47

As of March 31, 2015, there were approximately 101 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 B convertible preferred stock will not be entitled to receive any dividends, unless and until specifically declared by our Board.





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The following table describes our capitalization and cash and cash equivalents as of March 31, 2015, on an actual basis and on an as adjusted basis to reflect our assumed sale of 145,000 units at a price of \$100 per unit for net proceeds of approximately \$10.0 million after (i) deducting underwriting discounts and commissions and estimated offering expenses by us, and (ii) the repurchase of all of our outstanding shares of the Series A-4 convertible preferred stock for an aggregate purchase price of \$3.2 million and the forfeiture of warrants to purchase 1,571,744 shares of our common stock, which we anticipate will occur simultaneous with the closing of this offering, and on an as adjusted, converted basis assuming (i) the Series B convertible preferred stock sold in this offering has a conversion price of \$1.20 per share, which was 100% of the closing price of our common stock on The NASDAQ Capital Market on May 21, 2015 and (ii) the conversion of all shares of Series B convertible preferred stock sold in this offering into 12,180,000 shares of common stock. 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, 2014 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, both of which are incorporated by reference into this prospectus.

	As of March 31, 2015 (000 \$)		
	Actual	As adjusted <sup>(1)</sup>	As adjusted, converted <sup>(1)</sup>
Cash and cash equivalents	\$6,403	\$ 16,403	\$ 16,403
Common stock warrant liability	\$4,121	\$ 2,787	\$ 2,787
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; 11,083 shares designated March 31, 2015, actual, and 156,083 shares designated at March 31, 2015, as adjusted and as adjusted, converted; and 3,206.357 shares issued and outstanding at March 31, 2015, actual, 145,000 shares issued and outstanding at March 31, 2015, as adjusted, and zero shares issued and outstanding as adjusted, converted			
Common stock, \$0.0001 par value: 50,000,000 shares authorized; 8,519,151 shares issued and outstanding, at March 31, 2015 and as adjusted, and 20,699,151 shares issued and outstanding, as adjusted, converted	1	1	2
Additional paid-in capital	158,131	168,945	168,944
Accumulated deficit	(156,450)	(155,930 )	(155,930 )
Total stockholders' equity	1,682	13,016	13,016
Total capitalization	\$5,803	\$ 15,803	\$ 15,803

(1) Each increase of 10,000 units offered by us at \$100 per unit would increase each of our as adjusted cash and cash equivalents, total stockholders' equity and total capitalization by approximately \$925,000. Similarly, each decrease of 10,000 units offered by us at \$100 per unit would decrease each of our as adjusted cash and cash equivalents,

total stockholders' equity and total capitalization by approximately \$925,000. 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.

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The preceding table excludes 1,571,744 shares of common stock issuable upon the conversion of 3,206,357 shares of Series A-4 convertible preferred stock (which we anticipate such shares of Series A-4 convertible preferred stock will be repurchased simultaneously with the closing of this offering), 5,760,847 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2015, at a weighted average exercise price of \$2.70 per share (of which we anticipate warrants to purchase 1,571,744 shares of our common stock will be forfeited simultaneously with the closing of this offering), 809,257 shares of common stock issuable upon the exercise of options outstanding as of March 31, 2015, at a weighted average exercise price of \$4.95 per share, 454,614 shares of common stock available for future issuance under our 2004 Stock Option and Incentive Plan and an additional 850,000 shares of common stock available for future issuance under our 2004 Stock Option and Incentive Plan that were approved by our stockholders at our 2015 Annual Meeting of Stockholders held on May 5, 2015, 200,000 shares of common stock available for future issuance under our 2009 Non-qualified Inducement Stock Plan, and 140,947 shares of our common stock available for future issuance under our 2010 Employee Stock Purchase Plan. The preceding table also excludes 12,180,000 shares of common stock issuable upon the exercise of the warrants to be sold in this offering.

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If you purchase securities in this offering, your interest in the common stock underlying the Series B convertible preferred stock and the warrants offered hereunder will be diluted to the extent of the difference between the price you pay for each share of common stock underlying the Series B convertible preferred stock and the adjusted, as converted net tangible book value per share of our common stock immediately after this offering.

Our net tangible book value as of March 31, 2015 was approximately \$1.7 million, or approximately \$0.20 per share. Net tangible book value per share represents our total tangible assets less total liabilities, divided by the number of shares of common stock outstanding as of March 31, 2015.

Net tangible book value dilution per share of common stock to purchasers in this offering represents the difference between the amount per share paid by purchasers in this offering and the as adjusted, converted net tangible book value per share of common stock immediately after the completion of this offering (assuming that a value of \$0.0000001 is attributed to each warrant). Assuming (i) that we issue 145,000 units at a price of \$100 per unit, (ii) that the Series B convertible preferred stock sold in this offering has a conversion price of \$1.20 per share, which was 100% of the closing price of our common stock on The NASDAQ Capital Market on May 21, 2015, (iii) the conversion of all the shares of Series B convertible preferred stock sold in this offering at the assumed conversion price into 12,180,000 shares of common stock, and after deducting the estimated underwriter discounts and commissions and estimated offering expenses and after the repurchase of all of the outstanding shares of our Series A-4 convertible preferred stock, payable by us, our adjusted, as converted net tangible book value as of March 31, 2015 would have been approximately \$13.0 million, or \$0.63 per share of our common stock. This calculation assumes the conversion of Series B convertible stock into common stock because of the probability this will occur over time. It excludes the proceeds, if any, from the exercise of warrants issued in this offering which is uncertain. This amount represents an immediate increase in as adjusted, converted net tangible book value of \$0.43 per share to our existing stockholders and an immediate dilution in net tangible book value of \$0.57 per share to purchasers in this offering, as illustrated in the following table:

Assumed conversion price per share		\$ 1.20
Net tangible book value per share as of March 31, 2015	\$ 0.20	
Increase in as adjusted, converted net tangible book value per share attributable to purchasers in this offering	\$ 0.43	
As adjusted, converted net tangible book value per share as of March 31, 2015, after giving effect to the offering		\$ 0.63
Dilution to purchasers in this offering		\$ 0.57

Assuming that the number of units offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, a \$0.50 increase in the assumed conversion price of \$1.20 per share would not change the adjusted, as converted net tangible book value. The adjusted, as converted net tangible book value per share would increase and the dilution to purchasers in this offering would increase by \$0.37 per share. A \$0.50 decrease in the assumed conversion price of \$1.20 per share would not change the adjusted, as converted net tangible book value. The adjusted, as converted net tangible book value per share would decrease and the dilution to purchasers in this offering would decrease by \$0.31 per share. The as adjusted, converted information presented is illustrative only and will change based on the actual offering price and other terms of this offering determined at pricing.

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The above discussion and table excludes 1,571,744 shares of common stock issuable upon the conversion of 3,206,357 shares of Series A-4 convertible preferred stock (which we anticipate such shares of Series A-4 convertible preferred stock will be repurchased simultaneously with the closing of this offering), 5,760,847 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2015, at a weighted average exercise price of \$2.70 per share (of which we anticipate warrants to purchase 1,571,744 shares of our common stock will be forfeited simultaneously with the closing of this offering), 809,257 shares of common stock issuable upon the exercise of options outstanding as of March 31, 2015, at a weighted average exercise price of \$4.95 per share, 454,614 shares of common stock available for future

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issuance under our 2004 Stock Option and Incentive Plan and an additional 850,000 shares of common stock available for future issuance under our 2004 Stock Option and Incentive Plan that were approved by our stockholders at our 2015 Annual Meeting of Stockholders held on May 5, 2015, 200,000 shares of common stock available for future issuance under our 2009 Non-qualified Inducement Stock Plan, and 140,947 shares of our common stock available for future issuance under our 2010 Employee Stock Purchase Plan. The preceding table also excludes 12,180,000 shares of common stock issuable upon the exercise of the warrants to be sold in this offering.

To the extent that any of our outstanding options or warrants, including the warrants issued in this offering, are exercised or preferred stock converted, we grant additional options under our stock option plans or issue additional warrants or preferred stock, or we issue additional shares of common stock in the future, there may be further dilution to purchasers in this offering.

An investor that acquires additional shares of common stock through the exercise of the warrants offered hereby may experience additional dilution depending on our net tangible book value at the time of exercise. Assuming that we issue 145,000 units, that the warrants have an assumed exercise price of \$1.32 per share, which is 110% of the closing price of our common stock on The NASDAQ Capital Market on May 21, 2015, and that all such warrants are exercised, our as adjusted, converted net tangible book value as of March 31, 2015 would have been approximately \$29.1 million, or \$0.88 per share of our common stock. This amount represents an increase in net tangible book value of \$0.69 per share to our existing stockholders and a dilution in net tangible book value of \$0.44 per share to purchasers in this offering exercising such warrants.

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## **BUSINESS**

### **Our Business An Overview**

NeuroMetrix is an innovative health-care company that develops wearable medical technology and point-of-care tests that help patients and physicians better manage chronic pain, nerve diseases, and sleep disorders. Our business is fully integrated with in-house capabilities spanning product development, manufacturing, regulatory affairs and compliance, sales and marketing, and customer support. We derive revenues from the sale of medical devices and after-market consumable products and accessories. Our products are sold in the United States and selected overseas markets, and are cleared by the U.S. Food and Drug Administration, or FDA, and regulators in foreign jurisdictions where appropriate. We have two principal product lines:

Wearable neuro-stimulation therapeutic devices

Point-of-care neuropathy diagnostic tests

Our core expertise in biomedical engineering has been refined over nearly two decades of designing, building and marketing medical devices that stimulate nerves and analyze nerve response for diagnostic and therapeutic purposes. We created the market for point-of-care nerve testing and were first to market with sophisticated, wearable technology for management of chronic pain. We have an experienced management team and Board of Directors. Our Scientific Advisory Board includes internationally recognized experts in diabetes and pain.

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, 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. Within the US chronic pain population one of the largest segments is patients with neuropathic pain estimated at 25 million persons. A significant subset of these patients is persons with diabetes of which 16% to 25% suffer painful diabetic neuropathy, or PDN, estimated at 6 to 8 million patients. 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, 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



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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 two years.

Our primary objective for 2015 is revenue growth. We expect this to be led by the successful introduction and market adoption of a new over-the-counter analgesic category featuring Quell, our wearable device for pain relief which builds upon the core SENSUS neuro-stimulation technology. We also expect an important contribution to revenue growth from DPNCheck, our rapid, accurate diagnostic test for diabetic peripheral neuropathy, which we previously referred to as NC-stat DPNCheck.

Our key business strategies for 2015 include:

### ***Driving Commercial Adoption of Our Proprietary Products.***

**Quell**, our over-the-counter (OTC) wearable device for pain relief, was unveiled at the January 2015 Consumer Electronics Show (CES). Quell utilizes Opti Therapy™, our proprietary non-invasive neuro-stimulation technology to provide relief from chronic intractable pain, particularly nerve pain due to diabetes and lower back problems. 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 will also have the option of using their smartphones to automatically track and personalize their pain therapy. Response to Quell at CES and from independent market studies has been positive. We began making shipments to physicians and thought leaders in chronic pain in May 2015 and anticipate making Quell commercially available in the United States in June 2015. Our commercial launch plan involves two distribution channels: a professional channel using a direct sales force to target podiatrists, pain physicians, primary care physicians, and chiropractors who would resell the product, and a direct-to-consumer channel using online marketing and lead generation. During 2016 we plan to evaluate additional U.S. retail distribution opportunities. We believe there are significant opportunities to market Quell outside of the United States, particularly in Western Europe, Japan and China; however, we do not intend to approach those markets until we have established a solid presence in the United States.

During March 2015, we initiated a month-long, Quell pre-order campaign on the crowdfunding platform Indiegogo.

Our goal was to receive 500 preorders for the device and to obtain funding of approximately \$100,000. We have received preorders for approximately 1,900 Quell devices, generating gross proceeds of approximately \$390,000.

**SENSUS**, our prescription neuro-stimulation therapeutic device for relief of chronic pain, was launched in the first quarter of 2013 and provides the technological foundation for Quell. SENSUS revenues in 2014 and 2013 were

approximately \$0.9 million and \$0.2 million, respectively. SENSUS is distributed through durable medical equipment (DME) suppliers who call on pain medicine physicians, neurologists, endocrinologists, podiatrists, and primary care physicians to create awareness among physicians who are challenged with trying to manage chronic pain in their patients. These physicians prescribe SENSUS to their patients who, in turn, have their prescriptions fulfilled by a DME. The DME is also responsible for billing and collection from third party payers

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such as Medicare and other insurers. This is a high cost distribution channel with tight margins. The DME channel is under pressure from Medicare's competitive bidding initiative. We believe that the U.S. growth opportunity for this prescription neuro-stimulation device is limited and that there are more attractive opportunities in the OTC market. **DPNCheck**, our diagnostic test for peripheral neuropathies was made commercially available in the fourth quarter of 2011. DPNCheck revenues for 2014 and 2013 were approximately \$1.8 million and \$1.3 million, respectively. 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 opportunities are developing in Japan where we received regulatory approval and launched DPNCheck with Omron Healthcare in 2014; in China where we are working with Omron Healthcare on the regulatory process and anticipate commercial launch in 2016; in Mexico where our distributor Scienta Farma recently received regulatory approval and plans to launch in mid-2015; and in the Middle East.

***Maintaining a High Level of Research and Development Productivity.*** New products commercialized over the past three years made up nearly fifty percent of our 2014 revenues, and we expect them to comprise the majority of our revenues in 2015. During those three years, we brought to market DPNCheck and SENSUS. Our research and development team faces its greatest challenge of the past few years in completing development of the Quell device, smartphone application and electrode in time for commercial launch in June of 2015. This is our top priority and we believe Quell has the potential to be the largest contributor to 2015 revenues of our marketed products, including SENSUS and DPNCheck.

## **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, SENSUS and DPNCheck, conform to this model. Quell and other products in our development pipeline are based on the device plus consumables business 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 a therapeutic stimulation intensity and compensate for nerve desensitization, and automated detection of user sleep and appropriate adjustment of stimulation level. Quell is comprised of (1) an electronic device carried in a neoprene band that is worn on the upper calf and (2) an electrode that attaches to the device and is the interface between the device and the skin. The device is lightweight and can be worn during the day while active, and at night while sleeping. It has been cleared by the FDA for treatment of chronic intractable pain and will be available OTC. Users of the device will have the option of using their smartphones to automatically track and personalize their pain therapy. The device was unveiled at the Consumer Electronics Show in

January 2015. We began making shipments to physicians and thought leaders in chronic pain in May 2015 and anticipate making Quell commercially available in the United States in June 2015. Our commercial launch plan involves two distribution channels: a professional channel using a direct sales force to target podiatrists, pain physicians, primary care physicians, and chiropractors who would resell the product, and a direct-to-consumer channel using online marketing and lead generation.

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During March 2015 we initiated a month-long, pre-order campaign for Quell on the crowdfunding platform Indiegogo. This campaign offered the opportunity to order Quell in advance of market launch and be one of the first to receive the product. The campaign was designed as a learning opportunity to test market interest in Quell and obtain feedback on design features. Our goal was to receive 500 preorders for the device and to obtain funding of approximately \$100,000. We received preorders for approximately 1,900 Quell devices, generating gross proceeds of approximately \$390,000.

We anticipate that the Quell device will sell for a retail price ranging between \$200 and \$250 and that the electrodes will be sold pursuant to monthly subscription programs at approximately \$30 per month. We anticipate that our gross margins on Quell products will be in the range of 50% to 75% and that our sales and promotional spending will be approximately \$200 to \$300 per new user.

## SENSUS

The SENSUS pain therapy device 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 2014, 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. We used our expertise in peripheral nerve stimulation in the development of SENSUS which incorporates several proprietary features for ease of patient use and physician reporting. The SENSUS device and electrodes were cleared by the FDA for commercial distribution. When medically indicated and supported by proper documentation, TENS are generally reimbursed by Medicare and many commercial insurance companies under the DME benefit.

An evidence-based review by the American Academy of Neurology determined that TENS was a useful modality for managing pain associated with DPN. Our assessment of currently available TENS devices indicated that many do not meet the needs of patients due to limitations of the devices and their difficulty to use.

## DPNCheck

DPNCheck is a fast, accurate, and quantitative nerve conduction test that is used to evaluate systemic neuropathies such as DPN. It is designed to be used by primary care physicians, endocrinologists, podiatrists and other clinicians at the point-of-care to objectively detect, stage, and monitor 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 and has the same clinical indications with respect to DPN. The modified device has the same functionality with respect to sural nerve testing as the original device; however, the cost of the electronic hand-held unit and the consumable biosensors has been reduced by approximately 50%. More than 1.8 million patient studies have been performed using our NC-stat technology and there have been approximately 6.3 million nerve tests, including nearly 700,000 sural 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.

## 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 and invasive electromyography procedures. 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

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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.

Historically, the ADVANCE System has been 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.

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	Launch planned Q2 2015	Transcutaneous Electrical Nerve Stimulation	Relief for chronic, intractable pain	Not yet applicable
SENSUS	Q1 2013 present	Transcutaneous Electrical Nerve Stimulation	Relief for chronic, intractable pain, such as PDN	> 7,000
DPNCheck	Q4 2011 present	Nerve Conduction	Diagnosis and evaluation of peripheral neuropathies, such as DPN	> 300,000
ADVANCE	Q2 2008 present	Nerve Conduction Invasive Needle EMG	Diagnosis and evaluation of CTS, low back pain, peripheral neuropathies (including DPN)	> 1,800,000
NC-stat*	Q2 1999 Q3 2010	Nerve Conduction	Diagnosis and evaluation of CTS, lowback pain, peripheral neuropathies (including DPN)	(ADVANCE and NC-stat)

\* Support was discontinued in the first quarter of 2012.

## Customers

Our customers include physicians, clinics, hospitals, managed care organizations, retail health businesses, independent distributors in the United States and abroad, and durable medical equipment (DME) suppliers. With the commercial launch of Quell planned for June of 2015 we expect our customers will expand to include patients who will purchase the device directly from us. SENSUS was launched in early 2013 and is sold to DME suppliers who, in turn, distribute the product along with consumables directly to patients. SENSUS customers purchased approximately 5,800 devices during 2014 and 1,300 devices during 2013. DPNCheck shipments commenced in late 2011 and approximately 2,200 devices had been placed with customers through December 31, 2014. These customers include managed care organizations, retail health businesses, endocrinologists, podiatrists and primary care physicians. As of December 31, 2014, we had an installed base of approximately 610 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 December 31, 2014, one customer accounted for 30% of accounts receivable and more than 10% of revenue. For the years ended

December 31, 2013 and 2012 no single customer accounted for more than 10% of revenue.

## **Geographic Information**

Substantially all of our assets, revenues, and expenses for 2014, 2013, and 2012 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 2014, 2013, and 2012, international revenues accounted for approximately 19%, 16%, and 7%, respectively, of our total revenues.



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## **Sales, Marketing, and Distribution**

We plan to begin commercial shipments of Quell in the United States during June of 2015. Our launch plan involves two distribution channels: a professional channel using a direct sales force to target podiatrists, pain physicians, primary care physicians, and chiropractors who would resell the product, and a direct-to-consumer channel using online marketing and lead generation. Marketing for Quell is led by our Senior Vice President and General Manager Consumer with support from marketing staff and supplemented by outside consultants. We believe there are opportunities for Quell outside the United States, particularly in Western Europe, Japan and China; however, we do not plan to address those markets until we have established a solid presence in the United States.

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 are focused on managed care, and specifically Medicare Advantage providers and patient screening services, which we believe represents the most attractive market opportunity. We believe that attractive opportunities are developing in Japan where we received regulatory approval and launched DPNCheck with Omron Healthcare in 2014; in China where we are working with Omron Healthcare on the regulatory process and anticipate commercial launch in 2016; in Mexico where our distributor Scienta Farma recently received regulatory approval and plans to launch in mid-2015; and in the Middle East.

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

Our marketing support for SENSUS, NC-stat DPNCheck and ADVANCE is provided by our Senior Vice President of Commercial Operations and staff in our corporate office.

We invest significant effort and expense in technical, clinical, and business practices training for our commercial operations team, marketing staff and independent sales representatives. We also require attendance at periodic sales and product training programs. 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 SENSUS and DPNCheck devices at our corporate headquarters facility and also intend to perform final assembly and servicing for Quell at this location. We rely on an outside contractor for the manufacture and servicing of our ADVANCE device and also for the components that we use in manufacturing SENSUS and DPNCheck. We rely on outside contractors for the manufacture of our consumable biosensor/electrodes. With the exception of the biosensors for use with our DPNCheck devices which we acquire from two manufacturers, we do not currently maintain alternative manufacturing sources for our SENSUS, DPNCheck or ADVANCE devices, communication hubs, biosensors/electrodes, or any other finished goods products. 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., or Sunburst, has been manufacturing our NC-stat devices since November 2005. We entered into a supply agreement with Sunburst during 2006 for the manufacturing and supply of our

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neurodiagnostic devices. Sunburst manufactures the current generation of our ADVANCE device as well as the DPNCheck and SENSUS subassemblies at a facility in Massachusetts.

Polymer Flexible Circuits, Inc., or Parlex, has been manufacturing our nerve specific electrodes since early 1999. In August 2006 we entered into a manufacturing and supply agreement with Parlex pursuant to which Parlex will manufacture and supply to us, and we will purchase from Parlex, at agreed upon prices per unit, our requirements of nerve conduction testing electrodes for resale in the United States. Under the agreement, Parlex has 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., or Katecho, a full service original equipment manufacturer, or OEM, specializing in medical and cosmetic devices, manufactures biosensors for use with our DPNCheck devices and electrodes for use with our SENSUS devices, and will manufacture electrodes for use with Quell, 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. In addition, our neuro-stimulation systems, SENSUS and Quell, are cleared for marketing in the United States. 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. R&D works closely with our marketing group and customers to design products that are focused on improving clinical outcomes. The team consists of 10 people including two who hold M.D. degrees 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:

*Development of Quell.* This wearable device for pain relief utilizes our proprietary non-invasive neuro-stimulation technology to provide relief from chronic pain, particularly nerve pain such as due to diabetes and lower back problems. It is lightweight and can be worn during the day while active, and at night while sleeping. It has been cleared by the FDA for treatment of chronic pain without a doctor's prescription and will be available OTC. Users of the device will have the option of using their smartphone to automatically track and personalize their pain therapy. Quell development is the primary focus of our R&D group. This spans completing Quell development for commercial shipments in June of 2015, initiation of work on a second generation product and enhanced controls on proprietary

electrodes, and development of new clinical indications.

*Support of DPNCheck.* We recently launched DPNCheck, our quantitative nerve conduction test for peripheral neuropathies, in the Japan market. DPNCheck is in the midst of regulatory review in China. The characteristics of these markets often require device modification for local acceptance. We are collaborating with Omron Healthcare in Asia for DPNCheck and anticipate continuing engineering support requirements.

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*Support clinical studies that employ our products.* We presently are involved in eight studies that use DPNCheck in the evaluation of neuropathy in persons with diabetes under various study conditions.

We are planning Quell clinical studies to support our marketing and business plans. These studies will be designed to expand the clinical foundation for use of DPNCheck and Quell which, in turn, should support future adoption of these products.

Research and development expenses were approximately \$4.1 million, \$3.4 million, and \$3.5 million for 2014, 2013, and 2012, respectively.

## Clinical Programs

We maintain a clinical program 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.

Following is a list of external studies involving the use of our products which are currently underway.

Institution	Initiated	Study Focus	Product	Duration	Subjects
Ipswich Diabetes Centre, Ipswich Hospital (UK)	2011	Evaluation of small fiber neuropathy in patients with diabetes	DPNCheck	4 years	400
Royal Hallamshire Hospital University of Sheffield (UK)	2012	Evaluation of DPN based on severity of diabetes	DPNCheck	3 years	100
Royal Hallamshire Hospital, University of Sheffield (UK)	2014	One-stop Screening Service (OPPS) study	DPNCheck	2 years	1000
Joslin Diabetes Center	2012	Effect of weight loss on DPN	DPNCheck	3 years	50
Institute for Clinical Diabetology, Heinrich Heine University	2012	Assessment of DPN in newly diagnosed Type 2 diabetes patients	DPNCheck	3 year	400
Institute for Clinical Diabetology, Heinrich Heine University	2013	Assessment of DPN in an elderly population	DPNCheck	2 years	700
First Vitals Health	2013	Effect of aggressive intervention on foot disease for high risk patients	DPNCheck	3 years	600

Mass General Hospital      2014      SENSUS efficacy in patients  
with restless leg syndrome      SENSUS      1 year      9

## Competition

We believe there is no direct competition to our 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 a large 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*

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As of March 1, 2015, we had 39 issued U.S. patents, 1 issued foreign patent, and 32 pending patent applications, including 18 U.S. applications, two international PCT applications, and 12 foreign national applications. We have filed 2 utility patent applications for DPNCheck and 10 utility patent applications related to SENSUS and Quell product lines.

Our issued design patents begin to expire in 2015, and our issued utility patents begin to expire in 2017. In particular, seven of our issued U.S. utility patents covering various aspects of our current products will expire on the same date in 2017. Although the patent protection for material aspects of our products covered



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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 marks NEUROMETRIX, NC-stat, DPNCheck and SENSUS. We use a trademark for ADVANCE, Quell, and OptiTherapy. We hold certain foreign trademark registrations for the marks NEUROMETRIX, 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 2015 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 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

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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 believe 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 the DPNCheck and SENSUS devices and the ADVANCE System 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, 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, which must be cleared by the FDA prior to the start of a clinical investigation, unless the device and clinical

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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 (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. 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.

## ***Manufacturing Facilities***

Our facility, and the facility utilized by Sunburst, our contract device manufacturer, 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

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we believe that we and our contract manufacturer are in substantial compliance with the QSR. We expect that our facility 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 Medicare fiscal intermediaries assumed coverage for CPT 95905 for at least some clinical indications; however, the health care environment has been such that we have been 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

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million. We reported revenue for our legacy Neurodiagnostics business of \$2.8 million, \$3.8 million, and \$6.1 million in 2014, 2013 and 2012, respectively. We currently manage this business to optimize cash flow.

## **Employees**

As of March 31, 2015, we had a total of 45 full time employees. Of these employees, 11 were in research and development, 20 in sales and marketing, 8 in production/distribution, and 6 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.

TABLE OF CONTENTS**MANAGEMENT****Executive Officers and Directors**

The following table sets forth information regarding our executive officers and directors, including their ages, as of March 31, 2015.

Name	Age	Position
Shai N. Gozani, M.D., Ph.D.	50	Chairman of the Board, Chief Executive Officer, President and Secretary
Thomas T. Higgins	63	Senior Vice President, Chief Financial Officer and Treasurer
Francis X. McGillin	54	Senior Vice President General Manager Consumer
David E. Goodman, M.D. <sup>(1)(2)</sup>	58	Director
Allen J. Hinkle, M.D. <sup>(2)(3)</sup>	64	Director
Nancy E. Katz <sup>(1)</sup>	55	Director
Timothy R. Surgenor <sup>(1)(3)</sup>	55	Director
David Van Avermaete	63	Director

(1) Member of Audit Committee

(2) Member of Compensation Committee

(3) Member of Nominating and Corporate Governance Committee

**Shai N. Gozani, M.D., Ph.D.** founded our Company in 1996 and currently serves as Chairman of our Board of Directors and as our President, Chief Executive Officer and Secretary. Since founding our Company in 1996, Dr. Gozani has served in a number of positions at our company including Chairman since 1996, President from 1996 to 1998 and from 2002 to the present, Chief Executive Officer since 1997 and Secretary since July 2008. Dr. Gozani

holds a B.A. in computer science, an M.S. in Biomedical Engineering and a Ph.D. in Neurobiology, from the University of California, Berkeley. He also received an M.D. from Harvard Medical School and the Harvard-M.I.T.

Division of Health Sciences at M.I.T. Prior to forming our Company, Dr. Gozani completed a neurophysiology research fellowship in the laboratory of Dr. Gerald Fischbach at Harvard Medical School. Dr. Gozani has published articles in the areas of basic and clinical neurophysiology, biomedical engineering and computational chemistry. The

Board has concluded that Dr. Gozani should serve as a director because Dr. Gozani's extensive knowledge of engineering and neurophysiology, combined with the unique understanding of our technology and business he has gained as our founder and as a key executive, provides invaluable insight to our Board and to the entire organization.

**Thomas T. Higgins** has served as our Senior Vice President, Chief Financial Officer and Treasurer since September 2009. Prior to joining NeuroMetrix, from January 2005 to March 2008, Mr. Higgins was Executive Vice President and Chief Financial Officer at Caliper Life Sciences, Inc, a provider of technology and services for life sciences research.

Before Caliper, Mr. Higgins was Executive Vice President, Operations and Chief Financial Officer at V.I. Technologies, Inc. (Vitex), a biotechnology company addressing blood safety. Before Vitex, Mr. Higgins served at Cabot Corporation in various senior finance and operations roles. His last position at Cabot was President of Distrigas of Massachusetts Corporation, a subsidiary involved in the liquefied natural gas business, and prior to that he was responsible for Cabot's Asia Pacific carbon black operations. Before joining Cabot, Mr. Higgins was with PricewaterhouseCoopers where he started his career. Mr. Higgins holds a BBA with honors from Boston University.

**Francis X. McGillin** has served as Senior Vice President and General Manager Consumer Wearables since August

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

**David E. Goodman, M.D., M.S.E.** has served as a member of our Board of Directors since June 2004. Since 2013, Dr. Goodman has served as CEO of FeetFirst, a technology-focused healthcare services company

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he co-founded with operations in California and Hawaii that is committed to preventing the devastating and expensive microvascular complications of diabetes. Since 2012, Dr. Goodman has served as CMO of FirstVitals, a healthcare services company focused on wellness and prevention. Since 2011, Dr. Goodman has also served as an independent consultant. During 2010, Dr. Goodman has served as President and Chief Executive Officer of SEDline, Inc., a research-focused company with the mission to expand the scope and applications for neuromonitoring. From 2008 to 2009, Dr. Goodman served as Executive Vice President of Business Development for Masimo Corporation, a manufacturer of non-invasive patient monitors. From 2006 to 2008, Dr. Goodman served as an independent consultant providing product design, regulatory and analytical consulting services to medical device and biopharmaceutical companies and also served in this capacity from 2003 to 2004 and from 2001 to 2002. From 2005 to 2006, Dr. Goodman served as President and Chief Executive Officer of BaroSense, Inc., a medical device company focused on developing minimally invasive devices for the long-term treatment of obesity. From 2004 to 2005, Dr. Goodman served as President and Chief Executive Officer of Interventional Therapeutic Solutions, Inc., an implantable drug delivery systems company. From 2002 to 2003, Dr. Goodman served as Chairman, President and Chief Executive Officer of Pherin Pharmaceuticals, a pharmaceutical discovery and development company. From 1994 to 2001, Dr. Goodman held various positions, including Chief Executive Officer, Chief Medical Officer and director, for LifeMasters Supported SelfCare, Inc., a disease management services company that Dr. Goodman founded. Dr. Goodman also served as a director of Sound Surgical Technologies LLC, a private manufacturer of aesthetic surgical tools from 2011 until its acquisition by Solta Medical (Nasdaq:SLTM) in 2013. Dr. Goodman holds a B.A.S. in applied science and bioengineering and a M.S.E. in bioengineering from the University of Pennsylvania. He also received an M.D. from Harvard Medical School and the Harvard-M.I.T. Division of Health Sciences and Technology. Dr. Goodman holds 18 patents and is a practicing physician with licenses in California and Hawaii. The Board has concluded that Dr. Goodman should serve as a director because Dr. Goodman's medical and engineering background and his many years of executive experience in the medical device industry provide important experience and expertise to the Board.

**Allen J. Hinkle, M.D.** has served as a member of our Board of Directors since January 2006. From December 2010 through the present, Dr. Hinkle has served as the Chief Medical Officer of MVP Health Care, a not-for-profit health insurer. Dr. Hinkle was the Chief Medical Officer and Senior Vice President for Tufts Health Plan in Massachusetts, a health insurance provider, where he was responsible for medical management programs and initiatives from 2004 to 2009. Prior to becoming the Chief Medical Officer of Tufts Health Plan, Dr. Hinkle was Senior Medical Director and Vice President of Health Care Quality, Policy and Innovations at Blue Cross Blue Shield of Massachusetts, a health insurance provider, from 2001 through September 2004. From 1995 to 2001, Dr. Hinkle was the Chief Medical Officer and Senior Vice President of Quality Healthcare Management for Anthem Blue Cross Blue Shield of New Hampshire and Matthew Thornton Plan, health insurance provider organizations. Dr. Hinkle has over 40 years of experience in the healthcare field. Dr. Hinkle received a B.S. from the University of Massachusetts at Amherst and an M.D. from Albert Einstein College of Medicine in New York. He is board certified in pediatrics and anesthesiology and is an Associate Professor at Dartmouth Medical School. He also owns several U.S. patents on medical devices. The Board has concluded that Dr. Hinkle should serve as a director because Dr. Hinkle's years of experience as a physician and in executive positions in the health insurance industry provide the Board with valuable insights in the areas of product development and reimbursement.

**Nancy E. Katz** has served as a member of our Board of Directors since December 2010. From May 2011 to August 2014, Ms. Katz served as Vice President, Consumer Marketing at Medtronic, Inc., a medical technology company. From July 2005 to July 2010, Ms. Katz was Senior Vice President, Bayer Diabetes Care North America. Prior to this position, she was President and Chief Executive Officer of Calypte Biomedical Corporation, a manufacturer of HIV diagnostics, President of Zila Pharmaceutical, Inc, a manufacturer of oral care products, and held senior marketing positions with the Lifescan division of Johnson & Johnson (blood glucose diabetes products), Schering-Plough Healthcare Products, and with American Home Products. She has previously served on the Boards of Directors of

Neoprobe Corporation (AMEX: NEOP), Calypte Biomedical Corporation, LXN Corporation and Pepgen Corporation. She received a B.S. in business from the University of South Florida. The Board has concluded that Ms. Katz should serve as a director because her experience in diabetes care and marketing into the diabetes sector provides valuable insight to the Board and management in our diabetes strategy.

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

**David Van Avermaete** has served as a member of our Board of Directors since September 2013. From April 2004 to February 2013, Mr. Van Avermaete served as Chief Executive Officer of VeraLight, Inc., a medical device company he founded, that focuses on non-invasive screening for type 2 diabetes. From 2000 to 2004, Mr. Van Avermaete served as Senior Vice President Non-Invasive Technology of InLight Solutions, a Johnson & Johnson company focused on transformational technology in the diabetes field. From 1998 to 2000, Mr. Van Avermaete served as U.S. President of the LifeScan division of Johnson & Johnson and, from 1990 to 1998, in various senior level positions at LifeScan concentrating in sales and marketing. Previously, Mr. Van Avermaete served as Vice President Sales and Marketing at Biotope, Director of Marketing at Roche Diagnostics, and Director of Marketing and Sales at Syntex Medical Diagnostics. Mr. Van Avermaete received a Master of Business Administration and a Master of Science Degree in Microbiology from the University of Arizona and a Bachelor of Science Degree in medical technology and chemistry from Ball State University. The Board has concluded that Mr. Van Avermaete should serve as a director because his executive level experience in the medical device and diabetes field, as well as in entrepreneurial ventures, provides the Board with a valuable perspective in commercializing diabetes products.

## **Board Independence**

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

## **Committee Independence**

Our Board of Directors has an Audit Committee currently consisting of Mr. Surgenor, Chairman, Dr. Goodman and Ms. Katz. Dr. Goodman, Ms. Katz, and Mr. Surgenor are all independent as that term is defined in the rules of the SEC and the applicable NASDAQ Listing Rules relating to audit committee membership. Our Board of Directors has determined that Mr. Surgenor qualifies as an audit committee financial expert as such term is defined in the rules of the SEC.

Our Board of Directors has a Compensation Committee consisting of Drs. Goodman and Hinkle. Drs. Goodman and Hinkle are independent directors as that term is defined in the NASDAQ Listing Rules.



Our Board of Directors has a Nominating and Corporate Governance Committee consisting of Dr. Hinkle and Mr. Surgenor. Dr. Hinkle and Mr. Surgenor are each independent directors as that term is defined in the NASDAQ Listing Rules.

TABLE OF CONTENTS**EXECUTIVE COMPENSATION****Summary of Executive Compensation**

The following table sets forth compensation information with respect to services rendered to us in all capacities during the fiscal years ended December 31, 2014 and 2013 for (i) the individual who served as the Chief Executive Officer during the year ended December 31, 2014, (ii) the individual who served as the Chief Financial Officer during the year ended December 31, 2014, (iii) the other most highly compensated executive officer who was serving as executive officer at December 31, 2014; and (iv) two additional executive officers who would have been among the executive officers included in (iii), but were not serving as executive officers as of December 31, 2014 (we refer to these individuals in (i) through (iv), collectively, as the named executive officers ):

**Summary Compensation Table**

Name and Principal Position	Year	Salary	Bonus	Stock Option	All Other	Total
		(\$)	(\$) <sup>(2)</sup>	Awards (\$)	Awards <sup>(1)</sup> (\$)	
Shai N. Gozani, M.D. Ph.D. Chairman of the Board, Chief Executive Officer, President and Secretary	2014	414,200	233,438	207,080		854,718
	2013	375,000	61,828	128,884		565,712
Thomas T. Higgins Senior Vice President, Chief Financial Officer and Treasurer	2014	300,398	137,003	91,115		528,516
	2013	275,000	36,273	56,535		367,808
Francis X. McGillin <sup>(3)</sup> Senior Vice President, General Manager Consumer	2014	115,104	41,030	219,660	35,000 <sup>(6)</sup>	410,794
Guy Daniello <sup>(4)</sup> Senior Vice President of Information Technology	2014	191,398				191,398
	2013	239,532	23,696	35,977		299,205
Michael Williams, Ph.D. <sup>(5)</sup> Senior Vice President of Engineering, Chief Technology Officer	2014	131,800			143,854	275,654
	2013	260,201	25,740	35,977		321,918

These amounts include the aggregate grant date fair value for option and stock awards granted during fiscal years 2014 and 2013 computed in accordance with FASB ASC Topic 718. The amount of each grant is set forth below

(1) under Discussion of Summary Compensation Table Long-Term Incentive Compensation. A discussion of the assumptions used in determining grant date fair value may be found in Note 3 to our Financial Statements, included in our Annual Report on Form 10-K for fiscal year 2013.

(2) Executive officer bonuses in 2014 and 2013 were paid in shares of the Company's common stock.

(3) Represents compensation paid pursuant to an Employment Agreement dated August 14, 2014. Mr. McGillin started work with the Company on August 25, 2014.

(4) Represents compensation paid until the date of Mr. Daniello's retirement on September 30, 2014.

- (5) Represents compensation paid pursuant to a Separation Agreement, dated August 11, 2014. See Discussion of Summary Compensation Table Cash Compensation. Dr. Williams left the Company effective June 23, 2014.
- (6) Represents a sign-on bonus paid in the third quarter of 2014.

## Discussion of Summary Compensation Table

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

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### **Cash Compensation**

We pay our executive officers a base salary which we review and determine annually. As of December 31, 2014, base salaries for our executive officers are Dr. Gozani \$415,000, Mr. Higgins \$325,000 and Mr. McGillin \$325,000.

In connection with Dr. Williams' resignation, we entered into a separation agreement with Dr. Williams on August 11, 2014. Pursuant to the terms and conditions of the separation agreement, Dr. Williams was entitled to receive twelve months of his then-current annual base salary, made in equal installments pursuant to our normal payroll practices over the twelve months. Additionally, Dr. Williams was entitled to continue to be enrolled in our medical benefit plans during such twelve month period.

### **Bonus Payments**

Each executive officer has an annual bonus target which is expressed as a percentage of base salary. For 2014, executive officer bonus targets as a percentage of base salary were as follows: Dr. Gozani 62.5%; Mr. Higgins 50%; and Mr. McGillin 40%.

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

The management pool metrics for 2014 encompass targets for new equity funding, sales revenue, and product development. Based on their overall evaluation of performance against these metrics, including application of the quantitative formula, the Compensation Committee voted to approve a corporate factor for the management bonus pool which includes the executive officers. The Compensation Committee decided that 2014 bonuses would be paid to the executive officers in the form of fully vested shares of the Company's common stock. On March 13, 2015 executive bonuses were distributed in shares of our common stock, after applicable tax withholding, based on the \$1.69 closing price of NeuroMetrix common stock on the day preceding the Compensation Committee decision. The executive officers received the following shares of common stock, after applicable tax withholding: Dr. Gozani 73,783 shares; Mr. Higgins 43,064 shares; Mr. McGillin 12,631 shares.

### **Long-Term Incentive Compensation**

We grant long-term equity incentive awards in the form of stock options and restricted shares to executives as part of our total compensation package. The Compensation Committee awarded in August 2014 the following equity grants comprised of stock options, to our named executive officers under our 2004 Stock Plan in the following amounts: Dr. Gozani 200,000 options; and Mr. Higgins 88,000 options. Mr. McGillin received a stock option grant of 200,000 under our Inducement Plan in connection with joining the Company. We also made the following equity grants in July 2013, comprised of stock options, to our named executive officers under our 2004 Stock Plan: Dr. Gozani 125,000 options; Mr. Higgins 55,000 options; Mr. Daniello 35,000 options; and Dr. Williams 35,000 options.

Stock options referred to above have a term of ten years and, other than the performance-based stock options, vest over four years with 25% of the total award vesting after one year and the remainder vesting in equal quarterly installments thereafter. Generally, to the extent vested, each stock option is exercisable during the term of the option while the grantee is employed by us and for a period of three months thereafter, unless such termination is upon death or disability, in which case the grantee may continue to exercise the option for a period of 12 months, or for cause, in which case the option terminates immediately. Vesting

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of stock options is also subject to acceleration in some certain circumstances in connection with a change-in-control as described below in Employment Agreements and Potential Payments upon Termination or Change-in-Control.

## Outstanding Equity Awards at Fiscal Year-End

The table below sets forth information with respect to our named executive officers concerning the outstanding equity awards as of December 31, 2014.

	Option Awards			Option Exercise Price (\$)	Option Expiration Date	
	Number of Securities Underlying Unexercised Options Exercisable (#)	Unexercisable (#)				
Shai N. Gozani, M.D., Ph.D.	973			71.64	4/01/18	
	5,556			61.20	2/12/19	
	2,327			60.84	4/02/20	
	2,793			19.80	2/01/21	
	1,744	117	(1)	19.80	2/01/21	
	78,125	46,875	(2)	1.77	7/26/23	
		200,000	(3)	1.77	7/31/24	
Thomas T. Higgins	1,173			19.80	2/01/21	
	733	49	(4)	19.80	2/01/21	
	34,375	20,625	(5)	1.77	7/26/23	
		88,000	(6)	1.77	7/31/24	
Francis X. McGillin			200,000	(7)	1.88	8/25/24

Reflects the unexercised portion of a stock option for 1,861 shares of common stock that was granted on February (1) 1, 2011. The option vests 25% on the first anniversary of the vesting start date and then 1/16<sup>th</sup> each quarter thereafter until fully vested.

Reflects the unexercised portion of a stock option for 125,000 shares of common stock that was granted on July 26, (2) 2013. The option vests 50% on the first anniversary of the vesting start date and then 1/8<sup>th</sup> each quarter thereafter until fully vested.

Reflects the unexercised portion of a stock option for 200,000 shares of common stock that was granted on July 31, (3) 2014. The option vests 50% on the first anniversary of the vesting start date and then 1/8<sup>th</sup> each quarter thereafter until fully vested.

Reflects the unexercised portion of a stock option for 782 shares of common stock that was granted on February 1, (4) 2011. The option vests 25% on the first anniversary of the vesting start date and then 1/16<sup>th</sup> each quarter thereafter until fully vested.

Reflects the unexercised portion of a stock option for 55,000 shares of common stock that was granted on July 26, (5) 2013. The option vests 50% on the first anniversary of the vesting start date and then 1/8<sup>th</sup> each quarter thereafter until fully vested.

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Reflects the unexercised portion of a stock option for 88,000 shares of common stock that was granted on July 31, (6) 2014. The option vests 50% on the first anniversary of the vesting start date and then 1/8<sup>th</sup> each quarter thereafter until fully vested.

Reflects the unexercised portion of a stock option for 200,000 shares of common stock that was granted on August (7) 25, 2014. The option vests 25% on the first anniversary of the vesting start date and then 1/16<sup>th</sup> each quarter thereafter until fully vested.

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

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

We entered into an employment agreement with Dr. Gozani, effective as of June 21, 2004 and amended on December 31, 2008. Under the terms of the employment agreement, Dr. Gozani is to be paid an annual base salary determined by the Compensation Committee but not less than \$250,000. Dr. Gozani's salary for 2014 was \$415,000. Dr. Gozani is also eligible to receive an annual cash performance bonus of up to 62.5% of his annual salary if certain performance objectives, determined by Dr. Gozani and our Compensation Committee, are met. The employment agreement may be terminated by us with or without cause or by Dr. Gozani. Under the terms of the employment agreement, if (1) we terminate Dr. Gozani for any reason other than willful non-performance of his duties under the employment agreement, intentional fraud or dishonesty with respect to our business or conviction of a felony, which we refer to as a termination without cause, or (2) Dr. Gozani resigns as a result of a reduction in his responsibilities with us, reduction in his status with us, reduction of his salary, relocation of our corporate offices more than 35 miles from their current location or breach by us of the employment agreement, which we refer to as a termination for good reason, Dr. Gozani will be entitled to his full base salary at his then-current annual rate of pay, plus benefits and applicable bonus payments, through the date of his termination. In addition, in the event of such a termination, we will continue to pay Dr. Gozani his then-current annual base salary for one year following the termination. Additionally, Dr. Gozani will be entitled to his full annual cash performance bonus in the year that any of the following transactions occurs:

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

### **Thomas T. Higgins**

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



## **Francis X. McGillin**

We entered into an Employment Agreement with Mr. McGillin on August 14, 2014 in connection with his joining the Company which provides for our employment of Mr. McGillin, as our Senior Vice President and General Manager

Consumer for a three year term at an annual salary of \$325,000, subject to periodic review and adjustment at our discretion. Under the Employment Agreement, Mr. McGillin is also eligible to receive an annual performance bonus, payable in cash or stock, of up to 40% of his annual salary. Under the terms of the Employment Agreement, if (1) we terminate Mr. McGillin for cause or if he resigns for other than good reason, Mr. McGillin will not be entitled to any separation benefits; (2) we terminate Mr. McGillin's employment without cause other than within 6 months prior to or 12 months following a change in control of the company or Mr. McGillin resigns for good reason, he will be entitled to receive

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separation benefits equal to his base salary, target bonus amount and continuation of health benefits for a period of twelve months from the date of such termination; (3) we terminate Mr. McGillin's employment within 6 months prior to or 12 months following a change in control of the company or Mr. McGillin resigns for good reason, he will be entitled to the same benefits as described in (2) above, and in addition, we will accelerate his rights to exercise shares under any stock option grants; and (4) Mr. McGillin dies or becomes totally disabled, we will accelerate the rights of his representative to exercise shares under and stock option grants. In connection with the Employment Agreement, Mr. McGillin executed a Confidentiality & Non-Compete Agreement with the Company.

### **Management Retention and Incentive Plan**

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

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

### **Confidentiality and Non-Competition Agreements**

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

### **Seventh Amended and Restated 2004 Stock Option and Incentive Plan**

Under our 2004 Stock Plan, in the event of a merger, sale or dissolution of our company, or a similar sale event, all outstanding awards under our 2004 Stock Plan, unless otherwise provided for in a particular award, will terminate unless the parties to the transaction, in their discretion, provide for assumption, continuation or appropriate substitutions or adjustments of these awards. In the event that the outstanding awards under our 2004 Stock Plan terminate in connection with a sale event, all stock options and stock appreciation rights granted under our 2004 Stock Plan will automatically become fully exercisable and all other awards granted under our 2004 stock plan will become fully vested and non-forfeitable as of the effective time of the sale event. The administrator may also provide for a cash payment with respect to outstanding options and stock appreciation rights in exchange for the cancellation of

such awards.

TABLE OF CONTENTS**DIRECTOR COMPENSATION**

As of December 31, 2014, the non-employee members of our Board of Directors were entitled to receive annual cash compensation in the amount of \$15,000 for service as a member of our Board of Directors, which is paid following each annual meeting of our stockholders. In addition, these non-employee directors were entitled to receive \$2,000 for each board or committee meeting that they attend, provided that they are not entitled to additional compensation for attending committee meetings that occur on the same day as a board meeting which they attend. This cash compensation is in addition to any stock options or other equity compensation that we determine to grant to our directors. Dr. Gozani, the only member of our Board of Directors who is also an employee, is not separately compensated for his service on our Board of Directors.

In addition to the compensation described above, we reimburse all non-employee directors for their reasonable out-of-pocket expenses incurred in attending meetings of our Board of Directors or any committees thereof. The following table shows compensation information with respect to services rendered to us in all capacities during the fiscal year ended December 31, 2014 for each non-employee member of the Board of Directors.

**DIRECTOR COMPENSATION TABLE 2014**

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (\$) <sup>(1)</sup>	Option Awards (\$)	Total Compensation (\$)
David E. Goodman, M.D. <sup>(2)</sup>	34,750		5,462	40,212
Allen J. Hinkle, M.D. <sup>(3)</sup>	28,250		5,462	33,712
Nancy E. Katz <sup>(4)</sup>	29,250		5,462	34,712
Timothy R. Surgenor <sup>(5)</sup>	34,250		5,462	39,712
David Van Avermaete <sup>(6)</sup>	22,750		5,462	28,212

(1) These amounts represent the aggregate grant date fair value for 5,000 stock options granted to each director during fiscal year 2014.

(2) As of December 31, 2014, Dr. Goodman held 834 restricted shares, 626 of which were vested, and options to purchase 5,972 shares of common stock, 963 of which were vested.

(3) As of December 31, 2014, Dr. Hinkle held 834 restricted shares, 626 of which were vested, and options to purchase 6,972 shares of common stock, 1,963 of which were vested.