

NeuroMetrix, Inc.  
Form 10-K  
February 12, 2016

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

**FORM 10-K**

(Mark One)

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

**For the fiscal year ended December 31, 2015**

**OR**

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

**For the transition period from                      to**

**Commission File Number 001-33351**

**NEUROMETRIX, INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or Other Jurisdiction of  
Incorporation or Organization)

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

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

02451  
(Zip Code)

**(781) 890-9989**

(Registrant's Telephone Number, Including Area Code)

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

Title of each class	Name of exchange on which registered
Common Stock, \$0.0001 par value per share	<b>The NASDAQ Stock Market LLC</b>
Preferred Stock Purchase Rights	<b>The NASDAQ Stock Market LLC</b>
Warrants to Purchase Common Stock	<b>The NASDAQ Stock Market LLC</b>

## **Securities registered pursuant to Section 12(g) of the Act None**

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports); and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during

the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  
 No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

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

As of June 30, 2015, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately \$10,242,247 based on the closing sale price of the common stock as reported on the NASDAQ Capital Market on June 30, 2015.

As of February 1, 2016, there were 4,049,807 shares of Common Stock outstanding.

## DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K:  
Certain information required by Part III of this Annual Report on Form 10-K is incorporated from the Registrant's Proxy Statement for the Annual Meeting of Stockholders to be held on May 3, 2016, or the 2016 Annual Meeting of Stockholders.

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

All share amounts in this Annual Report on Form 10-K have been adjusted to reflect a 1-for-4 reverse stock split that was effected on December 1, 2015.

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## **PART I**

The statements contained in this Annual Report on Form 10-K, including under the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and other sections of this Annual Report, include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including, without limitation, statements regarding our or our management’s expectations, hopes, beliefs, intentions or strategies regarding the future, such as our estimates regarding anticipated operating losses, future revenues and projected expenses, our future liquidity and our expectations regarding our needs for and ability to raise additional capital; our ability to manage our expenses effectively and raise the funds needed to continue our business; our belief that there are unmet needs for the management of chronic pain and in the diagnosis and treatment of diabetic neuropathy; our expectations surrounding Quell and DPNCheck; our expected timing and our plans to develop and commercialize our products; our ability to meet our proposed timelines for the commercial availability of our products; our ability to obtain and maintain regulatory approval of our existing products and any future products we may develop; regulatory and legislative developments in the United States and foreign countries; the performance of our third-party manufacturers; our ability to obtain and maintain intellectual property protection for our products; the successful development of our sales and marketing capabilities; the size and growth of the potential markets for our products and our ability to serve those markets; our plan to make Quell more broadly available through retail distribution; our belief that there are significant opportunities to market Quell outside the United States; our estimate of our customer returns of our products; the rate and degree of market acceptance of any future products; our reliance on key scientific management or personnel; the payment and reimbursement methods used by private or government third party payers; and other factors discussed elsewhere in this Annual Report on Form 10-K or any document incorporated by reference herein or therein. The words believe, may, will, estimate, continue, anticipate, intend, expect, plan and similar expressions are used in our forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. The forward-looking statements contained in this Annual Report on Form 10-K are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in the section titled “Risk Factors.” Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. Unless the context otherwise requires, all references to “we”, “us”, “the Company”, or “NeuroMetrix” in this Annual Report on Form 10-K refer to NeuroMetrix, Inc.

## **ITEM 1. BUSINESS**

### **Our Business – An Overview**

NeuroMetrix is 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

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Our core expertise in biomedical engineering has been refined over nearly two decades of designing, building and marketing medical devices that stimulate nerves and analyze nerve response for diagnostic and therapeutic purposes. We created the market for point-of-care nerve testing and were first to market with sophisticated, wearable technology for management of chronic pain. We also have an experienced management team and Board of Directors. Chronic pain is a significant public health problem. It is defined by the National Institutes of Health as any pain lasting more than 12 weeks in contrast to acute pain which is a normal bodily response to injury or trauma. Chronic pain conditions include painful diabetic neuropathy, or PDN, arthritis, fibromyalgia, sciatica, musculoskeletal pain, cancer pain and many others. Chronic pain may be triggered by an injury or there may be an ongoing cause such as disease or illness. There may also be no clear cause. Pain signals continue to be transmitted in the nervous system over extended periods of time often leading to other health problems. These can include fatigue, sleep disturbance, decreased appetite, and mood changes which cause difficulty in carrying out important activities and contributing to disability and despair. In general, chronic pain cannot be cured. Treatment of chronic pain is focused on reducing pain and improving function. The goal is effective pain management.

Chronic pain is widespread. It affects over 100 million adults in the United States and more than 1.5 billion people worldwide. The global market for pain management drugs and devices alone was valued at \$35 billion in 2012. The estimated incremental impact of chronic pain on health care costs in the United States is over \$250 billion per year and lost productivity is estimated to exceed \$300 billion per year.

The most common approach to chronic pain is pain medication. This includes over-the-counter drugs (such as Advil and Motrin), and prescription drugs including anti-convulsants (such as Lyrica and Neurontin) and anti-depressants (such as Cymbalta and Elavil). Topical creams may also be used (such as Zostrix and Bengay). With severe pain, narcotic pain medications may be prescribed (such as codeine, fentanyl, morphine, and oxycodone). The approach to treatment is individualized, drug combinations may be employed, and the results are often hit or miss. Side effects and the potential for addiction are real and the risks are substantial.

Reflecting the difficulty in treating chronic pain, we believe that inadequate relief leads 25% to 50% of pain sufferers to turn to the over-the-counter market for supplements or alternatives to prescription pain medications. These include non-prescription medications, topical creams, lotions, electrical stimulators, dietary products, braces, sleeves, pads and other items. In total they account for over \$4 billion in annual spending in the United States on pain relief products.

High frequency nerve stimulation is an established treatment for chronic pain supported by numerous clinical studies demonstrating efficacy. In simplified outline, the mechanism of action involves intensive nerve stimulation to activate the body's central pain inhibition system resulting in widespread analgesia, or pain relief. The nerve stimulation activates brainstem pain centers leading to the release of endogenous opioids that act primarily through the delta opioid receptor to reduce pain signal transmission through the central nervous system. This therapeutic approach is available through deep brain stimulation and through implantable spinal cord stimulation, both of which require surgery and have attendant risks. Non-invasive approaches to neuro-stimulation (transcutaneous electrical nerve stimulation, or TENS) have achieved limited efficacy in practice due to device limitations, ineffective dosing and low patient compliance.

## **Our Strategy**

There are large and important unmet medical needs in chronic pain treatment. Prescription pain medications and over-the-counter therapies are often inadequate and can lead to other health issues. We believe that controlled, personalized, neuro-stimulation to suppress pain provides an important complement to pain medications. As a medical device company with unique experience in designing devices to manage and alter peripheral nerve function, we



believe we are well positioned to make neuro-stimulation widely available to chronic pain sufferers. We have direct experience with neuro-stimulation through our prescription SENSUS wearable pain management device which has been on the market for the past three years and Quell, our over-the-counter, or OTC, wearable device for pain relief which was launched in the second quarter of 2015 and builds upon the core SENSUS neuro-stimulation technology.

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

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Our key business strategies include:

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

**Quell**, our OTC wearable device for pain relief, was unveiled at the January 2015 Consumer Electronics Show (CES) and made commercially available in the United States during the second quarter of 2015. Following commercial launch through the end of 2015, approximately 13,800 Quell devices plus electrodes and accessories were shipped to consumers. Quell utilizes OptiTherapy, our proprietary non-invasive neuro-stimulation technology to provide relief from chronic intractable pain, such as nerve pain due to diabetes, fibromyalgia, arthritic pain, and lower back and leg pain. This advanced wearable device is lightweight and can be worn during the day while active, and at night while sleeping. It has been cleared by the FDA for treatment of chronic intractable pain without a doctor's prescription. Users of the device have the option of using their smartphones to automatically track and personalize their pain therapy. Quell was launched through two distribution channels: a professional channel using a direct sales force to target podiatrists, pain physicians, primary care physicians, and chiropractors who resell the product, and a direct-to-consumer channel using online marketing and lead generation. After establishing the professional and direct to consumer channels, we expanded distribution to include Amazon e-commerce sales and QVC direct response TV, or DRTV, sales. We are developing other distribution channels for broader access to the retail markets. We believe there are significant opportunities to market Quell outside of the United States, particularly in Western Europe, Japan and China; however, we do not intend to approach those markets until we have established a solid presence in the United States.

**DPNCheck**, our diagnostic test for peripheral neuropathies, was made commercially available in the fourth quarter of 2011. DPNCheck revenues for the years December 31, 2015 and 2014 were approximately \$2.3 million and \$1.8 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 exist outside the United States including Japan where we received regulatory approval and launched DPNCheck with our distribution partner Omron Healthcare in the third quarter of 2014; in China where we recently received regulatory approval and are working with Omron Healthcare toward commercial launch in the second half of 2016; and in Mexico where our distributor Scienta Farma received regulatory approval and initiated sales in the fourth quarter of 2015.

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

### **Our Business Model**

Our products consist of a medical device used in conjunction with a consumable electrode or biosensor. Other accessories and consumables are also available to customers. Our goal for these devices is to build an installed base of active customer accounts and distributors that regularly order aftermarket products to meet their needs. We successfully implemented this model when we started our business with the NC-stat system and applied it to

subsequent product generations including the ADVANCE system. Our recently developed products, Quell, SENSUS and DPNCheck, conform to this model.

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## Marketed Products

### Quell

Quell is a wearable device for relief of chronic intractable pain, such as nerve pain due to diabetes and lower back problems. It incorporates our OptiTherapy technology, a collection of proprietary approaches designed to optimize the clinical efficacy of nerve stimulation. These include high power electrical stimulation hardware with precise control, algorithms that automatically determine therapeutic stimulation intensity and compensate for nerve desensitization, and automated detection of user sleep and appropriate adjustment of stimulation level. Quell is comprised of (1) an electronic device carried in a neoprene band that is worn on the upper calf and (2) an electrode that attaches to the device and is the interface between the device and the skin. The device is lightweight and can be worn during the day while active, and at night while sleeping. It has been cleared by the FDA for treatment of chronic intractable pain and will be available OTC. Users of the device have the option of using their smartphones to automatically track and personalize their pain therapy. The device was unveiled at the Consumer Electronics Show in January 2015 and was made commercially available in June 2015. In an independent post-market clinical study of Quell initiated by NeuroMetrix, 81% of subjects reported an improvement in management of their chronic pain and health, and 67% reported a reduction in their use of pain medications. To encourage persons with chronic pain to try Quell, we offer a 60-day trial period during which the product can be returned for a full refund. We estimate, over time, we will see product returns in the range of 20%, as indicated by the results of the post-market clinical study. Quell is currently available at selected physician resellers including podiatrists, pain physicians, primary care physicians, and chiropractors, and also via e-commerce on our designated website at ([quellrelief.com](http://quellrelief.com)) and on Amazon.com, and via DRTV on QVC. We are developing other retail distribution channels to broaden access to consumers. Following commercial launch through the fourth quarter of 2015 approximately 13,800 devices and accessories were shipped to consumers with a total invoiced value of \$3.1 million prior to the impact of product returns.

### SENSUS

The SENSUS pain therapy device, the technological predecessor to Quell, is a prescription neuro-stimulation device based on TENS for relief of chronic, intractable pain. SENSUS, which was commercially launched in the first quarter of 2013, is a convenient and wearable device that offers physicians and their patients a non-narcotic pain relief option as a complement to medications. SENSUS is comprised of: (1) an electronic device with a strap that is worn on the upper calf and (2) an electrode which attaches to the device. We provide prescribing physicians with PC-based software that links to the device via a USB connection, thereby allowing them to download a record of the patient's use of the device. The SENSUS device and electrodes were cleared by the FDA for commercial distribution. When medically indicated and supported by proper documentation, TENS devices are generally reimbursed by Medicare and many commercial insurance companies under the DME benefit. We believe SENSUS will have a limited impact on future revenues. SENSUS customers have purchased approximately 10,000 devices through December 31, 2015.

### DPNCheck

DPNCheck is a fast, accurate, and quantitative nerve conduction test that is used to evaluate systemic neuropathies such as diabetic peripheral neuropathy, or DPN. It is designed to be used by primary care physicians, endocrinologists, podiatrists and other clinicians at the point-of-care to objectively detect, stage, and monitor DPN. The device measures nerve conduction velocity and response amplitude of the sural nerve, a nerve in the lower leg and ankle. These parameters are widely recognized as sensitive and specific biomarkers of DPN. DPNCheck is comprised of: (1) an electronic hand-held device and (2) a single patient use biosensor. In addition, we provide users with PC-based software that links to the device via a USB connection. This PC software allows physicians to generate reports and manage their sural nerve conduction data.

DPNCheck is a modified version of our previously marketed NC-stat nerve testing device that has the same clinical indications with respect to DPN. The modified device which costs less than the original device, has the same functionality with respect to sural nerve testing. More than 1.8 million patient studies have been performed using our NC-stat technology and there have been approximately 6.8 million nerve tests. It has

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been the subject of many published studies, including several studies specifically addressing the accuracy and clinical utility of the device in assessment of DPN. DPNCheck shipments commenced in late 2011 and approximately 2,900 device have been placed with customers through December 31, 2015

ADVANCE System

Our legacy neurodiagnostics business is based on the ADVANCE NCS/EMG System, or the ADVANCE System, which is a comprehensive platform for the performance of traditional nerve conduction studies. The ADVANCE System is comprised of: (1) the ADVANCE device and related modules, (2) various types of electrodes and needles, and (3) a communication hub that enables the physician's office to network their device to their personal computers and our servers for data archiving, report generation, and other network services. The ADVANCE System is most commonly used with proprietary nerve specific electrode arrays. These electrode arrays combine multiple individual electrodes and embedded microelectronic components into a single patient-use disposable unit. We currently market seven different nerve specific electrode arrays.

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. More than 1.8 million patient studies have been performed using our NC stat technology and there have been approximately 6.3 million nerve tests, including 700,000 sural nerve tests. As of December 31, 2015, we had an installed base of approximately 500 active customers using are ADVANCE System

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

Product	Time on Market	Technology	Primary Clinical Indications	No. Patients Tested/Treated
Quell	Q2 2015 present	Transcutaneous Electrical Nerve Stimulation	Relief for chronic, intractable pain	> 13,000
SENSUS	Q1 2013 present	Transcutaneous Electrical Nerve Stimulation	Relief for chronic, intractable pain, such as PDN	> 9,000
DPNCheck	Q4 2011 present	Nerve Conduction	Diagnosis and evaluation of peripheral neuropathies, such as DPN	> 473,000
ADVANCE	Q2 2008 present	Nerve Conduction Invasive Needle EMG	Diagnosis and evaluation of CTS, low back pain, peripheral neuropathies (including DPN)	> 1,800,000 (ADVANCE and NC-stat)
NC-stat*	Q2 1999 Q3 2010	Nerve Conduction	Diagnosis and evaluation of CTS, low back pain, peripheral neuropathies (including DPN)	

\*

Support was discontinued in the first quarter of 2012.

## Customers

Our customers include consumers, patients, 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 in the second quarter of 2015, our customer base has been expanded to include consumers and patients who purchase the device directly from us. Through December 31, 2015, approximately 13,800 devices were shipped. SENSUS was launched in early 2013 and is sold to DME suppliers who, in turn, distribute the product along with consumables directly to patients.

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SENSUS customers purchased approximately 2,900 devices during 2015. DPNCheck shipments commenced in late 2011 and approximately 2,900 devices had been placed with customers through December 31, 2015. These customers include managed care organizations, retail health businesses, endocrinologists, podiatrists and primary care physicians. As of December 31, 2015, we had an installed base of approximately 500 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, 2015, one customer accounted for 46% of accounts receivable and one customer accounted for 12% of revenue.

## **Geographic Information**

Substantially all of our assets, revenues, and expenses for 2015, 2014, and 2013 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 2015, 2014, and 2013, international revenues accounted for approximately 19%, 19%, and 16%, respectively, of our total revenues.

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

Quell was made commercially available in the United States during the second quarter of 2015. Initial distribution involved two channels: a professional channel using a direct sales force to target podiatrists, pain physicians, primary care physicians, and chiropractors who stock and resell the product, and a direct-to-consumer channel using our e-commerce website supported by social media plus traditional marketing. After establishing the professional and direct to consumer channels we expanded distribution to include ecommerce on Amazon.com and DRTV sales on QVC. We plan to make Quell more broadly available through retail distribution in 2016. 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 recently received regulatory approval and are working with Omron Healthcare toward commercial launch in the second half of 2016; and in Mexico where our distributor Scienta Farma received regulatory approval and initiated sales in the fourth quarter of 2015.

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.



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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 in technical, clinical, and business practices training for our commercial operations team, marketing staff and 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.

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## **Manufacturing and Supply**

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

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

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

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

We and our third-party manufacturers are registered with the FDA and subject to compliance with FDA quality system regulations. We are also ISO registered and undergo frequent quality system audits by European agencies. Our ADVANCE System and DPNCheck are cleared for marketing within the United States, Canada, and the European Union. In addition, our neuro-stimulation systems, Quell and SENSUS, 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. Our R&D team works closely with

our marketing group and customers to design products that are focused on improving clinical outcomes. The team consists of ten people including two who hold M.D. degrees and three who hold Ph.D. degrees. It includes the extensive involvement of our founder and Chief Executive Officer who holds both M.D. and Ph.D. degrees and who also coordinates the clinical programs that we support.

R&D efforts currently encompass the following areas:

*Quell Innovation.* Quell utilizes our proprietary wearable intensive nerve stimulation (WINS) technology to provide relief from chronic pain which can encompass lower back problems, fibromyalgia, arthritis, painful diabetic neuropathy and others. Quell is unique among OTC

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neuro-stimulation products in its clinical indications, technology, personalization and digital health features. Our R&D efforts to date have provided us first-to-market competitive advantage. We anticipate that success will attract competition and that we must continually innovate to maintain a leadership position. Accordingly, our R&D team is developing the next generation Quell to improve the user experience, optimize therapy, expand health tracking, and modify the electrodes to help ensure appropriate usage. Also, we are exploring new clinical indications such as restless leg syndrome. We intend to strengthen our intellectual property position with the development of additional know-how and a growing body of patent applications.

*Support for DPNCheck.* DPNCheck is our quantitative nerve conduction test for peripheral neuropathies including DPN. Its usage is growing in the Medicare Advantage market in the United States and in Japan where it was launched in 2014. DPNCheck recently received regulatory approval in China and we are working with Omron Healthcare toward commercial launch in the second half of 2016. The characteristics of these markets often require device modification for local acceptance which, in turn, involves our R&D team. We are collaborating with Omron Healthcare in Asia for DPNCheck and anticipate continuing engineering support requirements.

*Support clinical studies for our wearable technology.* We recently completed an independent post-market clinical study for Quell. Results were positive with 81% of subjects reporting an improvement in their chronic pain and overall health, and 67% reporting a reduction in their use of pain medications while using Quell. This study has been helpful to our marketing efforts and points to the need to continue to build the clinical foundation for Quell. During 2016 we intend to fund new clinical studies addressing the efficacy of our wearable technology.

Research and development expenses were approximately \$3.9 million, \$4.1 million, and \$3.4 million for 2015, 2014, and 2013, respectively.

## **Clinical Program**

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

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

## **Competition**

We believe there is no direct competition to our neuro-stimulation devices, Quell and SENSUS, for the treatment of chronic pain. The most common approach to chronic pain is pain medication. This includes over-the-counter drugs (such as Advil and Motrin), and prescription drugs including anti-convulsants (such as Lyrica and Neurontin) and

anti-depressants (such as Cymbalta and Elavil). Topical creams may also be used (such as Zostrix and Bengay). With severe pain, narcotic pain medications may be prescribed (such as codeine, fentanyl, morphine, and oxycodone). The approach to treatment is individualized, drug combinations may be employed, and the results are often hit or miss.

Side effects and the potential for addiction are real and the risks are substantial.

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

High frequency nerve stimulation is an established treatment for chronic pain supported by numerous clinical studies demonstrating efficacy. In simplified outline, the mechanism of action involves intensive nerve stimulation to activate the body's central pain inhibition system resulting in widespread analgesia, or pain relief. The nerve stimulation activates brainstem pain centers leading to the release of endogenous opioids that act primarily through the delta opioid receptor to reduce pain signal transmission through the central nervous system. This therapeutic approach is available through deep brain stimulation and through implantable spinal cord stimulation; however, both require surgery and have attendant risks. Non-invasive approaches to neuro-stimulation (transcutaneous electrical nerve stimulation, or TENS) have achieved limited efficacy in practice due to device limitations, ineffective dosing and low patient compliance. We believe that Quell and SENSUS clinical and market claims covering chronic pain and sleep, technical characteristics of high power and automation, and the digital health integration characteristics (Quell), place our products in a unique neuro-stimulation category. There are numerous manufacturers of transcutaneous electrical nerve stimulation devices including widely marketed over-the-counter TENS such as Sanofi's IcyHotSmartRelief, Omron PM3030 and Homedics RapidRelief.

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

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

## **Intellectual Property**

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

## Patents

As of December 31, 2015, we had 43 issued U.S. patents, two issued foreign patent, and 34 pending patent applications, including 15 U.S. applications, and 18 foreign national applications. Our wearable therapeutic products have one issued utility patent and two issued design patents. In addition, there are 26 pending utility and design patent applications. A utility patent was recently issued that covers the core technology deployed in our DPNCHECK diagnostic device. We have filed two additional utility patent applications for our DPNCHECK diagnostic device.

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With regard to our legacy neurodiagnostic products, our issued design patents began to expire in 2015, and our issued utility patents begin to expire in 2017. In particular, seven of our issued U.S. utility patents covering various aspects of the legacy neurodiagnostic products will expire on the same date in 2017. Although the patent protection for material aspects of these products covered by the claims of the patents will be lost at that time, we have additional patents and patent applications directed to other novel inventions that will have patent terms extending beyond 2017.

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

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

### **Trademarks**

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

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In turn, the insurer fully absorbs the risk of patient health care costs. Insurers may share a portion of the risk with provider organizations such as independent practice associations (IPAs) with whom they contract to provide medical services to their members. Proper assessment of each member's health status and accurate coding helps to assure that insurers receive capitation fees consistent with the cost of treating these members. Nerve conduction testing can provide valuable, early identification of neuropathy leading to clinical interventions that can reduce health care costs.

Also, these tests provide valuable input regarding each member's health risk status which can result in more appropriate capitated payments from CMS. We believe that the clinical and economic proposition for DPNCheck is attractive to Medicare Advantage insurers and risk bearing provider organizations. We are focusing our sales effort for DPNCheck on the Medicare Advantage managed care market segment.

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

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

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

## **FDA and Other Governmental Regulation**

### **FDA Regulation**

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

Class I, requiring general controls, including labeling, device listing, reporting and, for some products, adherence to good manufacturing practices through the FDA's quality system regulations and pre-market notification;

Class II, requiring general controls and special controls, which may include performance standards and post-market surveillance; and

Class III, requiring general controls and pre-market approval, or PMA, which may include post-approval conditions and post-market surveillance.

Before being introduced into the market, our products must obtain market clearance or approval through the 510(k) pre-market notification process, the *de novo* review process or the PMA process, unless they qualify for an exemption from these processes. See Risk Factors, *We are subject to extensive regulation by the FDA which could restrict the sales and marketing of the Quell, SENSUS and DPNCheck devices and the ADVANCE System, as well as other products for which we may seek FDA clearance or approval, and could cause us to incur significant costs.*

**510(k) Pre-Market Notification Process**

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

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

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

### **De Novo Review Process**

If a previously unclassified new medical device does not qualify for the 510(k) pre-market notification process because there is no predicate device to which it is substantially equivalent, and if the device may be adequately regulated through general controls or special controls, the device may be eligible for *de novo* classification through what is called the *de novo* review process. In order to use the *de novo* review process, a company must receive a letter from the FDA stating that, because the device has been found not substantially equivalent to a legally marketed Class I or II medical device or to a Class III device marketed prior to May 28, 1976 for which the FDA has not required the submission of a PMA application, it has been placed into Class III. After receiving this letter, the company, within 30 days, must submit to the FDA a request for a risk based down classification of the device from Class III to Class I or II based on the device's moderate or low risk profile which meets the definition of a Class I or Class II medical device.

The FDA then has 60 days in which to decide whether to down classify the device. If the FDA agrees that a lower classification is warranted, it will issue a new regulation describing the device type and, for a Class II device, publish a Special Controls guidance document. The Special Controls guidance document specifies the scope of the device type and the recommendations for submission of subsequent devices for the same intended use. If a product is classified as Class II through the *de novo* review process, then that device may serve as a predicate device for subsequent 510(k) pre-market notifications.

### **PMA Process**

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

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

enforcement or administrative actions, including the withdrawal of the approval. Approval of a new PMA application or a PMA supplement may be required in the event of modifications to the device, including to its labeling, intended use or indication, or its manufacturing process that affect safety and effectiveness.

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**Post-Approval Obligations**

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

the FDA's QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other good manufacturing practice and quality assurance procedures during all aspects of the manufacturing process;

labeling regulations and FDA prohibitions against the promotion of products for uncleared or unapproved uses (known as off-label uses), as well as requirements to provide adequate information on both risks and benefits;

medical device reporting regulations, which require that manufacturers report to FDA any device that may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;

correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections and device recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device which may present a risk to health;

post-market surveillance regulations, which apply to Class II or III devices if the FDA has issued a post-market surveillance order and the failure of the device would be reasonably likely to have serious adverse health consequences, the device is expected to have significant use in the pediatric population, the device is intended to be implanted in the human body for more than one year, or the device is intended to be used to support or sustain life and to be used outside a user facility;

regular and for cause inspections by FDA to review a manufacturer's facilities and their compliance with applicable FDA requirements; and

the FDA's recall authority, whereby it can ask, or order, device manufacturers to recall from the market a product that is in violation of applicable laws and regulations.

**Regulatory Approvals and Clearances**

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

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

As transcutaneous electrical nerve stimulators, the SENSUS and Quell pain therapy devices are Class II medical devices which received 510(k) clearance from the FDA in August 2012 and July 2014, respectively. In November 2012, the FDA provided 510(k) clearance for the disposable electrode used in conjunction with the SENSUS device, and in July 2013, the FDA provided 510(k) clearance for the use of SENSUS during sleep. The intended use of the SENSUS pain management therapeutic system is the symptomatic relief and management of chronic pain. In July 2014, our Quell device received 510(k) clearance for over-the-counter use and in November 2014, our Quell disposable electrode received 510(k) clearance for over-the-counter use. 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 and sub-assembly 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

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accepted by the FDA and 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

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\$55.3 million. We reported revenue for our legacy Neurodiagnostics business of \$2.3 million, \$2.8 million, and \$3.8 million in 2015, 2014, and 2013, respectively. We currently manage this business to optimize cash flow.

## **Employees**

As of December 31, 2015, we had a total of 48 full time employees. Of these employees, ten were in research and development, 20 in sales and marketing, eight in production/distribution, and ten in general and administrative services. One employee holds both M.D. and Ph.D. degrees, one employee holds an M.D. degree and two additional employees hold Ph.D. degrees. Our employees are not represented by a labor union and are not subject to a collective bargaining agreement. We have never experienced a work stoppage. We believe that we have good relations with our employees.

## **Available Information**

Access to our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to these reports filed with or furnished to the Securities and Exchange Commission, or SEC, may be obtained through the Investor Relations section of our website at [www.neurometrix.com/investor](http://www.neurometrix.com/investor) as soon as reasonably practical after we electronically file or furnish these reports. We do not charge for access to and viewing of these reports. Information on our Investor Relations page and on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein by reference. In addition, the public may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Also, our filings with the SEC may be accessed through the SEC's website at [www.sec.gov](http://www.sec.gov). All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

## **Corporate Information**

NeuroMetrix was founded in June 1996 by our President and Chief Executive Officer, Shai N. Gozani, M.D., Ph.D. We originally were incorporated in Massachusetts in 1996, and we reincorporated in Delaware in 2001. Our principal offices are located at 1000 Winter Street, Waltham, Massachusetts 02451.

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## ITEM 1A. Risk Factors

*You should carefully consider the following risks and all other information contained in this Annual Report on Form 10-K and our other public filings before making any investment decisions with respect to our securities. If any of the following risks occurs, our business, prospects, reputation, results of operations, or financial condition could be harmed. In that case, the trading price of our securities could decline, and our stockholders could lose all or part of their investment. This Annual Report also contains forward-looking statements that involve risks and uncertainties.*

*Our actual results could differ materially from those anticipated in the forward-looking statements as a result of specific factors, including the risks described below and elsewhere in this Annual Report on Form 10-K.*

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

We have incurred significant cumulative net losses since our inception. Our net losses for the years ended December 31, 2015, 2014, and 2013, were approximately \$9.2 million, \$7.8 million, and \$8.0 million, respectively. At December 31, 2015, we had an accumulated deficit of \$163.6 million. The extent of our future operating income or losses is highly uncertain, and we cannot assure you that we will be able to achieve or maintain profitability.

**Our future capital needs are uncertain and our independent auditor has expressed substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent on our ability to raise additional capital and our operations could be curtailed if we are unable to obtain the required additional funding when needed. We may not be able to do so when necessary, and/or the terms of any financings may not be advantageous to us.**

We held cash and cash equivalents of \$12.5 million as of December 31, 2015. We believe that these resources, and the cash to be generated from future product sales will be sufficient to meet our projected operating requirements through the second quarter of 2016. However, the amount of our future product sales is difficult to predict, especially in light of the limited nature of the recent commercialization of Quell, and actual sales may not be in line with our forecasts.

Our financial statements have been prepared assuming that we will continue as a going concern which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. We expect to incur further losses as we aim to successfully commercialize Quell and DPNCheck and the operations of our business and will be dependent on funding our operations through additional public or private financing, collaborative arrangements with strategic partners, or through additional credit lines or other debt financing sources to increase the funds available to fund operations. These circumstances raise substantial doubt about our ability to continue as a going concern. As a result of this uncertainty and the substantial doubt about our ability to continue as a going concern as of December 31, 2015, the report of our independent registered public accounting firm in this Annual Report on Form 10-K for the year ended December 31, 2015 includes a going concern explanatory paragraph. Management's plans include increasing revenue through the commercialization of Quell and DPNCheck. However, no assurance can be given at this time as

to whether we will be able to achieve these objectives. Our financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

We continue to face significant challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected due to (a) decreases in sales of our products and the uncertainty of future revenues from new products; (b) changes we may make to the business that affect ongoing operating expenses; (c) changes we may make in our business strategy; (d) regulatory developments affecting our existing products and delays in the FDA approval process for products under development; (e) changes in our research and development spending plans; and (f) other items affecting our forecasted level of expenditures and use of cash resources.

Accordingly, we will need to raise additional funds to support our future 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

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terms, if at all. Furthermore, if we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. If we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. Without additional funds, we may be forced to delay, scale back or eliminate some of our sales and marketing efforts, research and development activities, or other operations and potentially delay product development in an effort to provide sufficient funds to continue our operations. If any of these events occurs, our ability to achieve our development and commercialization goals would be adversely affected.

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

We are focused on the commercialization of Quell, our OTC wearable device for pain relief. Quell is based on our prescription product for pain relief, SENSUS. Quell has been on the market since June 2015 and we have shipped approximately 13,800 Quell devices since then. Additionally, DPNCheck, which was launched in 2011, is a quantitative nerve conduction test for systemic neuropathies, such as DPN. We also have other product candidates and product enhancements in our development pipeline. Our future prospects are closely tied to our success with Quell and DPNCheck, which, in turn, depend upon market acceptance and growth in future revenues. We cannot assure you that our commercialization strategy will be successful. If our strategy is not successful, it could materially affect our revenues and results of operations.

Our future success could be adversely affected by a number of factors, including:

inability to create market demand for Quell through a direct sales force, through online marketing efforts, direct response television and other retail channels;

manufacturing issues with Quell or our other products;

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

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

unfavorable changes to current Medicare, Medicare Advantage and commercial payer payment policies;

changes to payor policies under the Patient Protection and Affordable Care Act;

unfavorable experiences by patients and physicians using Quell and our other products; and,

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

If we are unable to expand exposure and penetrate the market for Quell and/or DPNCheck, our ability to increase our revenues will be limited and our business prospects will be adversely affected.

**Our current and future revenue is dependent upon commercial acceptance of Quell by the market. The failure of such acceptance will materially and adversely affect our operations.**

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

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

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

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

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

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

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

**DPNCheck devices and the ADVANCE System as well as other products for which we may seek FDA clearance or approval, and could cause us to incur significant costs.**

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

The FDA may remove our devices from the market or enjoin them from commercial distribution if safety or effectiveness problems develop. Further, we may not be able to obtain additional 510(k) clearances or



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pre-market approvals for new products or for modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and future profitability. We have made modifications to our devices in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices. If any of these events occurs or if the FDA takes other enforcement actions, we may not be able to provide our customers with the products they require on a timely basis, our reputation could be harmed, and we could lose customers and suffer reduced revenues and increased costs.

We also are subject to numerous post-marketing regulatory requirements, including the FDA's quality system regulations, which relate to the design, manufacture, packaging, labeling, storage, installation and servicing of our products, labeling regulations, medical device reporting regulations and correction and removal reporting regulations. Our failure or the failure by any manufacturer of our products to comply with applicable regulatory requirements could result in enforcement action by the FDA. FDA enforcement actions relating to post-marketing regulatory requirements or other issues, including any issues arising from the not substantially equivalent letter described above, may include any of the following:

- warning letters, untitled letters, fines, injunctions, product seizures, consent decrees and civil penalties;
- requiring repair, replacement, refunds, customer notifications or recall of our products;
- imposing operating restrictions, suspension or shutdown of production;
- refusing our requests for 510(k) clearance or PMA approval of new products, new intended uses, or modifications to existing products;
- requesting voluntary rescission of 510(k) clearances or withdrawing PMA approvals that have already been granted;
- and
- criminal prosecution.

If any of these events were to occur, they could harm our reputation, our ability to generate revenues and our profitability.

Also, from time to time, legislation is introduced into Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of medical devices. FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be. The FDA has publicly stated that it is reevaluating its longstanding 510(k) review program. It is not clear when the program will be modified and what effect the modified review process will have on our ability to bring our product candidates to market.

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

We rely on third-party manufacturers to manufacture components of our Quell, DPNCheck and SENSUS systems, and to fully manufacture electrodes for the ADVANCE system. In the event that our manufacturers cease to manufacture

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

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

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with Parlex Polymer Flexible Circuits, Inc. for the manufacture of the ADVANCE electrodes for nerve conduction testing. Katecho, Inc. manufactures biosensors for use with our DPNCheck devices and manufactures electrodes for Quell and SENSUS, and Sunburst EMS, Inc. manufactures electronic boards and other components of our Quell, DPNCheck and SENSUS products which we assemble at our Massachusetts facility to produce completed devices.

Moreover, due to the recent commercialization of Quell and the limited amount of our sales to date, other than Katecho, Inc., we do not have long-standing relationships with our manufacturers and may not be able to convince suppliers to continue to make components available to us unless there is demand for such components from their other customers. As a result, there is a risk that certain components could be discontinued and no longer available to us.

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

**If our manufacturers are unable to supply us with an adequate supply of product components as we expand our markets, we could lose customers, our potential future growth could be limited and our business could be harmed.**

In order for us to successfully expand our business within the United States and internationally, our contract manufacturers must be able to provide us with substantial quantities of components of our products in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable cost and on a timely basis. Our potential future growth could strain the ability of our manufacturers to deliver products and obtain materials and components in sufficient quantities. Manufacturers often experience difficulties in scaling up production, including problems with production yields and quality control and assurance. If we are unable to obtain sufficient quantities of high quality products to meet customer demand on a timely basis, we could lose customers, our growth may be limited and our business could be harmed.

**If we or our manufacturers fail to comply with the FDA's quality system regulation, the manufacturing and distribution of our products could be interrupted, and our product sales and operating results could suffer.**

We and our contract manufacturers are required to comply with the FDA's quality system regulation, or QSR, which is a complex regulation that governs the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our devices. The FDA enforces the QSR through periodic inspections. We cannot assure you that our facilities or the facilities of the manufacturers of our products would pass any future inspection. If our facilities or any of the facilities of the manufacturers of our products fail an inspection, the manufacturing or distribution of our products could be interrupted and our operations disrupted. Failure to take adequate and timely corrective action in response to an adverse inspection could result in a suspension or shutdown of our packaging and labeling operations and the operations of the manufacturers of our products or a

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

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

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the authority to require the recall of our products if there is a reasonable probability that the products would cause serious adverse health consequences or death. A government-mandated or voluntary recall by us could occur as a result of manufacturing defects, labeling deficiencies, packaging defects or other failures to comply with applicable regulations. Any recall would divert management attention and financial resources and harm our reputation with customers and could have a material adverse effect on our financial condition and results of operations.

**The success of our business depends upon our ability to advance our pipeline products to commercialization.**

We commenced commercialization of Quell in June 2015. We have additional product candidates and enhancements of our existing products in our R&D pipeline. We expect that advancing our pipeline products will require significant time and resources. We may not be successful in our commercialization efforts for any of the product candidates or product enhancements currently in our pipeline and we may not be successful in developing, acquiring, or in-licensing additional product candidates, to the extent we decide to do so. If we are not successful advancing new products through our development pipeline, the regulatory process and commercial launch, our business, financial condition, and results of operations will be adversely affected.

**Our ability to achieve profitability depends in part on maintaining or increasing our gross margins on product sales which we may not be able to achieve.**

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

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

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

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

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

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

the pending patent applications we have filed or to which we have exclusive rights may not result in issued patents or may take longer than we expect to result in issued patents;

the claims of any patents that are issued may not provide meaningful protection;

we may not be able to develop additional proprietary technologies that are patentable;

other parties may challenge patents, patent claims or patent applications licensed or issued to us; and

other companies may design around technologies we have patented, licensed or developed.

Our issued and filed patents for our wearable therapeutic products are recent. With regard to our legacy neurodiagnostic products, our issued design patents begin to expire in 2015, and our issued utility patents

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begin to expire in 2017. Although the patent protection for material aspects of these products covered by the claims of the patents will be lost at that time, we have additional patents and patent applications directed to other novel inventions that will have patent terms extending beyond 2017. We may not be able to protect our patent rights effectively in some foreign countries. For a variety of reasons, we may decide not to file for patent protection in the United States or in particular foreign countries. Our patent rights underlying our products may not be adequate, and our competitors or customers may design around our proprietary technologies or independently develop similar or alternative technologies or products that are equal or superior to our technology and products without infringing on any of our patent rights. In addition, the patents licensed or issued to us may not provide a competitive advantage. If any of these events were to occur, our ability to compete in the market would be harmed.

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

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

the agreements may be breached or not enforced in a particular jurisdiction;

we may have inadequate remedies for any breach;

trade secrets and other proprietary information could be disclosed to our competitors; or

others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technologies.

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

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

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

assert claims of infringement;

enforce our patents;

Other rights and measures we have taken to protect our intellectual property may not be adequate, which would ha

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

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



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

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

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

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

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

an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could harm our business and results of operations.

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

There are a number of federal and state laws protecting the confidentiality of individually identifiable patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services promulgated patient privacy rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. These privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most

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use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. Although we do not believe that we are subject to the HIPAA rules, the exact scope of these rules has not been clearly established. If we are found to be in violation of the privacy rules under HIPAA, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

**The use of our products could result in product liability claims that could be expensive, damage our reputation and harm our business.**

Our business exposes us to an inherent risk of potential product liability claims related to the manufacturing, marketing and sale of medical devices. The medical device industry historically has been litigious, and we face financial exposure to product liability claims if the use of our products were to cause or contribute to injury or death. Our products may be susceptible to claims of injury because their use involves the electric stimulation of a patient's nerves. Although we maintain product liability insurance for our products and other commercial insurance, the coverage limits of these policies may not be adequate to cover future claims. As sales and use of our products increase, we may be unable to maintain sufficient product liability or other commercial insurance on acceptable terms or at reasonable costs, and this insurance may not provide us with adequate coverage against potential liabilities. A successful claim brought against us in excess of, or outside of, our insurance coverage could have a material adverse effect on our financial condition and results of operations. A product liability claim, regardless of its merit or eventual outcome, could result in substantial costs to us, a substantial diversion of management attention and adverse publicity. A product liability claim could also harm our reputation and result in a decline in revenues and an increase in expenses.

**Our products are complex in design, and defects may not be discovered prior to shipment to customers, which could result in warranty obligations or product liability or other claims, reducing our revenues and increasing our costs and liabilities.**

We depend upon third parties for the manufacture of our products or components. Our products, particularly our electrodes, require a significant degree of technical expertise to produce. If these manufacturers fail to produce our products to specification, or if the manufacturers use defective materials or workmanship in the manufacturing process, the reliability and performance of our products will be compromised.

If our products contain defects that cannot be repaired quickly, easily and inexpensively, we may experience:

- loss of customer orders and delay in order fulfillment;
- damage to our brand reputation;
- increased cost of our warranty program due to product repair or replacement;
- inability to attract new customers;
- diversion of resources from our manufacturing and research and development departments into our service department; and
- legal action.

The occurrence of any one or more of the foregoing could harm our reputation and materially reduce our revenues and increase our costs and liabilities.

If we are found to have violated laws protecting the confidentiality of patient health information, we could be subject to

**If we lose any of our officers or key employees, our management and technical expertise could be weakened significantly.**

Our success largely depends on the skills, experience, and efforts of our executive officers, including Shai N. Gozani, M.D., Ph.D., our founder, Chairman, President and Chief Executive Officer, Thomas T. Higgins, our Senior Vice President and Chief Financial Officer; and Francis X. McGillin, our Senior Vice President and General Manager Consumer. We do not maintain key person life insurance policies covering any of our employees. The loss of any of our executive officers could weaken our management and technical expertise significantly and harm our business.

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**If we are unable to recruit, hire and retain skilled and experienced personnel, our ability to manage and expand our business will be harmed, which would impair our future revenues and profitability.**

We are a small company with 48 employees as of December 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 and marketing personnel would materially harm our ability to compete effectively and grow our business.

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

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

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

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

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

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

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

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price new products competitively;  
manufacture and deliver our products in sufficient volumes on time, and accurately predict and control costs associated with manufacture of the products; and

meet our product development plan and launch timelines.

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

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

**We currently compete, and may in the future need to compete, against other medical device and consumer companies with greater resources, more established distribution channels and other competitive advantages, and the success of these competitors may harm our ability to generate revenues.**

We currently do, and in the future may need to, compete directly and indirectly with a number of other companies that may have competitive advantages over us. Our diagnostic devices for nerve testing compete with companies that sell traditional nerve conduction study and electromyography equipment including Cadwell Laboratories, Inc. and Natus Medical Incorporated. These companies enjoy significant competitive advantages, including:

greater resources for product development, sales and marketing;

more established distribution networks;

greater name recognition;

more established relationships with health care professionals, customers and third-party payers; and

additional lines of products and the ability to offer rebates or bundle products to offer discounts or incentives.

As we develop the market for wearable technology for chronic pain, we will likely be faced with competition from other companies that decide and are able to enter the market. Some or all of our future competitors in the diagnostic nerve testing market and the consumer market for pain relief may enjoy competitive advantages such as those described above. If we are unable to compete effectively against existing and future competitors, our sales will decline and our business will be harmed.

**Security breaches and other disruptions could compromise our information and expose us to liability, which could cause our business and reputation to suffer.**

In the ordinary course of our business, we collect and store sensitive data in our data centers, on our networks, including intellectual property, our proprietary business information, and that of our customers, suppliers and business partners, and personally identifiable information of our employees. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance

We currently compete, and may in the future need to compete, against other medical device and consum55compar

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



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

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

Foreign markets represented approximately 19% and 19% of our revenues in 2015 and 2014, respectively. 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;

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pay dividends or make distributions on, or repurchase, our capital stock; and  
merge or consolidate.

In addition, we are required to meet certain financial covenants customary with this type of credit facility, including maintaining a minimum specified tangible net worth. The credit facility also contains other customary covenants, which we may not be able to comply with in the future. Our failure to comply with these covenants may result in the declaration of an event of default and could cause us to be unable to borrow under the credit facility. In addition to preventing additional borrowings under the credit facility, an event of default, if not cured or waived, may result in the acceleration of the maturity of indebtedness outstanding under the credit facility at the time of the default, which would require us to pay all amounts outstanding. If an event of default occurs, we may not be able to cure it within any applicable cure period, if at all. If the maturity of our indebtedness is accelerated, we may not have sufficient funds available for repayment or we may not have the ability to borrow or obtain sufficient funds to replace the accelerated indebtedness on terms acceptable to us, or at all. We have not borrowed any funds under this agreement; however, as of December 31, 2015, \$226,731 of the amounts available under the agreement are restricted to support letters of credit issued in favor of our landlords.

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

Until we are profitable, we will need significant additional funds to develop our business and sustain our operations. We sold shares of our common stock, convertible preferred stock and warrants in December and May 2015, 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 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 December 31, 2015, our stock price has fluctuated from a low of \$1.88 to a high of \$99.33, 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;

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

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;

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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.

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. .

## **Our recently implemented reverse stock split could adversely affect the market liquidity of our common stock.**

On October 30, 2015, our stockholders approved an amendment to our restated certificate of incorporation, as amended, and authorized our Board of Directors, if in their judgment they deemed it necessary, to effect a reverse stock split of our common stock at a ratio in the range of 1:2 to 1:4. We implemented this reverse stock split on December 1, 2015 with a ratio of 1:4. We cannot predict whether the reverse stock split will increase the market price for our common stock on a sustained basis. The history of similar stock split combinations for companies in like circumstances is varied, and we cannot predict whether:

the market price per share of our common stock after the reverse stock split will rise in proportion to the reduction in the number of shares of our common stock outstanding before the reverse stock split;  
the reverse stock split will result in a per share price that will attract brokers and investors who do not trade in lower priced stocks;  
the reverse stock split will result in a per share price that will increase our ability to attract and retain employees and other service providers; or  
the market price per share will either exceed or remain in excess of the \$1.00 minimum bid price as required by NASDAQ, or that we will otherwise meet the requirements of NASDAQ for continued inclusion for trading on The NASDAQ Capital Market.

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

We cannot assure you that we will be able to comply with the standards that we are required to meet in order to maintain a listing of our common stock on The NASDAQ Capital Market. In 2015, we received two notices from the Listing Qualifications Department of the NASDAQ Stock Market, and we regained

Our recently implemented reverse stock split could adversely affect the market liquidity of our common stock.



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compliance with respect to both of these notices before the end of fiscal year 2015. If we fail to continue to meet all applicable NASDAQ Capital Market requirements in the future and NASDAQ determines to delist our common stock, the delisting could substantially decrease trading in our common stock and adversely affect the market liquidity of our common stock; 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 December 31, 2015 as reported by NASDAQ was approximately 120,000 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; 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.



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**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.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

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

**ITEM 3. LEGAL PROCEEDINGS**

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

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

TABLE OF CONTENTS**PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY,  
RELATED STOCKHOLDER MATTERS AND ISSUER  
PURCHASES OF EQUITY SECURITIES****Market Information**

Our common stock is traded on the NASDAQ Capital Market under the symbol NURO. 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 and has been adjusted to reflect a 1-for-4 reverse stock split of our common stock completed on December 1, 2015.

	Years ended December 31,			
	2015		2014	
	High	Low	High	Low
First quarter	\$ 8.20	\$ 6.40	\$ 12.56	\$ 8.68
Second quarter	6.80	3.37	10.44	6.68
Third quarter	4.96	2.84	12.60	6.28
Fourth quarter	3.72	1.88	8.04	6.08

**Stockholders**

On February 1, 2016, there were approximately 77 stockholders of record of our common stock. This number does not include stockholders for whom shares were held in a nominee or street name. On February 1, 2016, the last reported sale price per share of our common stock on the NASDAQ Capital Market was \$1.74.

**Dividends**

We have never declared or paid any cash dividends on our common stock. We currently intend to retain future earnings, if any, to finance the expansion and growth of our business and do not expect to pay any cash dividends in the foreseeable future. Payment of future cash dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, and plans for expansion. Additionally, the credit facility restricts our ability to pay dividends.

**Issuers Purchases of Equity Securities**

In December 2015, we completed a private equity offering with a single institutional investor providing for the issuance of (i) 13,800 shares of Series C convertible preferred stock at a price of \$1,000 per share, and (ii) warrants to purchase up to 10,823,528 shares of our common stock, at an exercise price of \$2.30 per share. See Management's Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources below for details of this offering. In conjunction with this offering, we reacquired 63,000 shares of our Series B convertible preferred stock from the single institutional investor, at an average price of \$100 per share, during the quarter ended

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December 31, 2015. The following table sets forth the purchases that we made during the quarter ended December 31, 2015:

Period	Total Number of Series B Preferred Stock Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
October 1, 2015 to October 31, 2015			N/A	N/A
November 1, 2015 to November 30, 2015			N/A	N/A
December 1, 2015 to December 31, 2015	63,000	\$ 100	N/A	N/A

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The following selected financial data are derived from our audited financial statements, which have been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm. The selected financial data below should be read in conjunction with Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, Item 7A, Quantitative and Qualitative Disclosures About Market Risk and our financial statements and related notes for the years ended 2015, 2014, and 2013 appearing elsewhere in this Annual Report on Form 10-K:

	Years Ended December 31,				
	2015	2014	2013	2012	2011
	(In thousands, except share and per share data)				
Statement of Operations Data:					
Revenues	\$7,300	\$5,513	\$5,279	\$7,575	\$10,397
Cost of revenues	3,951	2,569	2,194	3,589	4,722
Gross profit	3,349	2,944	3,085	3,986	5,675
Operating expenses:					
Research and development	3,895	4,076	3,438	3,546	3,877
Sales and marketing	7,233	2,913	2,780	5,727	6,689
General and administrative	5,497	4,725	4,225	4,735	5,112
Total operating expenses	16,625	11,714	10,443	14,008	15,678
Loss from operations	(13,276)	(8,770)	(7,358)	(10,022)	(10,003)
Interest and other income	5	5	5	14	22
Warrants offering costs		(51)	(376)		
Changes in fair value of warrant liability	4,084	1,050	(290)		
Net loss	\$(9,187)	\$(7,766)	\$(8,019)	\$(10,008)	\$(9,981)
Net loss per common share applicable to common stockholders, basic and diluted	\$(7.75)	\$(6.15)	\$(12.28)	\$(20.86)	\$(62.14)

Note: Net loss per common share applicable to common stockholders has been adjusted to reflect our 1-for-4 reverse stock split effected December 2015.

	As of December 31,				
	2015	2014	2013	2012	2011
	(in thousands)				
Balance Sheet Data:					
Cash and cash equivalents	\$ 12,463	\$ 9,222	\$ 9,196	\$ 8,699	\$ 10,290
Working capital	11,956	8,392	8,919	8,567	10,482
Total assets	16,034	11,402	10,797	10,877	14,221
Total liabilities	3,471	8,015	3,602	2,077	3,132
Total stockholders' equity	12,563	3,387	7,195	8,800	11,089

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## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion of our financial condition and results of operations in conjunction with our selected financial data, our financial statements, and the accompanying notes to those financial statements included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. For a description of factors that may cause our actual results to differ materially from those anticipated in these forward-looking statements, please refer to the section titled "Risk Factors", contained in Item 1A of this Annual Report on Form 10-K.*

### Overview

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

Wearable neuro-stimulation therapeutic devices  
Point-of-care neuropathy diagnostic tests

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

Chronic pain is a significant public health problem. It is defined by the National Institutes of Health as any pain lasting more than 12 weeks in contrast to acute pain which is a normal bodily response to injury or trauma. Chronic pain conditions include painful diabetic neuropathy, or PDN, arthritis, fibromyalgia, sciatica, musculoskeletal pain, cancer pain and many others. Chronic pain may be triggered by an injury or there may be an ongoing cause such as disease or illness. There may also be no clear cause. Pain signals continue to be transmitted in the nervous system over extended periods of time often leading to other health problems. These can include fatigue, sleep disturbance, decreased appetite, and mood changes which cause difficulty in carrying out important activities and contributing to disability and despair. In general, chronic pain cannot be cured. Treatment of chronic pain is focused on reducing pain and improving function. The goal is effective pain management.

Chronic pain is widespread. It affects over 100 million adults in the United States and more than 1.5 billion people worldwide. The global market for pain management drugs and devices alone was valued at \$35 billion in 2012. The estimated incremental impact of chronic pain on health care costs in the United States is over \$250 billion per year and lost productivity is estimated to exceed \$300 billion per year.

The most common approach to chronic pain is pain medication. This includes over-the-counter drugs (such as Advil and Motrin), and prescription drugs including anti-convulsants (such as Lyrica and Neurontin) and anti-depressants (such as Cymbalta and Elavil). Topical creams may also be used (such as Zostrix and Bengay). With severe pain, narcotic pain medications may be prescribed (such as codeine, fentanyl, morphine, and oxycodone). The approach to

treatment is individualized, drug combinations may be employed, and the results are often hit or miss. Side effects and the potential for addiction are real and the risks are substantial.

Reflecting the difficulty in treating chronic pain, we believe that inadequate relief leads 25% to 50% of pain sufferers to turn to the over-the-counter market for supplements or alternatives to prescription pain medications. These include non-prescription medications, topical creams, lotions, electrical stimulators, dietary products, braces, sleeves, pads and other items. In total they account for over \$4 billion in annual spending in the United States on pain relief products.

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High frequency nerve stimulation is an established treatment for chronic pain supported by numerous clinical studies demonstrating efficacy. In simplified outline, the mechanism of action involves intensive nerve stimulation to activate the body's central pain inhibition system resulting in widespread analgesia, or pain relief. The nerve stimulation activates brainstem pain centers leading to the release of endogenous opioids that act primarily through the delta opioid receptor to reduce pain signal transmission through the central nervous system. This therapeutic approach is available through deep brain stimulation and through implantable spinal cord stimulation, both of which require surgery and have attendant risks. Non-invasive approaches to neuro-stimulation (transcutaneous electrical nerve stimulation, or TENS) have achieved limited efficacy in practice due to device limitations, ineffective dosing and low patient compliance.

Quell, our OTC wearable device for pain relief, was unveiled at the January 2015 Consumer Electronics Show (CES) and made commercially available in the United States during the second quarter of 2015. Following commercial launch through the end of 2015, approximately 13,800 Quell devices plus electrodes and accessories were shipped to consumers with a total invoiced value of \$3.1 million prior to the impact of product returns. Quell utilizes OptiTherapy™, our proprietary non-invasive neuro-stimulation technology to provide relief from chronic intractable pain, such as nerve pain due to diabetes, fibromyalgia, arthritic pain, and lower back and leg pain. This advanced wearable device is lightweight and can be worn during the day while active, and at night while sleeping. It has been cleared by the FDA for treatment of chronic intractable pain without a doctor's prescription. Users of the device have the option of using their smartphones to automatically track and personalize their pain therapy. Quell was launched through two distribution channels: a professional channel using a direct sales force to target podiatrists, pain physicians, primary care physicians, and chiropractors who resell the product, and a direct-to-consumer channel using online marketing and lead generation. After establishing the professional and direct to consumer channels, we expanded distribution to include Amazon e-commerce sales and QVC direct response TV, or DRTV, sales. We are developing other distribution channels for broader access to the retail markets. We believe there are significant opportunities to market Quell outside of the United States, particularly in Western Europe, Japan and China; however, we do not intend to approach those markets until we have established a solid presence in the United States.

DPNCheck, our diagnostic test for peripheral neuropathies, was made commercially available in the fourth quarter of 2011. DPNCheck revenues for 2015, 2014, and 2013 were approximately \$2.3 million, \$1.8 million, and \$1.3 million, respectively. Our U.S. sales efforts focus on Medicare Advantage providers who assume financial responsibility and the associated risks for the health care costs of their patients. We believe that DPNCheck presents an attractive clinical case with early detection of neuropathy allowing for earlier clinical intervention to help mitigate the effects of neuropathy on both patient quality of life and cost of care. Also, the diagnosis and documentation of neuropathy provided by DPNCheck helps clarify the patient health profile which, in turn, may have a direct, positive effect on the Medicare Advantage premium received by the provider. We believe that attractive opportunities exist outside the United States, including Japan where we received regulatory approval and launched DPNCheck with our distribution partner Omron Healthcare in the third quarter of 2014; in China where we recently received regulatory approval and are working with Omron Healthcare toward commercial launch in the second half of 2016; and in Mexico where our distributor Scienta Farma received regulatory approval and initiated sales in the fourth quarter of 2015.

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 ADVANCE. Our recent products, Quell, SENSUS and DPNCheck, conform to this model. Other products in our development pipeline are based on the device plus consumables business model.





TABLE OF CONTENTS**Results of Operations****Comparison of Years Ended December 31, 2015 and December 31, 2014****Revenues**

The following table summarizes our revenues:

	Years Ended December 31,			
	2015	2014	Change	% Change
Revenues	\$ 7,299.8	\$ 5,512.8	\$ 1,787.0	32.4 %

(in thousands)

Revenues include sales from Quell and SENSUS, our wearable therapeutic devices for relief of chronic intractable pain; DPNCheck, our diagnostic test for diabetic peripheral neuropathy, or DPN; and our legacy ADVANCE neurodiagnostics business. Quell was made commercially available during the second quarter of 2015.

During 2015 revenues increased by \$1.8 million, or 32.4%, from the prior year. Quell revenues of \$2.1 million in 2015 were the largest contributor to revenue growth. During 2015, 13,800 Quell devices and 14,900 electrode packs with a total invoiced value of \$3.1 million were shipped to Quell customers. Approximately \$0.5 million of invoiced Quell shipments was made to new distribution channels where we have insufficient product return history to recognize revenue, and an additional \$0.5 million in invoiced Quell shipments constituted either actual or estimate product returns by customers under our right-of-return policy and are excluded from revenue.

SENSUS, our prescription wearable device, posted shipments of about 2,900 devices and 19,800 electrode packs with total revenue of \$0.6 million. This is in comparison with approximately 5,800 SENSUS devices and 17,600 electrode packs and total revenue of \$0.9 million in 2014. The decline in SENSUS revenue reflects stress in the durable medical equipment distribution channel from the Medicare competitive bidding initiative, as well as sales encroachment from Quell. There were approximately 700 DPNCheck devices plus 159,000 electrodes shipped during 2015 with revenue of \$2.3 million compared to approximately 680 DPN devices and 109,500 electrodes with \$1.8 million in revenue in 2014. Revenues also include sales from our ADVANCE neurodiagnostic products totaling \$2.3 million in the year ended December 31, 2015, compared to \$2.8 million in 2014.

**Cost of Revenues and Gross Margin**

The following table summarizes our cost of revenues and gross margin:

	Years Ended December 31,			
	2015	2014	Change	% Change
Cost of revenues	\$ 3,950.7	\$ 2,568.6	\$ 1,382.1	53.8 %
Gross profit	\$ 3,349.1	\$ 2,944.2	\$ 404.9	13.8

(in thousands)

Our cost of revenues increased to \$4.0 million in 2015, compared to \$2.6 million in 2014, primarily due to the increase in orders and shipment volumes during the comparable periods. Gross margin decreased to 45.9% in 2015 compared to 53.4% in 2014. The contraction in gross margin reflects two factors: growing Quell sales which are weighted toward lower margin devices rather than higher margin electrodes, and operating costs of our new manufacturing facility. As we build our installed base of Quell users we expect recurring electrode sales at higher margins. Also, continued growth in Quell sales will improve manufacturing cost absorption contributing to margin gains.

TABLE OF CONTENTS**Operating Expenses**

The following table summarizes our operating expenses:

	Years Ended December			
	2015	2014	Change	% Change
	(in thousands)			
Operating expenses:				
Research and development	\$ 3,894.8	\$ 4,076.0	\$ (181.2 )	(4.4 )%
Sales and marketing	7,233.0	2,913.1	4,319.9	148.3
General and administrative	5,497.5	4,725.1	772.4	16.3
Total operating expenses	\$ 16,625.3	\$ 11,714.2	\$ 4,911.1	41.9

**Research and Development**

Research and development expenses for 2015 and 2014 were \$3.9 million and \$4.1 million, respectively. The decrease of \$0.2 million primarily reflects decreased spending of \$0.5 million in personnel costs, partially offset by increased spending of \$0.3 million in consulting fees to develop Quell for launch in June 2015 and in transitioning the engineering focus to Quell enhancements and eventually the next product generation.

**Sales and Marketing**

Sales and marketing expenses increased to \$7.2 million in 2015 from \$2.9 million in 2014. The increase of \$4.3 million included incremental expenses for direct-to-consumer and physician online advertising and paid search of \$1.6 million and incremental public relations expenses of \$0.3 million to support the Quell launch. An increase in personnel costs of \$1.7 million and travel and expense of \$0.3 million as compared to the same period last year is attributed to the addition of 14 new employees hired specifically to support the commercialization of Quell, which included a new marketing team, a field sales force, and expansion of the customer care function.

**General and Administrative**

General and administrative expenses increased by \$0.8 million to \$5.5 million in 2015 compared to \$4.7 million in the prior year. This increase reflected \$0.3 million in incremental temporary staffing and consulting services and recruiting fees of \$0.1 million related to staff turnover in accounting and information technology as well as costs related to relocating the company's corporate offices and production to new facilities in the first quarter of 2015.

**Interest Income**

Interest income was approximately \$5,200 and \$4,600 during 2015 and 2014, respectively. Interest income was earned from investments in cash equivalents.

**Change in fair value of warrant liability**

The change in fair value of warrant liability of \$4.1 million for 2015 reflects the combined effects of a lower base of outstanding warrants for valuation purposes plus a lower stock price and a declining term of the remaining warrants.

In connection with the May 2015 financing (See Liquidity and Capital Resources ) we redeemed \$0.9 million in outstanding warrants. The remaining warrants were then valued at fair value at the end of the year using the Black

Scholes valuation method. The change in the fair value of the warrant liability in the year ended December 31, 2014 was \$1.1 million.

**Net loss per common share applicable to common stockholders, basic and diluted**

The net loss per common share applicable to common stockholders, basic and diluted, was \$7.75 and \$6.15 for 2015 and 2014, respectively.

Net loss per common share applicable to common stockholders in 2015 of \$7.75 included a deemed dividend attributable to preferred stockholders in connection with beneficial conversion features of \$4.1 million, or \$1.52 per share, related to our May 2015 equity offering; a deemed dividend attributable to preferred stockholders in connection with preferred stock modifications of \$8.3 million, or \$3.06 per share, related to our December 2015 equity offering; a return of capital to common shareholders attributable to the

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repurchase of preferred shares and related embedded beneficial conversion of \$0.6 million, or \$0.22 per share, related to our December 2015 equity offering; and our 2015 net loss reported in our Statement of Operations of \$9.2 million, or \$3.38 per share. The above per share amounts are calculated using 2,719,085 weighted average number of shares outstanding as of December 31, 2015.

Net loss per common share applicable to common stockholders in 2014 of \$6.15 included a deemed dividend attributable to preferred stockholders in connection with beneficial conversion features of \$3.0 million, or \$1.70 per share, related to our 2014 equity offering; and our 2014 net loss reported in our Statement of Operations of \$7.8 million, or \$4.45 per share. The above per share amounts are calculated using 1,743,494 weighted average number of shares outstanding at December 31, 2014.

## Comparison of Years Ended December 31, 2014 and December 31, 2013

### Revenues

The following table summarizes our revenues:

	Years Ended December 31,			
	2014	2013	Change	% Change
Revenues	\$ 5,512.8	\$ 5,278.8	\$ 234.0	4.4 %

(in thousands)

Revenues include sales from SENSUS, our wearable therapeutic device for relief of chronic, intractable pain launched in January 2013; DPNCheck, our diagnostic test for diabetic peripheral neuropathy, or DPN, launched in Q4 2011; and our legacy ADVANCE neurodiagnostics business. Overall revenues increased by 4.4% from 2013. Revenue from our newer products, SENSUS and DPNCheck, grew by over 80% in 2014. The ADVANCE business, managed for cash flow and not growth, contracted by 25%. ADVANCE has few direct operating costs.

Revenue from SENSUS devices and consumable electrodes totaled \$0.9 million in 2014 versus \$0.2 million in 2013.

Reflecting expanded distribution through national durable medical equipment suppliers in 2014, we shipped approximately 5,800 SENSUS devices and posted a 350% increase when compared to 1,300 devices shipped in 2013.

SENSUS electrode shipments totaled approximately 17,600 in 2014 versus approximately 3,500 in 2013.

Revenue from DPNCheck increased over 40% to \$1.8 million in 2014 from \$1.3 million in 2013. Our Asia distribution partner, Omron Healthcare, received regulatory approval and launched DPNCheck in Japan during the third quarter of 2014, contributing positively to 2014 revenue. The United States Medicare Advantage business expanded with approximately a 50% growth in tests shipped in 2014 in comparison with 2013. Overall, there were approximately 680 DPNCheck devices and 110,000 tests shipped in 2014 in comparison with 540 devices and 85,000 tests in 2013.

ADVANCE recorded about \$2.8 million in 2014 revenue in comparison to \$3.8 million in 2013.

**Cost of Revenues and Gross Margin**

The following table summarizes our cost of revenues and gross margin:

	Years Ended December			
	2014	2013	Change	% Change
	(in thousands)			
Cost of revenues	\$ 2,568.6	\$ 2,194.3	\$ 374.3	17.1 %
Gross profit	\$ 2,944.2	\$ 3,084.5	\$ (140.3 )	(4.5 )

We recorded an increase in cost of revenues to \$2.6 million in 2014 from \$2.2 million in 2013 and a decline in our gross margin to 53.4% of revenues in 2014 from 58.4% of revenues in 2013. The decline in gross margin is primarily attributable to the SENSUS product line which comprised a greater percentage of total revenues in 2014 versus 2013, and has lower margins than our other products. The lower SENSUS margins reflect the high cost structure in the durable medical equipment sales channel which accounts for the majority of our SENSUS sales. The effect of low SENSUS margins was compounded by strong growth in that

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product. SENSUS represented 16% of total revenue in 2014 in comparison with 4% of revenue in 2013. Inventory write-down charges primarily related to excess ADVANCE inventory were insignificant in 2014 and were about \$0.2 million in 2013.

**Operating Expenses**

The following table summarizes our operating expenses:

	Years Ended December			
	31, 2014	2013	Change	% Change
	(in thousands)			
Operating expenses:				
Research and development	\$ 4,076.0	\$ 3,438.2	\$ 637.8	18.6 %
Sales and marketing	2,913.1	2,779.7	133.4	4.8
General and administrative	4,725.1	4,225.5	499.6	11.8
Total operating expenses	\$ 11,714.2	\$ 10,443.4	\$ 1,270.8	12.2

**Research and Development**

Research and development expenses were approximately \$4.1 million and \$3.4 million in 2014 and 2013, respectively, an increase of \$0.6 million or 19%. The increased spending was in support of our initiative to launch Quell in the first half of 2015. R&D investments totaling approximately \$0.8 million were made in outside engineering support for product design, smart phone application development and consulting services. During 2013, similar outside support costs were approximately \$0.2 million. This spending was offset by reductions of approximately \$0.1 million in 2014 clinical study costs.

**Sales and Marketing**

Sales and marketing expenses were approximately \$2.9 million and \$2.8 million in 2014 and 2013, respectively, an increase of \$0.1 million or 5%. Marketing costs for outside services related to Quell accounted for approximately \$0.4 million in incremental spending in 2014. This encompassed product branding, pricing studies, consulting services as well as promotional materials for trade shows scheduled for early 2015. Personnel costs declined about \$0.1 million in 2014 versus 2013. Sales and Marketing personnel spending in 2014 included fourth quarter hiring of a new management team responsible for Quell. Trade show and travel costs declined approximately \$0.1 million in 2014 versus 2013.

**General and Administrative**

General and administrative expenses were approximately \$4.7 million and \$4.2 million in 2014 and 2013, respectively, an increase of \$0.5 million of 12%. Personnel costs increased by \$0.2 million reflecting incentive compensation and stock based compensation adjustments during 2014. Outside services, including temporary staffing, increased by \$0.3 million in response to staff turnover and the support requirements for relocation of the corporate office and production activities planned for early 2015. Professional services for legal and accounting support declined by approximately \$0.1 million in 2014 from 2013.

### **Interest Income**

Interest income was approximately \$4,600 and \$5,700 during 2014 and 2013, respectively. Interest income was earned from investments in cash equivalents.

### **Warrant offering costs, and Change in fair value of warrant liability**

Costs related to the issuance of common stock warrants in connection with equity offerings was about \$0.1 million and \$0.4 million in 2014 and 2013, respectively. Outstanding warrants from those offerings were valued at fair value at quarterly reporting periods and on warrant transaction dates. The total fair value adjustments to outstanding warrants was a reduction in the net loss of \$1.1 million in 2014 and an increase in the net loss of \$0.3 million in 2013.

### **Net loss per common share applicable to common stockholders, basic and diluted**

The net loss per common share applicable to common stockholders, basic and diluted, was \$6.15 and \$12.28 for 2014 and 2013, respectively.



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Net loss per common share applicable to common stockholders in 2014 of \$6.15 included a deemed dividend attributable to preferred stockholders in connection with beneficial conversion features of \$3.0 million, or \$1.70 per share related to our 2014 equity offering; and our 2014 net loss reported in our Statement of Operations of \$7.8 million, or \$4.45 per share. The above per share amounts are calculated using 1,743,494 weighted average number of shares outstanding as of December 31, 2014.

Net loss per common share applicable to common stockholders in 2013 of \$12.28 included a deemed dividend attributable to preferred stockholders in connection with beneficial conversion features of \$0.8 million, or \$1.07 per share related to our 2013 equity offering; and our 2013 net loss reported in our Statement of Operations of \$8.0 million, or \$11.21 per share. The above per share amounts are calculated using 715,524 weighted average number of shares outstanding as of December 31, 2013.

## Liquidity and Capital Resources

Our principal source of liquidity is our cash and cash equivalents. As of December 31, 2015, cash and cash equivalents totaled \$12.5 million. During 2015 we completed two equity offerings, or the 2015 Offerings, which are detailed below.

Our ability to generate revenue to fund our operations will largely depend on the success of our wearable therapeutic products for chronic pain and our diagnostic products for neuropathy. A low level of market interest in Quell or DPNCheck, an accelerated decline in our neurodiagnostics consumables sales, or unanticipated increases in our operating costs would have an adverse effect on our liquidity and cash generated from operations. The following table sets forth information relating to our cash and cash equivalents:

	December 31, 2015	December 31, 2014	Change	% Change
	(in thousands)			
Cash and cash equivalents	\$ 12,462.9	\$ 9,222.0	\$ 3,240.9	35.1 %

During 2015 our cash and cash equivalents increased by \$3.2 million reflecting the net proceeds provided by our 2015 equity offerings, offset by \$13.1 million of net cash used in operations and \$0.6 million used in investing activities.

The 2015 Equity Offerings resulted in net proceeds of approximately \$16.8 million, after redemptions of certain equity instruments and after deducting financial institution discounts and fees, and other offering expenses.

In December 2015, we completed a private equity offering providing for the issuance of (i) 13,800 shares of Series C convertible preferred stock at a price of \$1,000 per share, and (ii) warrants to purchase up to 10,823,528 shares of our common stock, at an exercise price of \$2.30 per share. The closing of the offering occurred on December 31, 2015. The offering resulted in approximately \$6.7 million in net proceeds after deducting placement agent fees and expenses and the redemption of 63,000 shares of Series B convertible preferred stock from the May 2015 public offering.

In May 2015, we completed an underwritten public offering of (i) 147,000 shares of Series B convertible preferred stock at a price of \$100 per share, and (ii) five year warrants to purchase up to 3,638,250 shares of our common stock at an exercise price of \$5.00 per share. This offering resulted in approximately \$14.7 million in gross proceeds, before deducting underwriting discounts and commission and expenses. In conjunction with this offering, approximately \$3.2 million of the proceeds were used to repurchase the outstanding Series A-4 preferred shares from the 2014 offering.

Net proceeds from this offering, after deducting underwriting discount and commissions and offering expenses and repurchase of outstanding Series A-4 preferred shares, were approximately \$10.1 million. See Note 12, Stockholders

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Equity, of our Notes to Financial Statements contained elsewhere in this Annual Report on Form 10-K for further information regarding the 2015 Equity Offerings.

In order to supplement our access to capital, we are party to an amended Loan and Security Agreement, most recently amended January 14, 2016, with a bank which provides us with a credit facility in the amount of \$2.5 million on a revolving basis. The amended credit facility expires on January 15, 2017. Amounts borrowed under the credit facility will bear interest equal to the prime rate plus 0.5%. Any borrowings under the credit facility will be collateralized by our cash, accounts receivable, inventory, and equipment. As of

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December 31, 2015 the Company was in default under a provision of the Agreement that requires the prior written consent by the bank for any repurchase on the Company's capital stock. This default was waived by the bank on January 14, 2016. The Credit Facility also includes traditional lending and reporting covenants. These include certain financial covenants applicable to liquidity that are to be maintained by us. As of December 31, 2015, we were in compliance with these covenants and had not borrowed any funds under the credit facility. However, approximately \$0.2 million of the amount under the Credit Facility is restricted to support letters of credit issued in favor of our landlords in connection with lease arrangements. Consequently, the amount available for borrowing under the credit facility as of December 31, 2015 was approximately \$2.3 million.

In managing working capital, two important financial measurements are days sales outstanding (DSO) and inventory turnover as presented below:

	Years Ended December 31,	
	2015	2014
Days sales outstanding (days)	27	38
Inventory turnover rate (times per year)	5.9	4.0

Customer payment terms generally vary from payment-on-order for Quell e-commerce sales to 30 days from invoice date. Both days sales outstanding and inventory turnover improved during 2015.

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

	Years Ended December 31,		
	2015	2014	2013
	(in thousands)		
Net cash used in operating activities	\$ (13,099.9)	\$ (7,678.5)	\$ (6,554.9)
Net cash (used in) provided by investing activities	(594.6)	(227.3)	(86.1)
Net cash provided by financing activities	16,935.3	7,932.0	7,137.3

Our operating activities used \$13.1 million for the year ended December 31, 2015 primarily attributable to our net loss of \$9.2 million. This loss included non-cash credits of approximately \$4.1 million for revaluing outstanding warrants at fair value. In addition, operating activities included increases in inventories of \$0.4 million, increases in prepaid expenses and other assets of \$0.4 million, partially offset by increases in accounts payable of \$0.5 million.

During the year ended December 31, 2015, our investing activities reflected \$0.6 million spent for the acquisition of fixed assets, primarily related to information technology system upgrades.

Following our 2015 equity offerings, we ended the year with 16.0 million warrants outstanding with a weighted average exercise price of \$3.57 per common share. Of these, 10.8 million cash exercise warrants have an exercise price of \$2.30 per common share, totalling \$24.9 million.

We held cash and cash equivalents of \$12.5 million as of December 31, 2015. We believe that these resources and the cash to be generated from expected product sales 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 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; (e) changes we may make 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 in the third quarter of 2016 and beyond. These factors raise substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. We will 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. We filed a shelf registration

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statement on Form S-3 with the SEC covering shares of our common stock and other securities for sale, giving us the opportunity to raise funding when needed or otherwise considered appropriate at prices and on terms to be determined at the time of any such offerings. However, pursuant to the instructions to Form S-3, we only have the ability to sell shares under the shelf registration statement, during any 12-month period, in an amount less than or equal to one-third of the aggregate market value of our common stock held by non-affiliates. If we raise additional funds by issuing equity or debt securities, either through the sale of securities pursuant to a registration statement or by other means, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. If we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. Without additional funds, we may be forced to delay, scale back or eliminate some of our sales and marketing efforts, research and development activities, or other operations and potentially delay product development in an effort to provide sufficient funds to continue our operations. If any of these events occurs, our ability to achieve our development and commercialization goals would be adversely affected.

As of December 31, 2015, we have federal and state net operating loss, or NOL, carryforwards available to offset future taxable income of \$118.2 million and \$34.9 million, respectively, and federal and state tax credits of \$1.3 million and \$1.1 million, respectively, which may be available to reduce future taxable income and the related taxes thereon. The federal NOL s begin to expire in 2019 and the state NOL s begin to expire in 2017. The federal and state research and development credits both begin to expire in 2018. A full valuation allowance has been provided against our NOL carryforwards and research and development credit carryforwards and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the balance sheet or statement of operations if an adjustment were required.

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

As of December 31, 2015, we did not have any off-balance sheet financing arrangements.

The following table summarizes our principal contractual obligations as of December 31, 2015 and the effects such obligations are expected to have on our liquidity and cash flows in future periods.

Contractual Obligations	Total	Payments due in			
		Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating lease obligations	\$ 3,186,439	\$ 517,566	\$ 1,071,045	\$ 1,028,887	\$ 568,941
Purchase order obligations	1,526,459	1,526,459			
Total contractual obligations	\$ 4,712,898	\$ 2,044,025	\$ 1,071,045	\$ 1,028,887	\$ 568,941

### **Critical Accounting Policies and Estimates**

Our financial statements are based on the selection and application of generally accepted accounting principles, which require us to make estimates and assumptions about future events that affect the amounts reported in our financial statements and the accompanying notes. Future events and their effects cannot be determined with certainty. Therefore, the determination of estimates requires the exercise of judgment. Actual results could differ significantly from those estimates, and any such differences may be material to our financial statements. We believe that the policies set forth below may involve a higher degree of judgment and complexity in their application than our other

accounting policies and represent the critical accounting policies used in the preparation of our financial statements. If different assumptions or conditions were to prevail, the results could be materially different from our reported results.

Our significant accounting policies are presented within Note 2 to our Financial Statements.

### **Revenue Recognition and Accounts Receivable**

We recognize revenue when the following criteria have been met: persuasive evidence of an arrangement exists, delivery has occurred and risk of loss has passed, the seller's price to the buyer is fixed or determinable, and collection is reasonably assured. Revenues associated with our medical devices and

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consumables, including single use nerve specific electrodes and other accessories are generally recognized upon shipment, assuming all other revenue criteria have been met.

Revenue recognition involves judgments, including assessments of expected returns and expected customer relationship periods. We analyze various factors, including a review of specific transactions, its historical product returns, average customer relationship periods, customer usage, customer balances, and market and economic conditions. Changes in judgments or estimates on these factors could materially impact the timing and amount of revenues and costs recognized. Should market or economic conditions deteriorate, our actual return or bad debt experience could exceed its estimate. Certain product sales are made with a 30-day or 60-day right of return. Where we can reasonably estimate future returns, we recognizes revenues upon shipment and record as a reduction of revenue a provision for estimated returns. Where we cannot reasonably estimate future returns, we defer revenues until we gain sufficient experience to estimate returns or until the right of return lapses.

Trade accounts receivable are recorded at the invoiced amount and do not bear interest.

Accounts receivable are recorded net of the allowance for doubtful accounts receivable. The allowance for doubtful accounts is our best estimate of the amount of probable credit losses in our existing accounts receivable. We review our allowance for doubtful accounts and determine the allowance based on an analysis of customer past payment history, product usage activity, and recent communications between us and the customer. Individual customer balances which are past due and over 90 days outstanding are reviewed individually for collectability. Account balances are written-off against the allowance when we feel it is probable the receivable will not be recovered. We do not have any off-balance sheet credit exposure related to our customers.

### **Inventories**

Inventories, consisting primarily of finished goods and purchased components, are stated at the lower of cost or market. Cost is determined using the first-in, first-out method. We write down inventory to its net realizable value for excess or obsolete inventory. Finished goods inventories owned by us, but stored in third party warehouses prior to order fulfillment, are disclosed separately as finished goods on consignment. The realizable value of inventories is based upon the types and levels of inventories held, forecasted demand, pricing, competition, and changes in technology. Our consumables have an eighteen to twenty-four month shelf life. Should current market and economic conditions deteriorate, our actual recoveries could be less than our estimates.

## **Recently Issued or Adopted Accounting Pronouncements**

In November 2015, the FASB issued Accounting Standards Update No. 2015-17, *Balance Sheet Classification of Deferred Taxes* (ASU 2015-17). ASU 2015-17 requires that deferred income tax liabilities and assets be classified as noncurrent in our balance sheet. The standard is effective for public entities for annual and interim periods beginning after December 15, 2016, with early adoption permitted. ASU 2015-17 has been adopted on a prospective basis by us for the year ended December 31, 2015, thus resulting in the reclassification of \$45,000 of current deferred tax liabilities to noncurrent on the accompanying balance sheet. The prior reporting period was not retrospectively adjusted. The adoption of this guidance had no impact on our results of operations or cash flows.

In August 2014, the FASB issued Accounting Standards Update No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* (ASU 2014-15). ASU 2014-15 requires management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The standard is effective for public entities for annual and interim periods beginning after December 15, 2016, with early

adoption permitted. We are currently evaluating the provisions of ASU 2014-15 and assessing the impact, if any, it may have on our financial position, results of operations or cash flows.

In May 2014, the FASB and the International Accounting Standards Board ( IASB ) jointly issued Accounting Standards Update ( ASU ) No. 2014-09, Revenue from Contracts with Customers ( ASU 2014-09 ), a comprehensive new revenue recognition standard that will supersede nearly all existing revenue recognition guidance. The objective of ASU 2014-09 is that a company will recognize revenue when it transfers promised



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goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 will be effective for the first quarter of 2017. An entity can elect to adopt ASU 2014-09 using one of two methods, either full retrospective adoption to each prior reporting period, or recognizing the cumulative effect of adoption at the date of initial application. We are in the process of evaluating the new standard and do not know the effect, if any, ASU 2014-09 will have on the Consolidated Financial Statements or which adoption method will be used.

## ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk

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

## ITEM 8. Financial Statements and Supplementary Data

The information required by this item may be found on pages F-1 through F-24 of this Annual Report on Form 10-K with the exception of the unaudited summarized quarterly financial data which is presented below. Net loss per common share is calculated independently for each of the periods presented. Therefore, the sum of the quarterly net loss per common share amounts will not necessarily equal the total for the full fiscal year. Per common share amounts have been adjusted for all periods to reflect a 1-for-4 reverse split of our common stock completed on December 1, 2015.

	Year Ended December 31, 2015				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Revenues	\$1,282,960	\$1,224,987	\$2,054,432	\$2,737,451	\$7,299,830
Cost of revenues	637,261	595,032	1,119,186	1,599,267	3,950,746
Gross profit	645,699	629,955	935,246	1,138,184	3,349,084
Net loss	(2,071,228)	(1,203,206)	(3,203,778)	(2,709,136)	(9,187,348)
Net loss per common share, basic and diluted	\$(1.00 )	\$(2.07 )	\$(1.06 )	\$(3.19 )	\$(7.75 )

	Year Ended December 31, 2014				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Revenues	\$1,331,537	\$1,343,770	\$1,427,828	\$1,409,629	\$5,512,764
Cost of revenues	615,081	655,337	639,025	659,159	2,568,602
Gross profit	716,456	688,433	788,803	750,470	2,944,162

Net loss	(1,224,599)	(2,170,710)	(1,461,713)	(2,909,200)	(7,766,222)
Net loss per common share, basic and diluted	\$(0.83 )	\$(3.42 )	\$(0.74 )	\$(1.44 )	\$(6.15 )

## **ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

There have been no changes in or disagreements with accountants on accounting and financial disclosure matters in the last fiscal year.

### **ITEM 9A. Controls and Procedures**

#### **(a) Evaluation of disclosure controls and procedures.**

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Form 10-K, have concluded that, based on such evaluation, our disclosure

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controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

## **(b) Management's Report on Internal Control Over Financial Reporting.**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2015 based on the criteria in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ( COSO ). Based on our evaluation under the framework in *Internal Control - Integrated Framework* (2013) issued by the COSO, our management concluded that our internal control over financial reporting was effective as of December 31, 2015.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to rules of the SEC that permit us to provide only management's report in this Annual Report on Form 10-K.

## **(c) Changes in internal control over financial reporting.**

There have been no changes to our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **ITEM 9B. Other Information**

On February 8, 2016, the Compensation Committee of the Board of Directors approved modifications to the Management Retention and Incentive Plan (the Plan ). A full description of the Plan is included under Part II, Item 5 of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2012, as filed on August 3, 2012, as modified and described in Part II, Item 5 of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, as filed on October 28, 2014, which are incorporated herein by reference. Under the Plan, a portion of the consideration payable upon a change of control transaction, as defined in the Plan, would be paid to executive officers and certain other key employees. The modifications of the Plan include clarifying changes as well as adding Frank McGillin, Senior Vice President, General Manager, Consumer, as a participant under the Plan. The description of the Plan, as modified, contained herein does not purport to be complete and is qualified in its entirety by reference to the full text of the Plan, as modified, a copy of which is set forth as Exhibit 10.15 to this Annual Report on Form 10-K and is incorporated herein by reference.



TABLE OF CONTENTS**PART III****ITEM 10. Directors, Executive Officers and Corporate Governance****DIRECTORS AND EXECUTIVE OFFICERS**

The following table and biographical descriptions set forth information regarding our executive officers and directors, based on information furnished to us by each executive officer and director, as of December 31, 2015:

Name	Age	Position
Shai N. Gozani, M.D., Ph.D.	51	Chairman of the Board, Chief Executive Officer, President and Secretary
Thomas T. Higgins	64	Senior Vice President, Chief Financial Officer and Treasurer
Francis X. McGillin	55	Senior Vice President, General Manager Consumer
David E. Goodman, M.D. <sup>(1)(2)</sup>	59	Director
Allen J. Hinkle, M.D. <sup>(2)(3)</sup>	65	Director
Nancy E. Katz <sup>(1)</sup>	56	Director
Timothy R. Surgenor <sup>(1)(3)</sup>	56	Director
David Van Avermaete	64	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,

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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 he co-founded that is committed to preventing the devastating and expensive microvascular complications of diabetes. Since 2014, Dr. Goodman has served as a director of Xtant Medical (OTC QX: BONE), a comprehensive supplier of orthopedic and spine surgery products. From 2012 – 2015, 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.

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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

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

**Timothy R. Surgenor** has served as a member of our Board of Directors since April 2009. Since April 2009, Mr. Surgenor has been a partner at Red Sky Partners, LLC, a provider of general management consulting services to the biotechnology 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. Since January 2015, Mr. Van Avermaete has served as President of Inject Safe Technologies, a privately held company that has developed a bandage specifically designed to support injections. From April 2004 to February 2013, Mr. Van Avermaete served as Chief Executive Officer of VeraLight, Inc., a medical device company he founded, that focuses on non-invasive screening for type 2 diabetes. From 2000 to 2004, Mr. Van Avermaete served as Senior Vice President Non-Invasive Technology of InLight Solutions, a Johnson & Johnson company focused on transformational technology in the diabetes field. From 1998 to 2000, Mr. Van Avermaete served as U.S. President of the LifeScan division of Johnson & Johnson and, from 1990 to 1998, in various senior level positions at LifeScan concentrating in sales and marketing. Previously, Mr. Van Avermaete served as Vice President Sales and Marketing at Biotope, Director of Marketing at Roche Diagnostics, and Director of Marketing and Sales at Syntex Medical Diagnostics. Mr. Van Avermaete received a Master of Business Administration and a Master of Science Degree in Microbiology from the University of Arizona and a Bachelor of Science Degree in medical technology and chemistry from Ball State University. The Board has concluded that Mr. Van Avermaete should serve as a director because his executive level experience in the medical device and diabetes field, as well as in entrepreneurial ventures, provides the Board with a valuable perspective in commercializing diabetes products.

## **BOARD MATTERS AND CORPORATE GOVERNANCE**

### **Board of Directors**

Our amended and restated certificate of incorporation, as amended, provides for a classified board of directors consisting of three staggered classes of directors (Class I, Class II and Class III). The members of each class of our Board of Directors serve for staggered three-year terms, with the terms of our Class III, Class I and Class II directors expiring upon the election and qualification of directors at the annual meetings of stockholders to be held in 2016, 2017, and 2018, respectively. Currently:

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

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

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

The Audit Committee currently consists of Mr. Surgenor, Chairman, Dr. Goodman, and Ms. Katz. The Audit Committee operates pursuant to a charter that was approved by our Board of Directors, a copy of which is available on our website at <http://www.neurometrix.com> under the heading Investor Relations and subheading Corporate Governance. The purposes of the Audit Committee are to, among other functions, assist the Board of Directors in overseeing the operation of a comprehensive system of internal controls covering the integrity of our financial statements and reports, compliance with laws, regulations and corporate policies, and the qualifications, performance and independence of our registered public accounting firm. Mr. Surgenor, Dr. Goodman, and Ms. Katz are all independent as that term is defined in the rules of the SEC and the applicable NASDAQ rules relating to audit committee members. Our Board of Directors has determined that Mr. Surgenor qualifies as an audit committee financial expert as such term is defined in the rules of the SEC. The Audit Committee held five meetings during 2015.

## **Procedures by which Stockholders may Nominate Directors**

There have been no changes to the procedures disclosed in our proxy statement for the 2015 annual meeting of stockholders by which stockholders may nominate directors.

## **Code of Business Conduct and Ethics**

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

## **Section 16(a) Beneficial Ownership Reporting Compliance**

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

## **ITEM 11. Executive Compensation**

The information required by this Item will be contained in our definitive proxy statement for our 2016 Annual Meeting of Stockholders under the captions Compensation of Executive Officers and Director Compensation and is incorporated by reference herein.

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

### **PRINCIPAL AND MANAGEMENT STOCKHOLDERS**

The following table sets forth certain information concerning beneficial ownership as of February 1, 2016, except as noted below, of our common stock by:

each of our directors;  
each of our named executive officers;

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

The number of common shares beneficially owned by each stockholder is determined under rules issued by the SEC regarding the beneficial ownership of securities. This information is not necessarily indicative of beneficial ownership for any other purpose. Under these rules, beneficial ownership of common stock includes (1) any shares as to which the person or entity has sole or shared voting power or investment power and (2) any shares as to which the person or entity has the right to acquire beneficial ownership within 60 days after February 1, 2016, including any shares that could be purchased by the exercise of options or warrants on or within 60 days after February 1, 2016. Each stockholder's percentage ownership is based on 4,049,807 shares of our common stock outstanding as of February 1, 2016 plus the number of shares of common stock that may be acquired by such stockholder upon exercise of options or warrants that are exercisable on or within 60 days after February 1, 2016.

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

Name and Address <sup>(1)</sup> of Beneficial Owner	Amount and Nature of Beneficial Ownership			Percent of Class of Total
	Common Stock	Options <sup>(2)</sup>	Total	
Directors and Executive Officers				
Shai N. Gozani, M.D., Ph.D.	56,999	72,132	129,131	3.1 %
Thomas T. Higgins	21,374	30,740	52,114	1.3 %
Francis X. McGillin	3,158	18,750	21,908	*
Allen Hinkle, M.D.	209	793	1,002	*
David E. Goodman, M.D.	209	793	1,002	*
Timothy R. Surgenor	1,834	793	2,627	*
Nancy E. Katz	209	793	1,002	*
David Van Avermaete		1,957	1,957	*
All Current Directors and Executive Officers as a group (8 persons)	83,992	126,751	210,743	5.0 %

Name and Address <sup>(1)</sup> of Beneficial Owner	Amount and Nature of Beneficial Ownership		Percent of Class of Total
	Common Stock	Warrants <sup>(3)</sup>	
Beneficial Owner of 5% or More Other than Directors and Executive Officers			
Sabby Management, LLC <sup>(3)</sup>	449,204	449,204	9.99 %

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

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

(2) Includes all options that are exercisable on or within 60 days from February 1, 2016 by the beneficial owner, except as otherwise noted.

(3)

Reflects shares of common stock issuable upon the exercise of warrants beneficially owned by Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. The amount does not include 14,250,826 shares of common stock issuable upon exercise of warrants issued to Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. in 2012, 2013, 2014 and 2015 and 5,411,765 shares of common stock issuable upon the conversion of 13,800 shares of Series C Convertible Preferred Stock issued to Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd., all of which are subject to a 9.99% beneficial ownership limitation and related warrant exercise restriction. Sabby Management, LLC and Hal Mintz do not directly own

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shares of common stock, but are deemed to have beneficial ownership over these shares of common stock because Sabby Management, LLC is the investment manager for both Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. and Hal Mintz is the manager of Sabby Management, LLC. The address for the reporting persons is 10 Mountainview Road, Suite 205, Upper Saddle River, New Jersey 07458.

**EQUITY COMPENSATION PLAN INFORMATION**

The following table sets forth information as of December 31, 2015 regarding the number of securities to be issued upon exercise, and the weighted average exercise price of outstanding options, warrants, and rights under our equity compensation plans and the number of securities available for future issuance under our equity compensation plans.

**Equity Compensation Plan Information as of December 31, 2015**

	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column a)
	(a)	(b)	(c)
Equity compensation plans approved by security holders <sup>(1)</sup>	164,813	\$ 22.23	291,846 <sup>(2)</sup>
Equity compensation plans not approved by security holders <sup>(3)</sup>	50,000	7.52	50,000
Totals	214,813	\$ 18.81	341,846

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

As of December 31, 2015, there were 272,054 shares available for future grant under the Seventh Amended and (2) Restated 2004 Stock Option and Incentive Plan and 19,792 shares available under the 2010 Employee Stock Purchase Plan. No new stock grants or awards will be made under the Amended and Restated 1996 Stock Option/Restricted Stock Plan or the Amended and Restated 1998 Equity Incentive Plan.

Includes information related to our Amended and Restated 2009 Non-Qualified Inducement Stock Plan, which is (3) designed to provide equity grants to new employees. Pursuant to this plan, we were authorized to issue Non-Qualified Stock Options, Restricted Stock Awards and Unrestricted Stock Awards.

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

### **TRANSACTIONS WITH RELATED PERSONS**

Pursuant to our audit committee charter currently in effect, the audit committee is responsible for reviewing and approving, prior to our entry into any such transaction, all transactions in which we are a participant and in which any parties related to us has or will have a direct or indirect material interest. The information required by this Item will be contained in our definitive proxy statement for our 2016 Annual Meeting of Stockholders under the caption Transactions with Related Persons and is incorporated by reference herein.

### **DIRECTOR INDEPENDENCE**

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

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## **ITEM 14. Principal Accounting Fees and Services**

### **ACCOUNTING FEES**

Aggregate fees for professional services rendered by PricewaterhouseCoopers LLP for the years ended December 31, 2015 and 2014 are as follows:

#### **Audit Fees**

The audit fees for PricewaterhouseCoopers LLP for professional services rendered for the 2015 audit of our annual financial statements and the review of the financial statements included in our quarterly reports on Form 10-Q, issuance of comfort letter, issuance of consents, and review of documents filed with the SEC totaled \$604,000, of which \$430,000 was billed in 2015 and 174,000 was billed in 2016.

The audit fees for PricewaterhouseCoopers LLP for professional services rendered for the 2014 audit of our annual financial statements, the review of the financial statements included in our quarterly reports on Form 10-Q, issuance of consents and review of documents filed with the SEC totaled \$475,000, of which \$308,000 was billed in 2014 and \$167,000 was billed in 2015.

#### **Audit-Related Fees**

There were no audit-related fees for PricewaterhouseCoopers LLP in 2015 and 2014.

#### **All Other Fees**

Fees for PricewaterhouseCoopers LLP for services other than audit-related services were \$1,800 for 2015 and \$19,300 for 2014, and included annual fees of \$17,500 in 2014 in connection with our Corporate Integrity Agreement with the Office of Inspector General of the United States Department of Health and Human Services regarding the previously-disclosed investigation into certain of our past sales and marketing practices relating to our NC-stat System and \$1,800 in both years for a software subscription used to review accounting literature.

#### **Tax Fees**

There were no tax fees for PricewaterhouseCoopers LLP in 2015 and 2014.

#### **Pre-Approval Policies and Procedures**

The Audit Committee approved all audit and non-audit services provided to us by PricewaterhouseCoopers LLP during the 2015 and 2014 fiscal years.

TABLE OF CONTENTS**PART IV****ITEM 15. Exhibits and Financial Statement Schedule****(a) 1. Financial Statements**

The consolidated financial statements are listed in the accompanying index to financial statements on page F-1.

**2. Financial Statement Schedule**

The Schedule on page S-1 is filed as part of this report. Other financial statement schedules required under this Item and Item 8 are omitted because they are not applicable or the required information is shown in the consolidated financial statements or the footnotes thereto.

**3. Exhibit Index**

The following is a list of exhibits filed as part of this Annual Report on Form 10-K:

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Registration Number
3.1.1	Third Amended and Restated Certificate of Incorporation of NeuroMetrix, Inc. dated July 27, 2004		S-8 (Exhibit 4.1)	8/9/04	333-118059
3.1.2	Certificate of Designations for Series A Junior Cumulative Preferred Stock, par value \$0.001 per share, dated March 7, 2007		8-A12(b) (Exhibit 3.1)	3/8/07	001-33351
3.1.3	Certificate of Amendment to Restated Certificate of Incorporation of NeuroMetrix, Inc. dated September 1, 2011		8-K (Exhibit 3.1)	9/1/11	001-33351
3.1.4	Certificate of Amendment to Restated Certificate of Incorporation of NeuroMetrix, Inc. dated February 15, 2013		8-K (Exhibit 3.1)	2/15/13	001-33351
3.1.5	Certificate of Amendment to Restated Certificate of Incorporation of NeuroMetrix, Inc. dated December 1, 2015		8-K (Exhibit 3.1)	12/1/15	001-33351
3.1.6	Certificate of Designation of Preferences, Rights and Limitations of Series A-1 Convertible Preferred Stock,		8-K (Exhibit 3.1)	6/6/13	001-33351

	par value \$0.001 per share, dated June 5, 2013			
3.1.7	Certificate of Designation of Preferences, Rights and Limitations of Series A-2 Convertible Preferred Stock, par value \$0.001 per share, dated June 5, 2013	8-K (Exhibit 3.2)	6/6/13	001-33351
3.1.8	Certificate of Designation of Preferences, Rights and Limitations of Series A-3 Convertible Preferred Stock, par value \$0.001 per share, dated June 24, 2014	8-K (Exhibit 3.1)	6/25/14	001-33351
3.1.9	Certificate of Designation of Preferences, Rights and Limitations of Series A-4 Convertible Preferred Stock, par value \$0.001 per share, dated June 24, 2014	8-K (Exhibit 3.2)	6/25/14	001-33351
3.1.10	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock, par value \$0.001 per share, dated May 26, 2015	8-K (Exhibit 3.1)	5/29/15	001-33351

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Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Registration Number
3.1.11	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock, par value \$0.001 per share, dated December 30, 2015		8-K (Exhibit 3.1)	12/30/15	001-33351
3.2.1	Second Amended and Restated Bylaws of NeuroMetrix, Inc.		S-8 (Exhibit 4.2)	8/9/04	333-118059
3.2.2	Amendment No. 1 to Second Amended and Restated Bylaws of NeuroMetrix, Inc.		8-K (Exhibit 3.1)	9/17/07	001-33351
4.1	Specimen Certificate for Shares of Common Stock		S-1/A (Exhibit 4.1)	7/19/04	333-115440
4.2.1	Shareholder Rights Agreement, dated as of March 7, 2007, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent		8-A12(b) (Exhibit 4.1)	3/8/07	001-33351
4.2.2	Amendment to Shareholder Rights Agreement, dated September 8, 2009, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent		8-K (Exhibit 4.1)	9/14/09	001-33351
4.2.3	Amendment No. 2 to Shareholder Rights Agreement, dated June 5, 2013, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent		8-K (Exhibit 4.2)	6/6/13	001-33351
4.2.4	Amendment No. 3 to Shareholder Rights Agreement, dated June 25, 2014, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent		8-K (Exhibit 4.2)	6/25/14	001-33351
4.2.5	Amendment No. 4 to Shareholder Rights Agreement, dated May 28, 2015, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent		10-Q (Exhibit 4.1)	7/23/15	001-33351
4.2.6	Amendment No. 5 to Shareholder Rights Agreement, dated December 29, 2015, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent		8-K (Exhibit 4.3)	12/30/15	001-33351
4.3.1				1/31/12	333-178165

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	Form of Unit Warrant to purchase Common Stock (February 2012)	S-1/A (Exhibit 4.5)		
4.3.2	Form of Placement Agent Warrant (February 2012)	S-1/A (Exhibit 4.6)	1/31/12	333-178165
4.4	Form of Common Stock Purchase Warrant (June 2013)	8-K/A (Exhibit 4.1)	6/7/13	001-33351
4.5	Form of Common Stock Purchase Warrant (June 2014)	8-K (Exhibit 4.1)	6/25/14	001-33351
4.6.1	Form of Warrant (2015) issued as part of a Unit on May 29, 2015	S-1/A (Exhibit 4.3)	5/4/15	333-188133
4.6.2	Form of Underwriter's Warrant (2015) issued on May 29, 2015	S-1/A (Exhibit 4.5)	4/13/15	333-188133
4.7	Form of Series A Common Stock Purchase Warrant (December 2015)	8-K (Exhibit 4.1)	12/30/15	001-33351
4.8	Form of Series B Common Stock Purchase Warrant (December 2015)	8-K (Exhibit 4.2)	12/30/15	001-33351

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Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Registration Number
Lease Agreements					
10.1.1	Lease Agreement, dated August 27, 2014, between Cummings Properties, LLC and NeuroMetrix, Inc.		10-Q (Exhibit 10.1)	10/28/14	011-33351
10.1.2	Lease Agreement, dated September 10, 2014, between, Boston Properties, Inc. and NeuroMetrix, Inc.		10-Q (Exhibit 10.2)	10/28/14	011-33351
Credit Facilities, Loan and Equity Agreements					
10.2.1	Loan and Security Agreement between NeuroMetrix, Inc. and Comerica Bank, dated March 5, 2010		10-Q (Exhibit 10.1)	5/14/10	001-33351
10.2.2	First Modification to Loan and Security Agreement between NeuroMetrix, Inc. and Comerica Bank, dated March 1, 2011		8-K (Exhibit 10.1)	3/3/11	001-33351
10.2.3	Fifth Modification to Loan and Security Agreement between NeuroMetrix, Inc. and Comerica Bank, dated January 31, 2014		10-Q (Exhibit 10.1)	4/24/14	001-33351
10.2.4	Sixth Modification to Loan and Security Agreement with Comerica Bank, dated January 23, 2015		10-Q (Exhibit 10.1)	4/24/15	001-33351
10.2.5	Seventh Modification to Loan and Security Agreement with Comerica Bank, dated January 14, 2016	X			
10.3.1	Securities Purchase Agreement by and between NeuroMetrix, Inc. and the purchasers named therein, as amended, dated June 24, 2014		8-K (Exhibit 10.1)	6/25/14	001-33351
10.3.2	Registration Rights Agreement by and between NeuroMetrix, Inc. and the purchasers named therein, dated June 24, 2014		8-K (Exhibit 10.2)	6/25/14	001-33351
10.4	Repurchase and Forfeiture Agreement by and between NeuroMetrix, Inc. and the parties named therein		10-Q (Exhibit 10.1)	7/23/15	001-33351
10.5.1	Securities Purchase Agreement by and between NeuroMetrix, Inc. and the purchasers named therein, dated December 29, 2015		8-K (Exhibit 10.1)	12/30/15	001-33351
10.5.2	Registration Rights Agreement by and between NeuroMetrix, Inc. and the		8-K (Exhibit	12/30/15	001-33351

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	purchasers named therein, dated December 29, 2015	10.2)		
Equity Compensation Plans				
10.6+	Amended and Restated 1996 Stock Option/Restricted Stock Plan	S-1/A (Exhibit 10.2)	6/22/04	333-115440
10.7.1+	Amended and Restated 1998 Equity Incentive Plan	S-1/A (Exhibit 10.3)	6/22/04	333-115440
10.7.2+	Second Amendment to Amended and Restated 1998 Equity Incentive Plan	S-1 (Exhibit 10.18)	6/22/04	333-115440

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Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Registration Number
10.8.1+	Seventh Amended and Restated 2004 Stock Option and Incentive Plan		14A (Appendix A)	3/30/15	001-33351
10.8.2+	Form of Restricted Stock Agreement		10-Q (Exhibit 10.4)	5/14/10	001-33351
10.8.3+	Form of Incentive Stock Option Agreement		10-Q (Exhibit 10.1)	11/15/04	000-50856
10.8.4+	Form of Non-Qualified Stock Option Agreement For Company Employees		10-Q (Exhibit 10.2)	11/15/04	