

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, 2014

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.)

**62 Fourth Avenue, 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:**

<u>Title of each class</u>	<u>Name of exchange on which registered</u>
<b>Common Stock, \$0.0001 par value per share</b>	<b>The NASDAQ Stock Market LLC</b>
<b>Preferred Stock Purchase Rights</b>	<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       Smaller reporting company   
(Do not check if a 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, 2014, 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 \$12,833,181 based on the closing sale price of the common stock as reported on the NASDAQ Capital Market on June 30, 2014.

As of February 1, 2015, there were 8,152,746 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 Item 11 in 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 5, 2015, or the 2015 Annual Meeting of Stockholders.

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ANNUAL REPORT ON FORM 10-K  
FOR THE YEAR ENDED DECEMBER 31, 2014

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“NEUROMETRIX”, “NC-STAT”, “ADVANCE”, “SENSUS”, “Quell”, “DPNCheck” and “NC-stat DPNCHECK” are the subject of 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.

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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, particularly as they relate to Quell and SENSUS; 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 in the treatment of chronic pain and our expectations surrounding Quell and our currently marketed products; our expectation that Quell has the potential to be the largest contributor to 2015 revenues of our marketed products; our expected timing and plans to develop and commercialize our products, including our hope to commercially launch Quell in the second quarter of 2015; our belief that controlled, personalized neuro-stimulation to suppress pain provides an important complement to existing pain medications and treatments and that we are well positioned to make neuro-stimulation widely available to chronic pain sufferers; our ability to execute our goal to build an installed base of active customer accounts and distributors for our marketed products; our plan to conduct Quell clinical studies to support our marketing and business plans and our hope that these studies will support future adoption of both Quell and SENSUS; 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, including developments related to third-party reimbursement; our expectation that we will continue to manufacture our current marketed products as well as Quell; our belief that our manufacturing relationships minimize our capital investment, provide us with manufacturing expertise, and help control costs; 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 domestic and international markets for our products and our ability to serve those markets; our belief that there are significant opportunities to market Quell outside of the United States and our plan to evaluate additional U.S. retail distribution opportunities after commercial launch of Quell; the rate and degree of market acceptance of any future products, including Quell; our reliance on key scientific management or personnel; 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 may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. The forward-looking statements contained in this annual report 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

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products are sold in the United States and selected overseas markets, and are cleared by the U.S. Food and Drug Administration, or FDA, and regulators in foreign jurisdictions where appropriate. We have two principal product lines:

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

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

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

Chronic pain is widespread. It affects over 100 million adults in the United States and more than 1.5 billion people worldwide. Within the US chronic pain population one of the largest segments is patients with neuropathic pain estimated at 25 million persons. A significant subset of these patients is persons with diabetes of which 16% to 25% suffer painful diabetic neuropathy, or PDN, estimated at 6 to 8 million patients. The global market for pain management drugs and devices alone was valued at \$35 billion in 2012. The estimated incremental impact of chronic pain on health care costs in the United States is over \$250 billion per year and lost productivity is estimated to exceed \$300 billion per year.

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

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

High frequency nerve stimulation is an established treatment for chronic pain supported by numerous clinical studies demonstrating efficacy. In simplified outline, the mechanism of action involves intensive nerve stimulation to activate the body's central pain inhibition system resulting in widespread analgesia, or pain 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.

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### **Our Strategy**

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

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

Our key business strategies for 2015 include:

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

- **Quell**, our over-the-counter (OTC) wearable device for pain relief, was unveiled at the January 2015 Consumer Electronics Show (CES). Quell utilizes our proprietary non-invasive neurostimulation technology to provide relief from chronic pain, particularly nerve pain due to diabetes and lower back problems. This advanced wearable device is lightweight and can be worn during the day while active, and at night while sleeping. It has been cleared by the FDA for treatment of chronic pain without a doctor's prescription. Users of the device will also have the option of using their smartphones to automatically track and personalize their pain therapy. Response to Quell at CES and from independent market studies has been positive. We hope to make Quell commercially available in the United States during the second quarter of 2015. Our commercial launch plan involves two distribution channels: a professional channel using a direct sales force to target podiatrists, pain physicians, primary care physicians, and chiropractors who would resell the product, and a direct-to-consumer channel using online marketing and lead generation. During 2016 we plan to evaluate additional US retail distribution opportunities. We believe there are significant opportunities to market Quell outside of the United States, particularly in Western Europe, Japan and China; however, we do not intend to approach those markets until we have established a solid presence in the United States.
- **SENSUS**, our prescription neuro-stimulation therapeutic device for relief of chronic pain, was launched in the first quarter of 2013 and provides the technological foundation for Quell. SENSUS revenues in 2014 and 2013 were approximately \$0.9 million and \$0.2 million, respectively. SENSUS is distributed through durable medical equipment (DME) suppliers who call on pain medicine physicians, neurologists, endocrinologists, podiatrists, and primary care physicians to create awareness among physicians who are challenged with trying to manage chronic pain in their patients. These physicians prescribe SENSUS to their patients who, in turn, have their prescriptions fulfilled by a DME. The DME is also responsible for billing and collection from third party payers such as Medicare and other insurers. This is a high cost distribution channel with tight margins. The DME channel is under pressure from Medicare's competitive bidding initiative. We believe that the US growth opportunity for this prescription neuro-stimulation device is limited and that there are more attractive opportunities in the OTC market.
- **DPNCheck**, our diagnostic test for peripheral neuropathies was made commercially available in the fourth quarter of 2011. DPNCheck revenues for 2014 and 2013 were approximately \$1.8 million and \$1.3 million, respectively. Our US sales efforts focus on Medicare Advantage providers who assume financial responsibility and the associated risks for the health care costs of their patients. We believe that DPNCheck presents an attractive clinical case with early detection of neuropathy allowing for earlier clinical intervention to help mitigate the effects of neuropathy on both patient quality of life and cost of care. Also, the diagnosis and documentation of neuropathy provided by DPNCheck helps clarify the patient health profile which, in turn, may have a direct, positive effect on the Medicare

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Advantage premium received by the provider. We believe that attractive opportunities are developing in Japan where we received regulatory approval and launched DPNCheck with Omron Healthcare in 2014; in China where we are working with Omron Healthcare on the regulatory process; in Mexico where our distributor Scienta Farma recently received regulatory approval and plans to launch in early 2015; and in the Middle East.

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

### **Our Business Model**

Our products consist of a medical device used in conjunction with a consumable electrode or biosensor. Other accessories and consumables are also available to customers. Our goal for these devices is to build an installed base of active customer accounts and distributors that regularly order aftermarket products to meet their needs. We successfully implemented this model when we started our business with the NC-stat system and applied it to subsequent product generations including the ADVANCE system. Our recently developed products, SENSUS and DPNCheck, conform to this model. Quell and other products in our development pipeline are based on the device plus consumables business model.

### **Marketed Products**

#### Quell

Quell is a wearable device for relief of chronic pain, such as nerve pain due to diabetes and lower back problems, incorporating our proprietary non-invasive neurostimulation technology. 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 pain and will be available OTC. Users of the device will have the option of using their smartphones to automatically track and personalize their pain therapy. The device was unveiled at the Consumer Electronics Show in January 2015 and we hope to make it commercially available in the United States during the second quarter of 2015. Our commercial launch plan involves two distribution channels: a professional channel using a direct sales force to target podiatrists, pain physicians, primary care physicians, and chiropractors who would resell the product, and a direct-to-consumer channel using online marketing and lead generation.

#### SENSUS

The SENSUS pain therapy device is a prescription neurostimulation device based on TENS for relief of chronic, intractable pain. SENSUS, which was commercially launched in the first quarter of 2014, is a convenient and wearable device that offers physicians and their patients a non-narcotic pain relief option as a complement to medications. SENSUS is comprised of: (1) an electronic device with a strap that is worn on the upper calf and (2) an electrode which attaches to the device. We provide prescribing physicians with PC-based software that links to the device via a USB connection, thereby allowing them to download a record of the patient's use of the device. We used our expertise in peripheral nerve stimulation in the development of SENSUS which incorporates several proprietary features for ease of patient use and physician reporting. The SENSUS device and electrodes were cleared by the FDA for commercial distribution. When medically indicated and supported by proper documentation, TENS are generally reimbursed by Medicare and many commercial insurance companies under the DME benefit.

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

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### DPNCheck

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

DPNCheck is a modified version of our previously marketed NC-stat nerve testing device and has the same clinical indications with respect to DPN. The modified device has the same functionality with respect to sural nerve testing as the original device; however, the cost of the electronic hand-held unit and the consumable biosensors has been reduced by approximately 50%. More than 1.8 million patient studies have been performed using our NC-stat technology and there have been approximately 6.4 million nerve tests, including more than 700,000 sural nerve tests. It has been the subject of many published studies, including several studies specifically addressing the accuracy and clinical utility of the device in assessment of DPN.

### ADVANCE System

Our legacy neurodiagnostics business is based on the ADVANCE NCS/EMG System, or the ADVANCE System, which is a comprehensive platform for the performance of traditional nerve conduction studies and invasive electromyography procedures. The ADVANCE System is comprised of: (1) the ADVANCE device and related modules, (2) various types of electrodes and needles, and (3) a communication hub that enables the physician's office to network their device to their personal computers and our servers for data archiving, report generation, and other network services. The ADVANCE System is most commonly used with 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.



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

<u>Product</u>	<u>Time on Market</u>	<u>Technology</u>	<u>Primary Clinical Indications</u>	<u>No. Patients Tested/Treated</u>
NC-stat*	Q2 1999 – Q3 2010	Nerve Conduction	Diagnosis and evaluation of CTS, low back pain, peripheral neuropathies (including DPN)	> 1,800,000 (NC-stac and Advance)
ADVANCE	Q2 2008 – present	Nerve Conduction Invasive Needle EMG	Diagnosis and evaluation of CTS, low back pain, peripheral neuropathies (including DPN)	
DPNCheck	Q4 2011 – present	Nerve Conduction	Diagnosis and evaluation of peripheral neuropathies, such as DPN	> 300,000
SENSUS	Q1 2013 – present	Transcutaneous Electrical Nerve Stimulation	Relief for chronic, intractable pain, such as PDN	> 7,000
Quell	Launch planned – Q2 2015	Transcutaneous Electrical Nerve Stimulation	Relief for chronic, intractable pain	Not yet applicable

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

### **Customers**

Our customers include physicians, clinics, hospitals, managed care organizations, retail health businesses, independent distributors in the United States and abroad, and durable medical equipment (DME) suppliers. With the launch of Quell planned for the second quarter of 2015 we expect our customers will expand to include patients who will purchase the device directly from us. SENSUS was launched in early 2013 and is sold to DME suppliers who, in turn, distribute the product along with consumables directly to patients. SENSUS customers purchased approximately 5,800 devices during 2014 and 1,300 devices during 2013. DPNCheck shipments commenced in late 2011 and approximately 2,200 devices had been placed with customers through December 31, 2014. These customers include managed care organizations, retail health businesses, endocrinologists, podiatrists and primary care physicians. As of December 31, 2014, we had an installed base of approximately 610 active customers using our ADVANCE System. These customers include primary care, internal medicine, orthopedic and hand surgeons, pain medicine physicians, neurologists, physical medicine and rehabilitation, or PM&R, physicians, and neurosurgeons. At December 31, 2014, one customer accounted for 30% of accounts receivable and more than 10% of revenue. For the years ended December 31, 2013 and 2012 no single customer accounted for more than 10% of revenue.

### **Geographic Information**

Substantially all of our assets, revenues, and expenses for 2014, 2013, and 2012 were located at or derived from operations in the United States. In addition, we have had sales through distributors in Europe, Asia, the Middle East and various regions. During 2014, 2013, and 2012, international revenues accounted for approximately 19%, 16%, and 7%, respectively, of our total revenues.

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

We plan to begin commercial shipments of Quell in the United States during the second quarter of 2015. Our launch plan involves two distribution channels: a professional channel using a direct sales force to target podiatrists, pain physicians, primary care physicians, and chiropractors who would resell the product, and a

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direct-to-consumer channel using online marketing and lead generation. Marketing for Quell is led by our Senior Vice President and General Manager Consumer with support from marketing staff and supplemented by outside consultants. We believe there are opportunities for Quell outside the United States, particularly in Western Europe, Japan and China; however, we do not plan to address those markets until we have established a solid presence in the United States.

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

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

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

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

We invest significant effort and expense in technical, clinical, and business practices training for our commercial operations team, marketing staff and independent sales representatives. We also require attendance at periodic sales and product training programs. Promotion and sales of medical devices are highly regulated not only by the FDA, but also by the U.S. Centers for Medicare and Medicaid Services, or CMS, and the Office of Inspector General, or OIG, and, outside the United States, by other international bodies, and are subject to federal and state fraud and abuse enforcement activities. See “— FDA and other Governmental Regulation” below.

### **Manufacturing and Supply**

We perform final assembly and servicing of our SENSUS and DPNCheck devices at our corporate headquarters facility and also intend to perform final assembly and servicing for Quell at this location. We rely on an outside contractor for the manufacture and servicing of our ADVANCE device and also for the components that we use in manufacturing SENSUS and DPNCheck. We rely on outside contractors for the manufacture of our consumable biosensor/electrodes. With the exception of the biosensors for use with our DPNCheck devices which we acquire from two manufacturers, we do not currently maintain alternative manufacturing sources for our SENSUS, DPNCheck or ADVANCE devices, communication hubs, biosensors/electrodes, or any other finished goods products. In outsourcing, we target companies that meet FDA, International Organization for Standardization, or ISO, and other quality standards supported by internal policies and procedures. Supplier performance is maintained and managed through a corrective action program ensuring all product requirements are met or exceeded. Following the receipt of products or product components from our third-party manufacturers, we conduct the necessary inspection, final assembly, packaging, and labeling at our corporate headquarters facility. We believe these manufacturing relationships minimize our capital investment, provide us with manufacturing expertise, and help control costs.

Sunburst EMS, Inc., or Sunburst, has been manufacturing our NC-stat devices since November 2005. We entered into a supply agreement with Sunburst during 2006 for the manufacturing and supply of our neurodiagnostic devices. Sunburst manufactures the current generation of our ADVANCE device as well as the DPNCheck and SENSUS subassemblies at a facility in Massachusetts.

Polymer Flexible Circuits, Inc., or Parlex, has been manufacturing our nerve specific electrodes since early 1999. In August 2006 we entered into a manufacturing and supply agreement with Parlex pursuant to which Parlex will manufacture and supply to us, and we will purchase from Parlex, at agreed upon prices per

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unit, our requirements of nerve conduction testing electrodes for resale in the United States. Under the agreement, Parlex has agreed not to manufacture electrodes to be used to measure nerve conduction for any other company during the term of the agreement and, in some cases, for a period of one year thereafter. This agreement will continue indefinitely until terminated by either party upon not less than 18 months prior written notice to the other party. Parlex manufactures our electrodes at a facility in Massachusetts and also has the ability to perform certain manufacturing steps for our electrodes at a second site located in the United Kingdom.

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

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

### **Research and Development**

We believe that we have research and development (R&D) capability that is unique to the industry with nearly two decades of experience in developing diagnostic and therapeutic devices involving the stimulation and measurement of nerve signals for clinical purposes. This group has extensive experience in neurophysiology, biomedical instrumentation, signal processing, biomedical sensors, and information systems. R&D works closely with our marketing group and customers to design products that are focused on improving clinical outcomes. The team consists of 10 people including two who hold M.D. degrees and three who hold Ph.D. degrees. It includes the extensive involvement of our founder and Chief Executive Officer who holds both M.D. and Ph.D. degrees and who also coordinates the clinical programs that we support.

R&D efforts currently encompass the following areas:

- *Development of Quell.* This wearable device for pain relief utilizes our proprietary non-invasive neurostimulation technology to provide relief from chronic pain, particularly nerve pain such as due to diabetes and lower back problems. It is lightweight and can be worn during the day while active, and at night while sleeping. It has been cleared by the FDA for treatment of chronic pain without a doctor's prescription and will be available OTC. Users of the device will have the option of using their smartphone to automatically track and personalize their pain therapy. Quell development is the primary focus of our R&D group. This spans completing Quell development for commercial shipments in the second quarter of 2015, initiation of work on a second generation product and enhanced controls on proprietary electrodes, and development of new clinical indications.
- *Support of DPNCheck.* We recently launched DPNCheck, our quantitative nerve conduction test for peripheral neuropathies, in the Japan market. DPNCheck is in the midst of regulatory review in China. The characteristics of these markets often require device modification for local acceptance. We are collaborating with Omron Healthcare in Asia for DPNCheck and anticipate continuing engineering support requirements.
- *Support clinical studies that employ our products.* We presently are involved in eight studies that use DPNCheck in the evaluation of neuropathy in persons with diabetes under various study conditions. We are planning Quell clinical studies to support our marketing and business plans. These studies will be designed to expand the clinical foundation for use of DPNCheck and Quell which, in turn, should support future adoption of these products.

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

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### **Clinical Programs**

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

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

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

<u>Institution</u>	<u>Initiated</u>	<u>Study Focus</u>	<u>Product</u>	<u>Duration</u>	<u>Subjects</u>
Ipswich Diabetes Centre, Ipswich Hospital (UK)	2011	Evaluation of small fiber neuropathy in patients with diabetes	DPNCheck	4 years	400
Royal Hallamshire Hospital, University of Sheffield (UK)	2012	Evaluation of DPN based on severity of diabetes	DPNCheck	3 years	100
Royal Hallamshire Hospital University of Sheffield (UK)	2014	One Stop Screening Service (OPSS) study	DPN Check	2 years	1,000
Joslin Diabetes Center	2012	Effect of weight loss on DPN	DPNCheck	3 years	50
Institute for Clinical Diabetology, Heinrich Heine University	2012	Assessment of DPN in newly diagnosed Type 2 diabetes patients	DPNCheck	3 year	400
Institute for Clinical Diabetology, Heinrich Heine University	2013	Assessment of DPN in an elderly population	DPNCheck	2 years	700
First Vitals Health	2013	Effect of aggressive intervention on foot disease for high risk patients	DPNCheck	3 years	600
Mass General Hospital	2014	SENSUS efficacy in patients with restless leg syndrome	SENSUS	1 year	9

### **Competition**

We believe there is no direct competition to our neurostimulation 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.

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.

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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 systemic 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. 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 neurostimulation category. There are numerous manufacturers of transcutaneous electrical nerve stimulation devices. We believe that the largest such company is Empi, Inc. which is part of DJO Incorporated.

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

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

### **Intellectual Property**

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

#### *Patents*

As of December 31, 2014, we had 39 issued U.S. patents, two issued foreign patents, and 29 pending patent applications, including 13 U.S. applications, two international PCT applications, and 14 foreign national applications. We have filed two utility patent applications for DPNCheck and five utility patent applications related to SENSUS and Quell product lines.

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

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business operations. Our success will also depend in part on our not infringing patents issued to others, including our competitors and potential competitors. If our products are found to infringe the patents of others, our development, manufacture, and sale of these potential products could be severely restricted or prohibited. In addition, our competitors may independently develop similar technologies. Because of the importance of our patent portfolio to our business, we may lose market share to our competitors if we fail to protect our intellectual property rights.

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

### *Trademarks*

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

### **Third-Party Reimbursement**

Procedures performed with our neurodiagnostic medical devices including ADVANCE and DPNCheck may be paid for by third-party payers, including government health programs, such as Medicare, and private insurance and managed care organizations. The 2015 Physicians Fee Schedule published by CMS includes CPT 95905 for nerve conduction studies performed with pre-configured electrode arrays such as are used with the DPNCheck device and the ADVANCE System.

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

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

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

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

Our success in selling the DPNCheck and SENSUS devices and the ADVANCE System will depend upon, among other things, our customers receiving, and our potential customers' expectation that they will receive sufficient reimbursement or patient capitated premium adjustments from third-party payers for procedures or therapies using these products. See Item 1A, "Risk Factors," *"If health care providers are unable to obtain sufficient reimbursement or other financial incentives from third-party health care payers related to the use of our products, the adoption of our products and our future product sales will be materially adversely affected."*

### **FDA and Other Governmental Regulation**

#### *FDA Regulation*

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

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

Before being introduced into the market, our products must obtain market clearance or approval through the 510(k) pre-market notification process, the *de novo* review process or the PMA process, unless they qualify for an exemption from these processes. See Item 1A, "Risk Factors," *"We are subject to extensive regulation by the FDA which could restrict the sales and marketing of the Quell, SENSUS and DPNCheck devices and the ADVANCE System, as well as other products for which we may seek FDA clearance or approval, and could cause us to incur significant costs."*

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

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



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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.

### *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;



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- medical device reporting regulations, which require that manufacturers report to FDA any device that may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections and device recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device which may present a risk to health;
- post-market surveillance regulations, which apply to Class II or III devices if the FDA has issued a post-market surveillance order and the failure of the device would be reasonably likely to have serious adverse health consequences, the device is expected to have significant use in the pediatric population, the device is intended to be implanted in the human body for more than one year, or the device is intended to be used to support or sustain life and to be used outside a user facility;
- regular and for cause inspections by FDA to review a manufacturer's facilities and their compliance with applicable FDA requirements; and
- the FDA's recall authority, whereby it can ask, or order, device manufacturers to recall from the market a product that is in violation of applicable laws and regulations.

### *Regulatory Approvals and Clearances*

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

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

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

### *Manufacturing Facilities*

Our facility, and the facility utilized by Sunburst, our contract device manufacturer, have each been inspected by FDA in the past, and observations were noted. There were no findings that involved a significant violation of regulatory requirements. The responses to these observations have been accepted by the FDA and 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

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are potentially applicable to manufacturers of medical devices, such as us, and to hospitals, physicians and other potential purchasers of our products.

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

### **Legacy Neurodiagnostics Business**

We were founded in 1996 as a science-based health care company. Our focus had been the development of innovative products for the detection, diagnosis, and monitoring of peripheral nerve and spinal cord disorders, such as those associated with carpal tunnel syndrome, lumbosacral disc disease and spinal stenosis, and diabetes. Our NC-stat System for the performance of nerve conduction studies at the point-of-care was commercially launched in 1999. The second generation NC-stat was released in 2002. In 2008, we brought to market the more sophisticated ADVANCE System for nerve conduction testing and performance of invasive needle electromyography. These systems were general purpose with broad application in evaluating and diagnosing nerve disorders. Numerous studies demonstrating the clinical accuracy and utility of these devices have been conducted and published in high quality peer-reviewed journals. Furthermore, these devices have been used in FDA sanctioned clinical trials for pharmacological agents and large scale epidemiological studies sponsored by the NIH, Center for Disease Control, or CDC, and other governmental agencies. The products have been cleared by the FDA, field tested for over a decade and highly regarded for their ease of use, accuracy and reproducibility of results.

Following launch of NC-stat in 1999, we experienced rapid revenue growth, which led to our initial public offering in 2004. The health market, particularly the physician office segment, embraced the opportunity to perform nerve conduction tests which previously had always required referral to specialists. Point-of-care nerve testing was seen to provide a combination of improved patient care and patient convenience. The success of point-of-care nerve testing, a market which we created, was met with resistance in some sectors of the medical community, particularly by neurologists and physical medicine and rehabilitation physicians, both of which had traditionally provided nerve testing services. As a consequence of successful lobbying by these specialists, physicians using our technology experienced increased denials of coverage by third party payers resulting in their discontinuing usage and our difficulty in accruing new customer accounts. In late 2009 CMS included in the Physician Fee Schedule a new Category I CPT Code, CPT 95905, for nerve conduction studies performed using preconfigured electrode such as those employed with our products. During 2010 most Medicare fiscal intermediaries assumed coverage for CPT 95905 for at least some clinical indications; however, the health care environment has been such that we have been unable to secure broad coverage among private payers, which is essential to the success of our ADVANCE System product. This experience was reflected in our revenues for the legacy Neurodiagnostics business, which peaked in 2006 at \$55.3 million. We reported revenue for our legacy Neurodiagnostics business of \$2.8 million, \$3.8 million, and \$6.1 million in 2014, 2013 and 2012, respectively. We currently manage this business to optimize cash flow.

### **Employees**

As of December 31, 2014, we had a total of 32 full time employees. Of these employees, 10 were in research and development, 11 in sales and marketing, 6 in production/distribution, and 5 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.

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### **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 62 Fourth Avenue, 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 common stock. 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 common stock 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 again achieve profitability.**

We have incurred significant cumulative net losses since our inception. Our net losses for 2014, 2013, and 2012, were approximately \$7.8 million, \$8.0 million, and \$10.0 million, respectively. At December 31, 2014, we had an accumulated deficit of approximately \$154.4 million. The extent of our future operating income or losses is highly uncertain, and we cannot assure you that we will be able to achieve or maintain profitability.

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

We held cash and cash equivalents of \$9.2 million as of December 31, 2014. 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 third quarter of 2015. Our financial statements have been prepared assuming that we will continue as a going concern which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. We expect to incur further losses as we aim to successfully commercialize DPNCheck and Quell and the operations of our business and will be dependent on funding our operations through public or private financing, collaborative arrangements with strategic partners, or through additional credit lines or other debt financing sources to increase the funds available to fund operations. These circumstances raise substantial doubt about our ability to continue as a going concern. As a result of this uncertainty and the substantial doubt about our ability to continue as a going concern as of December 31, 2014 the Report of Independent Registered Public Accounting Firm at the beginning of the Financial Statements section in this Form 10-K includes a going concern explanatory paragraph. Management's plans include increasing revenue through the commercialization of Quell and DPNCheck. However, no assurance can be given at this time as to whether we will be able to achieve these objectives. Our financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

We continue to face significant challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected due to (a) decreases in sales of our products and the uncertainty of future revenues from new products; (b) changes we may make to the business that affect ongoing operating expenses; (c) changes we may make in our business strategy; (d) regulatory developments affecting our existing products and delays in the FDA approval process for products under development; (e) changes in our research and development spending plans; and (f) other items affecting our forecasted level of expenditures and use of cash resources. Accordingly, we will need to raise additional funds to support our operating and capital needs for the fourth quarter of 2015 and beyond. We may attempt to obtain additional funding through public or private financing, collaborative arrangements with strategic partners, or through additional credit lines or other debt financing sources to increase the funds available to fund operations. However, we may not be able to secure such financing in a timely manner or on favorable terms, if at all. Furthermore, if we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and

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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 our wearable devices for chronic pain. We cannot assure you that we will be successful in this field or that our current commercial product for peripheral neuropathy, DPNCheck, or the product candidates in our development pipeline, will be successful.**

We are focused on the launch in the second quarter of 2015 and subsequent commercialization of Quell, our OTC wearable device for pain relief. Quell is based on our prescription product for pain relief, SENSUS, which has been on the market for two years. We have shipped over 7,000 SENSUS devices during that period. DPNCheck, which was launched in late 2011, is a fast, accurate, and quantitative nerve conduction test for systemic neuropathies, such as DPN. We have other product candidates in our development pipeline. Our future prospects are closely tied to our success with our wearable devices for chronic pain which, in turn, depend upon market acceptance and growth in future revenues. We cannot assure you that our commercialization strategy will be successful. If our strategy is not successful, it could materially affect our revenues and results of operations.

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

- inability to complete development and launch Quell in 2015;
- inability to create market demand for Quell through a direct sales force and through online marketing efforts;
- manufacturing issues with Quell, SENSUS or our other products;
- inability to increase adoption of DPNCheck within the Medicare Advantage market;
- unfavorable market response to DPNCheck in Japan and other Asia markets;
- unfavorable changes to current Medicare, Medicare Advantage and commercial payer payment policies;
- changes to payor policies under the Patient Protection and Affordable Care Act;
- unfavorable experiences by patients and physicians using Quell, SENSUS and our other products; and,
- physicians' reluctance to alter their existing practices and adopt the use of our devices.

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

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

Widespread adoption of our SENSUS and DPNCheck products by the medical community is unlikely to occur without a financial incentive from third-party payers for the use of these products. If health care providers are unable to obtain adequate reimbursement for procedures performed using these products, if managed care organizations do not receive improved capitated payments due to more accurate patient risk assessment using our products, and if DME suppliers are not adequately reimbursed for supplying our therapeutic products, we may be unable to sell our products at levels that are sufficient to allow us to achieve and maintain profitability, and our business would suffer significantly. Additionally, even if these products and procedures are adequately reimbursed by third-party payers today, adverse changes in payers future policies

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

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

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

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

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

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

The FDA may remove our devices from the market or enjoin them from commercial distribution if safety or effectiveness problems develop. Further, we may not be able to obtain additional 510(k) clearances or pre-market approvals for new products or for modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and future profitability. We have made modifications to our devices in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices. If any of these events occurs or if the FDA takes other enforcement actions, we may not be able to provide our customers with the products they require on a timely basis, our reputation could be harmed, and we could lose customers and suffer reduced revenues and increased costs.

We also are subject to numerous post-marketing regulatory requirements, including the FDA's quality system regulations, which relate to the design, manufacture, packaging, labeling, storage, installation and

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servicing of our products, labeling regulations, medical device reporting regulations and correction and removal reporting regulations. Our failure or the failure by any manufacturer of our products to comply with applicable regulatory requirements could result in enforcement action by the FDA. FDA enforcement actions relating to post-marketing regulatory requirements or other issues, including any issues arising from the not substantially equivalent letter described above, may include any of the following:

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

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

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

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

We rely on third-party manufacturers to manufacture components of our DPNCheck, SENSUS and Quell systems, and to fully manufacture the ADVANCE system. In the event that our manufacturers cease to manufacture sufficient quantities of our products or components in a timely manner and on terms acceptable to us, we would be forced to locate alternate manufacturers. Additionally, if our manufacturers experience a failure in their production process, are unable to obtain sufficient quantities of the components necessary to manufacture our products or otherwise fail to meet our quality requirements, we may be forced to delay the manufacture and sale of our products or locate an alternative manufacturer. We may be unable to locate suitable alternative manufacturers for our products or components for which the manufacturing process is relatively specialized, on terms acceptable to us, or at all. We have a manufacturing and supply agreement with Parlex Polymer Flexible Circuits, Inc. for the manufacture of the ADVANCE electrodes for nerve conduction testing. Katecho, Inc. manufactures biosensors for use with our DPNCheck devices and manufactures electrodes for SENSUS and Quell, and Sunburst EMS, Inc. manufactures electronic boards and other components of our DPNCheck, SENSUS and Quell products which we assemble at our Massachusetts facility to produce completed devices. Sunburst EMS, Inc. also manufactures our ADVANCE System monitors, docking stations, and communication hubs.

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

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

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

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

We and our contract manufacturers are required to comply with the FDA's quality system regulation, or QSR, which is a complex regulation that governs the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our devices. The FDA enforces the QSR through periodic inspections. We cannot assure you that our facilities or the facilities of the manufacturers of our products would pass any future inspection. If our facilities or any of the facilities of the manufacturers of our products fail an inspection, the manufacturing or distribution of our products could be interrupted and our operations disrupted. Failure to take adequate and timely corrective action in response to an adverse inspection could result in a suspension or shutdown of our packaging and labeling operations and the operations of the manufacturers of our products or a recall of our products, or other administrative or judicial sanctions. If any of these events occurs, we may not be able to provide our customers with the quantity of products they require on a timely basis, our reputation could be harmed, and we could lose customers and suffer reduced revenues and increased costs.

### **Our products may be subject to recalls, even after receiving FDA clearance or approval, which would harm our reputation, business and financial results.**

We are subject to the medical device reporting regulations, which require us to report to the FDA if our products may have caused or contributed to a death or serious injury, or have malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to occur. We are also subject to the correction and removal reporting regulations, which require us to report to the FDA any field corrections and device recalls or removals that we undertake to reduce a risk to health posed by the device or to remedy a violation of the Federal Food, Drug and Cosmetic Act, or FDCA, caused by the device which may present a risk to health. In addition, the FDA and similar governmental agencies in other countries have the authority to require the recall of our products if there is a reasonable probability that the products would cause serious adverse health consequences or death. A government-mandated or voluntary recall by us could occur as a result of manufacturing defects, labeling deficiencies, packaging defects or other failures to comply with applicable regulations. Any recall would divert management attention and financial resources and harm our reputation with customers and could have a material adverse effect on our financial condition and results of operations.

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

The primary focus of our research and development department is development of our Quell device for chronic pain and the initiation of commercial shipments of Quell in the second quarter of 2015. We have other products in our R&D pipeline. We expect that advancing our pipeline products will require significant time and resources. We may not be successful in our commercialization efforts for any of the product candidates currently in our pipeline and we may not be successful in developing, acquiring, or in-licensing additional product candidates, to the extent we decide to do so. If we are not successful advancing new products through our development pipeline, the regulatory process and commercial launch, our business, financial condition, and results of operations will be adversely affected.



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

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

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

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

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

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

- the pending patent applications we have filed or to which we have exclusive rights may not result in issued patents or may take longer than we expect to result in issued patents;
- the claims of any patents that are issued may not provide meaningful protection;
- we may not be able to develop additional proprietary technologies that are patentable;
- other parties may challenge patents, patent claims or patent applications licensed or issued to us; and
- other companies may design around technologies we have patented, licensed or developed.

Our issued design patents begin to expire in 2015. We also may not be able to protect our patent rights effectively in some foreign countries. For a variety of reasons, we may decide not to file for patent protection in the United States or in particular foreign countries. Our patent rights underlying our products may not be adequate, and our competitors or customers may design around our proprietary technologies or independently develop similar or alternative technologies or products that are equal or superior to our technology and products without infringing on any of our patent rights. In addition, the patents licensed or issued to us may not provide a competitive advantage. If any of these events were to occur, our ability to compete in the market would be harmed.

**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:

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

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

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

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

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

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

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

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

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

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

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

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

There are a number of federal and state laws protecting the confidentiality of individually identifiable patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services promulgated patient privacy rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. These privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. Although we do not believe that we are subject to the HIPAA rules, the exact scope of these rules has not been clearly established. If we are found to be in violation of the privacy rules under HIPAA, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

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

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

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

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

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

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

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

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

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

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

We are a small company with 32 employees as of December 31, 2014, 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 new products, such as Quell, SENSUS and DPNCheck, and enhance these products in response to customer demand. Developing new products and upgrades to existing and future products imposes burdens on our research and development department and our management. This process is costly, and we cannot assure you that we will be able to successfully develop new products or enhance our current products. We also may not be able to enter into relationships with other companies to sell additional products. In addition, as we develop the market for our products, future competitors may develop desirable product features earlier than we do which could make our competitors' products less expensive or more effective than our products and could 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.

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

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

- greater resources for product development, sales and marketing;
- more established distribution networks;
- greater name recognition;
- more established relationships with health care professionals, customers and third-party payers; and
- additional lines of products and the ability to offer rebates or bundle products to offer discounts or incentives.

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

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

In the ordinary course of our business, we collect and store sensitive data in our data centers, on our networks, including intellectual property, our proprietary business information, and that of our customers, suppliers and business partners, and personally identifiable information of our employees. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, disrupt our operations, damage our reputation, and cause a loss of confidence in our products and services, which could have a material adverse effect on our business, financial condition, results of operations or cash flows.

**If future clinical studies or other articles are published, or physician associations or other organizations announce positions that are unfavorable to our products, our sales efforts and revenues may be negatively affected.**

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

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

Foreign markets represented approximately 19% of our revenues in 2014, compared to 16% of our revenues in 2013. We are working to expand market penetration, particularly in Asia. Any such expansion will subject us to the possibility of new business risks, including:

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

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

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

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

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

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

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under the credit facility at the time of the default, which would require us to pay all amounts outstanding. If an event of default occurs, we may not be able to cure it within any applicable cure period, if at all. If the maturity of our indebtedness is accelerated, we may not have sufficient funds available for repayment or we may not have the ability to borrow or obtain sufficient funds to replace the accelerated indebtedness on terms acceptable to us, or at all.

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

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

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

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

- issuances of dilutive equity securities, which may be sold at a discount to market price;
- the use of significant amounts of cash;
- the incurrence of debt;
- the assumption of significant liabilities;
- increased operating costs or reduced earnings;
- financing obtained on unfavorable terms;
- large one-time expenses; and
- the creation of certain intangible assets, including goodwill, the write-down of which may result in significant charges to earnings.

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

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

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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 February 1, 2015, our stock price has fluctuated from a low of \$1.47 to a high of \$95.40. The market price for our common stock will be affected by a number of factors, including:

- the denial or delay of regulatory clearances or approvals for our products under development or receipt of regulatory approval of competing products;
- our ability to accomplish clinical, regulatory and other product development and commercialization milestones and to do so in accordance with our timing estimates;
- changes in policies affecting third-party coverage and reimbursement in the United States and other countries;
- changes in government regulations and standards affecting the medical device industry and our products;
- ability of our products to achieve market success;
- the performance of third-party contract manufacturers and component suppliers;
- actual or anticipated variations in our results of operations or those of our competitors;
- announcements of new products, technological innovations or product advancements by us or our competitors;
- developments with respect to patents and other intellectual property rights;
- sales of common stock or other securities by us or our stockholders in the future;
- additions or departures of key scientific or management personnel;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- trading volume of our common stock;
- changes in earnings estimates or recommendations by securities analysts, failure to obtain or maintain analyst coverage of our common stock or our failure to achieve analyst earnings estimates;
- public statements by analysts or clinicians regarding their perceptions of our clinical results or the effectiveness of our products;
- decreases in market valuations of medical device companies; and
- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors.

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.



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### **There have been instances in the past when we failed to satisfy certain continued listing requirements on NASDAQ and we could fail to satisfy those requirements again in the future which could affect the market price of our common stock and liquidity and reduce our ability to raise capital.**

Currently, our common stock trades on the NASDAQ Capital Market. During 2012 and 2010 we received notifications from NASDAQ informing us of certain listing deficiencies related to the minimum bid price listing requirements. Although we have since cured these deficiencies, it is possible that we could fall out of compliance again in the future. If we fail to maintain compliance with any NASDAQ listing requirements, we could be delisted and our stock would be considered a penny stock under regulations of the Securities and Exchange Commission, or SEC, and would therefore be subject to rules that impose additional sales practice requirements on broker-dealers who sell our securities. The additional burdens imposed upon broker-dealers by these requirements could discourage broker-dealers from effecting transactions in our common stock, which could severely limit the market liquidity of our common stock and your ability to sell our securities in the secondary market.

### **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 February 1, 2015 as reported by NASDAQ was approximately 70,300 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 is located in an approximately 30,000 square foot facility in Waltham, Massachusetts, which we occupy under an office lease expiring in March 2015. During the first quarter of 2015 we plan to relocate our corporate headquarters and engineering activities to a nearby 12,000 square foot facility in Waltham, Massachusetts and to relocate our manufacturing and fulfillment activities to a 6,000 square foot facility in Woburn, Massachusetts. We have signed leases for these new facilities and believe that they 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.

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**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-6 reverse stock split of our common stock completed on February 15, 2013.

	Years ended December 31,			
	2014		2013	
	High	Low	High	Low
First quarter	\$ 3.14	\$ 2.17	\$ 3.24	\$ 1.98
Second quarter	2.61	1.67	3.14	1.84
Third quarter	3.15	1.57	2.18	1.50
Fourth quarter	2.01	1.52	4.25	1.47

**Stockholders**

On February 1, 2015, there were approximately 101 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, 2015, the last reported sale price per share of our common stock on the NASDAQ Capital Market was \$1.68.

**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.

[TABLE OF CONTENTS](#)**ITEM 6. SELECTED FINANCIAL DATA**

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 2014, 2013, and 2012 appearing elsewhere in this Annual Report on Form 10-K:

	<b>Years Ended December 31,</b>				
	<b>2014</b>	<b>2013</b>	<b>2012</b>	<b>2011</b>	<b>2010</b>
	(In thousands, except share and per share data)				
<b>Statement of Operations Data:</b>					
Revenues	\$ 5,513	\$ 5,279	\$ 7,575	\$ 10,397	\$ 13,900
Cost of revenues	2,569	2,194	3,589	4,722	7,050
Gross profit	2,944	3,085	3,986	5,675	6,850
Operating expenses:					
Research and development	4,076	3,438	3,546	3,877	5,856
Sales and marketing	2,913	2,780	5,727	6,689	11,072
General and administrative	4,725	4,225	4,735	5,112	7,232
Total operating expenses	11,714	10,443	14,008	15,678	24,160
Loss from operations	(8,770)	(7,358)	(10,022)	(10,003)	(17,310)
Interest and other income	5	5	14	22	298
Warrants offering costs	(51)	(376)	—	—	—
Changes in fair value of warrant liability	1,050	(290)	—	—	—
Loss before taxes	(7,766)	(8,019)	(10,008)	(9,981)	(17,012)
Income tax benefit	—	—	—	—	121
Net loss	<u>\$ (7,766)</u>	<u>\$ (8,019)</u>	<u>\$ (10,008)</u>	<u>\$ (9,981)</u>	<u>\$ (16,891)</u>
Net loss per common share, basic and diluted	<u>\$ (1.54)</u>	<u>\$ (3.07)</u>	<u>\$ (5.22)</u>	<u>\$ (15.53)</u>	<u>\$ (26.41)</u>

	<b>As of December 31,</b>				
	<b>2014</b>	<b>2013</b>	<b>2012</b>	<b>2011</b>	<b>2010</b>
	(in thousands)				
<b>Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 9,222	\$ 9,196	\$ 8,699	\$ 10,290	\$ 16,987
Working capital	8,392	8,919	8,567	10,482	19,020
Total assets	11,402	10,797	10,877	14,221	23,066
Total liabilities	8,015	3,602	2,077	3,132	2,867
Total stockholders’ equity	3,387	7,195	8,800	11,089	20,199

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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 approved by the U.S. Food and Drug Administration, or FDA, and regulators in foreign jurisdictions where appropriate. We have two principal product lines:

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

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

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

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

A major initiative during 2014 was the design, development and branding of a new over-the-counter analgesic category featuring Quell, our wearable device for pain relief which builds upon the core SENSUS neuro-stimulation technology. Quell was unveiled at the January 2015 Consumer Electronics Show (CES) where the response was positive. We hope to make Quell commercially available in the United States during the second quarter of 2015. Our commercial launch plan involves two distribution channels: a professional channel using a direct sales force to target podiatrists, pain physicians, primary care physicians, and chiropractors who would resell the product, and a direct-to-consumer channel using online marketing and lead generation.

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

DPNCheck is our diagnostic test for peripheral neuropathies which commenced commercial shipments in the fourth quarter of 2011. DPNCheck revenues for 2014 and 2013 were about \$1.8 million and \$1.3 million, respectively. Our United States sales efforts focus on Medicare Advantage providers who assume financial responsibility and the associated risks for the health care costs of their patients. We believe that DPNCheck presents an attractive clinical case with early detection of neuropathy allowing for earlier clinical intervention to help mitigate the effects of neuropathy on both patient quality of life and cost of care. Also, the diagnosis and documentation of neuropathy provided by DPNCheck helps clarify the patient health profile which, in turn, may have a direct, positive effect on the Medicare Advantage premium received by the provider. We believe that attractive opportunities are developing in Japan where we received regulatory approval and launched DPNCheck with Omron Healthcare in 2014; in China where we are working with Omron Healthcare on the regulatory process; in Mexico where our distributor, Scienta Fama, recently received regulatory approval and plans to launch in early 2015; and in the Middle East.

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

### **Results of Operations**

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

##### *Revenues*

The following table summarizes our revenues:

	<u>Years Ended December 31,</u>		<u>Change</u>	<u>% Change</u>
	<u>2014</u>	<u>2013</u>		
	(in thousands)			
Revenues	<u>\$ 5,512.8</u>	<u>\$ 5,278.8</u>	<u>\$ 234.0</u>	4.4%

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.

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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. We expect that sales of ADVANCE System products will constitute approximately 20% of our sales during 2015.

### Cost of Revenues and Gross Margin

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

	Years Ended December 31,		Change	% Change
	2014	2013		
	(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 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,		Change	% Change
	2014	2013		
	(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 in the first half of 2015 a new wearable therapeutic device for chronic pain brand-named Quell. 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

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

Interest income earned from investments in cash equivalents was \$4,606 and \$5,666 in 2014 and 2013, respectively. 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.

## **Comparison of Years Ended December 31, 2013 and December 31, 2012**

### *Revenues*

The following table summarizes our revenues:

	<b>Years Ended December 31,</b>		<b>Change</b>	<b>% Change</b>
	<b>2013</b>	<b>2012</b>		
		(in thousands)		
Revenues	<u>\$ 5,278.8</u>	<u>\$ 7,575.3</u>	<u>\$(2,296.5)</u>	<u>(30.3)%</u>

During 2013 we shipped approximately 1,300 SENSUS devices and recorded revenue of approximately \$0.2 million while working to develop distribution in several sales channels, including DME suppliers addressing pain physicians, primary care physicians and endocrinologists, large clinic organizations and direct mail diabetes suppliers.

During 2013 we recorded DPNCheck revenue of \$1.3 million compared to \$1.4 million in the prior year when we had a direct sales force focused on the podiatry market. That sales force was disbanded at the end of 2012 when we shifted our focus to the Medicare Advantage sector and selected international opportunities.

ADVANCE revenues totaled \$3.8 million in 2013 in comparison with \$6.1 million in 2012. The decline in ADVANCE revenue continued the historical trend for this product line.

### *Cost of Revenues and Gross Margin*

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

	<b>Years Ended December 31,</b>		<b>Change</b>	<b>% Change</b>
	<b>2013</b>	<b>2012</b>		
		(in thousands)		
Cost of revenues	<u>\$ 2,194.3</u>	<u>\$ 3,588.8</u>	<u>\$(1,394.5)</u>	<u>(38.9)%</u>
Gross profit	<u>\$ 3,084.5</u>	<u>\$ 3,986.5</u>	<u>\$ (902.0)</u>	<u>(22.6)</u>

Corresponding to our decrease in revenues in 2013, our cost of revenues decreased to \$2.2 million in 2013, compared to \$3.6 million in 2012. Our gross margin improved to 58.4% in 2013 from 52.6% in 2012, which was primarily attributable to increases in sales from our DPNCheck product line which carries higher margins than ADVANCE and which contributed 23% of revenue in 2013 versus 19% of revenue in 2012. In addition, 2013 DPNCheck revenue was more heavily weighted to sales of high margin consumable biosensors rather than the lower margin devices sales during 2012. SENSUS had a minor effect on 2013 margins given its small, launch year revenue contribution. Inventory charges primarily related to excess ADVANCE inventory were approximately \$0.2 million in both 2013 and 2012.



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### Operating Expenses

The following table presents a breakdown of our operating expenses:

	Years Ended December 31,		Change	% Change
	2013	2012		
	(in thousands)			
Operating expenses:				
Research and development	\$ 3,438.2	\$ 3,545.8	\$ (107.6)	(3.0)%
Sales and marketing	2,779.7	5,727.5	(2,947.8)	(51.5)
General and administrative	4,225.5	4,735.2	(509.7)	(10.8)
Total operating expenses	<u>\$10,443.4</u>	<u>\$ 14,008.5</u>	<u>\$(3,565.1)</u>	(25.5)

### Research and Development

Research and development expenses for 2013 and 2012 were about \$3.4 million and \$3.5 million, respectively. The comparative results largely reflect a \$0.1 million decrease in personnel costs resulting from lower headcount and incentive compensation expense partially offset by a \$30,000 increase in the costs of clinical studies related to DPNCheck. Personnel costs for 2013 included \$0.1 million for severance costs.

### Sales and Marketing

Sales and marketing expenses decreased to \$2.8 million in 2013 from \$5.7 million in 2012. During 2012, we reduced our dependence on field clinical educators to support our neurodiagnostic business and we shifted our DPNCheck emphasis toward managed care, allowing us to eliminate our direct sales representatives. In addition, in 2013 we further reduced our sales staff which had primarily supported DPNCheck, resulting in severance cost of \$0.4 million. As a result, total sales and marketing personnel costs in 2013 were \$1.9 million lower than in the prior year. Personnel related travel costs decreased by \$0.5 million, trade show costs decreased by \$0.1 million, advertising and promotion costs decreased by \$0.1 million, recruiting and retention costs decreased by \$20,000, dues decreased by \$50,000, and depreciation decreased by \$44,000. Sales and marketing expenses for 2012 included \$58,000 for the write-off of loaner and demo systems.

### General and Administrative

General and administrative expenses decreased to \$4.2 million in 2013 compared to \$4.7 million in 2012. This decrease included \$0.3 million for consultants and temporary staff, \$0.2 million for personnel costs, \$0.1 million for taxes and fees, \$80,000 for travel costs, \$0.1 million for insurance and outside administration, and \$40,000 for stock-based compensation. These spending reductions were partially offset by an unfavorable year over year increase of \$0.3 million in bad debt expense. During 2013 we recorded \$0.1 million in bad debt expenses compared to the recognition of a net credit to bad debt expense of \$0.1 million in 2012.

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

Interest income was approximately \$5,700 and \$14,500 in 2013 and 2012, respectively. Interest income was earned from investments in cash equivalents. In connection with an equity offering during 2013, we recognized costs related to the issuance of common stock warrants of \$0.4 million. Outstanding warrants from that offering were valued at fair value at quarterly reporting periods and on warrant transaction dates. The total fair value adjustments to outstanding warrants during 2013 were \$0.3 million.

### Liquidity and Capital Resources

Our principal source of liquidity is our cash and cash equivalents. As of December 31, 2014, cash and cash equivalents totaled \$9.2 million. In June 2014 we entered into a securities purchase agreement providing for the issuance of (i) 664,600 shares of common stock at a price of \$2.04 per share, (ii) 2,621,859 shares of Series A-3 Preferred Stock at a price of \$1,000 per share, (iii) 4,022,357 shares of Series A-4 Preferred Stock at a price of \$1,000 per share, and (iv) five year warrants to purchase up to 3,921,569 shares of common stock with an exercise price of \$2.04 per share. We received net proceeds of approximately \$7.9 million from this offering, which we refer to as the 2014 Offering. See Note 12, Stockholders' Equity, of our Notes to Financial Statements contained elsewhere in this Annual Report on Form 10-K for further information regarding this transaction. Our ability to generate revenue to fund our operations will largely depend on the

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success of our wearable therapeutic products for chronic pain and our diagnostic products for neuropathy. A low level of market interest in Quell, SENSUS 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:

	<u>December 31,</u> <u>2014</u>	<u>December 31,</u> <u>2013</u>	<u>Change</u>	<u>% Change</u>
		(in thousands)		
Cash and cash equivalents	<u>\$ 9,222.0</u>	<u>\$ 9,195.8</u>	<u>\$ 26.2</u>	0.3%

In order to supplement our access to capital, we are party to an amended Loan and Security Agreement 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, 2016. 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. The credit facility 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, 2014, we were in compliance with these covenants and had not borrowed any funds under the credit facility. However, approximately \$0.5 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, 2014 was approximately \$2.0 million.

During 2014 our cash and cash equivalents increased slightly reflecting net cash provided by the 2014 Offering of \$7.9 million offset by \$7.7 million of net cash used in operations and \$0.2 million used in investing activities.

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

	<u>Years Ended December 31,</u>	
	<u>2014</u>	<u>2013</u>
Days sales outstanding (days)	38	32
Inventory turnover rate (times per year)	4.0	3.9

Payment terms extended to our customers generally require payment within 30 days from invoice date. The inventory turnover rate has remained constant since December 31, 2013.

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

	<u>Years Ended December 31,</u>		
	<u>2014</u>	<u>2013</u>	<u>2012</u>
		(in thousands)	
Net cash used in operating activities	<u>\$ (7,678.5)</u>	<u>\$ (6,554.9)</u>	<u>\$ (9,175.6)</u>
Net cash (used in) provided by investing activities	<u>(227.3)</u>	<u>(86.1)</u>	<u>122.0</u>
Net cash provided by financing activities	<u>7,932.0</u>	<u>7,137.3</u>	<u>7,462.6</u>

Our operating activities used \$7.7 million for the year ended December 31, 2014 primarily attributable to our net loss of \$7.8 million. This loss included non-cash charges of \$289,900 for stock-based compensation, \$145,100 for depreciation and amortization, and non-cash credits of approximately \$1.0 million for revaluing outstanding warrants at fair value.

During the year ended December 31, 2014, our investing activities reflected \$227,300 spent for the acquisition of fixed assets.

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Financing activities for the year ended December 31, 2014 included \$7.9 million from the net proceeds of the 2014 Offering. At December 31, 2014, there remain 3,921,569 outstanding common stock warrants from the 2014 Offering with an exercise price of \$2.04 per share and 1,057,323 outstanding common stock warrants from the equity offering that we conducted in 2013, which we refer to as the 2013 Offering, with an exercise price of \$2.00 per share.

We held cash and cash equivalents of \$9.2 million as of December 31, 2014. 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 third quarter of 2015. 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 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 fourth quarter of 2015 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 maintain a shelf registration 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. As a result of the 2014 Offering, we will be limited in the use of this shelf registration statement until June 2015. We have also filed a registration statement for an equity offering on Form S-1, which has not yet been declared effective. 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, 2014, we have federal and state net operating loss, or NOL, carryforwards available to offset future taxable income of \$105.4 million and \$24 million, respectively, and federal and state tax credits of \$1.2 million and \$1.0 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 began to expire in 2015. 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.

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

As of December 31, 2014, we did not have any off-balance sheet financing arrangements.

The following table summarizes our principal contractual obligations as of December 31, 2014 and the effects such obligations are expected to have on our liquidity and cash flows in future periods.

<u>Contractual Obligations</u>	<u>Total</u>	<u>Payments due in</u>			
		<u>Less than 1 year</u>	<u>1 – 3 years</u>	<u>3–5 years</u>	<u>More than 5 years</u>
Operating lease obligations	\$3,766,621	\$ 594,906	\$1,043,415	\$1,083,950	\$ 1,044,350
Purchase order obligations	76,338	76,338	—	—	—
Total contractual obligations	<u>\$3,842,959</u>	<u>\$ 671,244</u>	<u>\$1,043,415</u>	<u>\$1,083,950</u>	<u>\$ 1,044,350</u>

### **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 the sale of the ADVANCE devices to customers and distributors are recognized upon shipment, provided that the selling price is fixed or determinable, persuasive evidence of an arrangement exists, collection of receivables is reasonably assured, product returns are reasonably estimable, and no continuing obligations exist. The revenues from the sale of an ADVANCE communication hub together with access to NeuroMetrix information systems are considered one unit of accounting and deferred and recognized on a straight-line basis over the estimated period of time that we provide the service associated with the information systems of three years. The resulting deferred revenue and deferred costs are presented as separate line items on the accompanying balance sheet. Revenues related to extended service agreements for the devices are recognized ratably over the term of the extended service agreement.

Revenues associated with the sale of the SENSUS and NC-stat DPNCheck devices are recognized upon shipment, provided that the selling price is fixed or determinable, persuasive evidence of an arrangement exists, collection of receivables is reasonably assured, product returns are reasonably estimable, and no continuing obligations exist.

Revenues also include sales of consumables, including single use nerve specific electrodes and other accessories. These revenues are recognized upon shipment provided that the selling price is fixed or determinable, persuasive evidence of an arrangement exists, collection of receivables is reasonably assured, and product returns are reasonably estimable.

When multiple elements are contained in a single arrangement, we allocate revenue between the elements based on their relative selling prices. We determine selling price using vendor specific objective evidence, or VSOE, if it is available, third-party evidence, or TPE, if VSOE is not available, and best estimate of selling price, or BESP, if neither VSOE nor TPE are available. We generally expect that we will not be able to establish TPE due to the nature of the markets in which we compete, and, as such, we will typically determine selling price using VSOE or if not available, BESP. The objective of BESP is to determine the selling price of a deliverable on a standalone basis. Our determination of BESP involves a weighting of

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several factors based on the specific facts and circumstances of an arrangement. Specifically, we consider the cost to produce the deliverable, the anticipated margin on that deliverable, the selling price and profit margin for similar parts, our ongoing pricing strategy, the value of any enhancements that have been built into the deliverable, and the characteristics of the varying markets in which the deliverable is sold.

Revenue recognition involves judgments, including assessments of expected returns and expected customer relationship periods. We analyze various factors, including a review of specific transactions, our historical 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 our estimate.

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. Certain product sales are made with a 30-day right of return. Since we can reasonably estimate future returns, we recognize revenues associated with product sales that contain a right of return upon shipment and at the same time we record a sales return reserve, which reduces revenue and accounts receivable by the amount of estimated returns.

Accounts receivable on the balance sheet are recorded net of the allowance for doubtful accounts receivable and the reserve for estimated returns. 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*

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-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 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 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.

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### **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-23 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.

	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	\$ (0.21)	\$ (0.85)	\$ (0.19)	\$ (0.36)	\$ (1.54)

  

	Year Ended December 31, 2013				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Revenues	\$ 1,401,454	\$ 1,160,472	\$ 1,314,728	\$ 1,402,152	\$ 5,278,806
Cost of revenues	569,784	501,161	578,484	544,830	2,194,259
Gross profit	831,670	659,311	736,244	857,322	3,084,547
Net loss	(2,253,415)	(1,345,830)	(716,264)	(3,703,628)	(8,019,137)
Net loss per common share, basic and diluted	\$ (1.06)	\$ (0.92)	\$ (0.26)	\$ (0.87)	\$ (3.07)

### **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 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

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inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, 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, 2014 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, 2014.

This Annual Report 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.

### **(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, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

None.

**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, 2014:

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

(1) Member of Audit Committee

(2) Member of Compensation Committee

(3) Member of Nominating and Corporate Governance Committee

**Shai N. Gozani, M.D., Ph.D.** founded our Company in 1996 and currently serves as Chairman of our Board of Directors and as our President, Chief Executive Officer and Secretary. Since founding our Company in 1996, Dr. Gozani has served in a number of positions at our company including Chairman since 1996, President from 1996 to 1998 and from 2002 to the present, Chief Executive Officer since 1997 and Secretary since July 2008. Dr. Gozani holds a B.A. in computer science, an M.S. in Biomedical Engineering and a Ph.D. in Neurobiology, from the University of California, Berkeley. He also received an M.D. from Harvard Medical School and the Harvard-M.I.T. Division of Health Sciences at M.I.T. Prior to forming our Company, Dr. Gozani completed a neurophysiology research fellowship in the laboratory of Dr. Gerald Fischbach at Harvard Medical School. Dr. Gozani has published articles in the areas of basic and clinical neurophysiology, biomedical engineering and computational chemistry. The Board has concluded that Dr. Gozani should serve as a director because Dr. Gozani's extensive knowledge of engineering and neurophysiology, combined with the unique understanding of our technology and business he has gained as our founder and as a key executive, provides invaluable insight to our Board and to the entire organization.

**Thomas T. Higgins** has served as our Senior Vice President, Chief Financial Officer and Treasurer since September 2009. Prior to joining NeuroMetrix, from January 2005 to March 2008, Mr. Higgins was Executive Vice President and Chief Financial Officer at Caliper Life Sciences, Inc, a provider of technology and services for life sciences research. Before Caliper, Mr. Higgins was Executive Vice President, Operations and Chief Financial Officer at V.I. Technologies, Inc. (Vitex), a biotechnology company addressing blood safety. Before Vitex, Mr. Higgins served at Cabot Corporation in various senior finance and operations roles. His last position at Cabot was President of DISTRIGAS of Massachusetts Corporation, a subsidiary involved in the liquefied natural gas business, and prior to that he was responsible for Cabot's Asia Pacific carbon black operations. Before joining Cabot, Mr. Higgins was with PricewaterhouseCoopers where he started his career. Mr. Higgins holds a BBA with honors from Boston University.

**Francis X. McGillin** has served as Senior Vice President and General Manager Consumer Wearables since August 2014. Prior to joining NeuroMetrix, from September 2001 to January 2014, Mr. McGillin was Vice President and General Manager at Philips, having served in a number of senior marketing and management positions in the company's consumer and healthcare businesses. His last role with Philips, was leading the globalization of Philips Sonicare business. Before Philips, Mr. McGillin, was Executive Director,



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

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

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

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Products. She has previously served on the Boards of Directors of Neoprobe Corporation (AMEX: NEOP), Calypte Biomedical Corporation, LXN Corporation and Peppen 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. 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 II, Class III and Class I directors expiring upon the election and qualification of directors at the annual meetings of stockholders to be held in 2015, 2016, and 2017, respectively. Currently:

- 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.

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

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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 2014.

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

There have been no changes to the procedures disclosed in our proxy statement for the 2014 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., 62 Fourth Avenue, 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, except that eight Forms 4 were not filed on a timely basis as a result of administrative error for one transaction for each of Dr. Shai N. Gozani, M.D., Ph.D., Thomas T. Higgins, Francis X. McGillin, Timothy R. Surgenor, David Van Avermaete, Nancy E. Katz, Allen Hinkle, M.D. and David E. Goodman, M.D., all in connection with the grant of equity awards by us. 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 2015 Annual Meeting of Stockholders under the captions “Compensation of Executive Officers” and “Director Compensation Table — 2015” and is incorporated by reference herein.

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**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, 2015, except as noted below, of our common stock by:

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

The number of common shares “beneficially owned” by each stockholder is determined under rules issued by the SEC regarding the beneficial ownership of securities. This information is not necessarily indicative of beneficial ownership for any other purpose. Under these rules, beneficial ownership of common stock includes (1) any shares as to which the person or entity has sole or shared voting power or investment power and (2) any shares as to which the person or entity has the right to acquire beneficial ownership within 60 days after February 1, 2015, including any shares that could be purchased by the exercise of options or warrants on or within 60 days after February 1, 2015. Each stockholder’s percentage ownership is based on 8,152,746 shares of our common stock outstanding as of February 1, 2015 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, 2015.

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	
<b>Directors and Executive Officers</b>				
Shai N. Gozani, M.D., Ph.D.	87,053	107,260	194,313	2.4%
Thomas T. Higgins	32,430	43,205	75,635	*
Francis X. McGillin	—	—	—	*
Allen Hinkle, M.D.	834	1,972	2,806	*
David E. Goodman, M.D.	834	972	1,806	*
Timothy R. Surgenor	834	972	1,806	*
Nancy E. Katz	834	972	1,806	*
David Van Avermaete	—	3,125	3,125	*
Michael Williams, Ph.D.	—	—	—	*
Guy Daniello	—	—	—	*
All Current Directors and Executive Officers as a group (10 persons)	122,819	158,478	281,297	3.4%

Name and Address <sup>(1)</sup> of Beneficial Owner	Amount and Nature of Beneficial Ownership			Percent of Class of Total
	Common Stock	Warrants <sup>(2)</sup>	Total	
<b>Beneficial Owner of 5% or More Other than Directors and Executive Officers</b>				
Sabby Management, LLC <sup>(3)</sup>	793,631	—	793,631	9.9%

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

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- (1) Unless otherwise indicated, the address of each stockholder is c/o NeuroMetrix, Inc., 62 Fourth Avenue, Waltham, Massachusetts 02451.
- (2) Includes all options that are exercisable on or within 60 days from February 1, 2015 by the beneficial owner, except as otherwise noted.
- (3) This information is based on a Schedule 13G/A filed by the Reporting Person with the SEC on January 8, 2015, which reported beneficial ownership as of December 31, 2014. Reflects shares of common stock beneficially owned by Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd.. The amount does not include 823,320 and 234,003 shares of common stock issuable upon exercise of warrants issued to Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd., respectively, 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 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 Mountainside Road, Suite 205, Upper Saddle River, New Jersey 07458.

## EQUITY COMPENSATION PLAN INFORMATION

The following table sets forth information as of December 31, 2014 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, 2014

	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>	561,767	\$ 6.31	626,384 <sup>(2)</sup>
Equity compensation plans not approved by security holders <sup>(3)</sup>	200,000	1.88	200,000
Totals	<u>761,767</u>	<u>\$ 5.15</u>	<u>826,384</u>

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

(2) As of December 31, 2014, there were 502,104 shares available for future grant under the Sixth Amended and Restated 2004 Stock Option and Incentive Plan and 124,280 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.

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

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### **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. As required under SEC rules, transactions that involve an amount in excess of \$120,000, in which we are a participant and a related person is determined to have a direct or indirect material interest, are disclosed in our proxy statement.

#### **DIRECTOR INDEPENDENCE**

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

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

#### **ACCOUNTING FEES**

Aggregate fees for professional services rendered by PricewaterhouseCoopers LLP for the years ended December 31, 2014 and 2013 are as follows:

##### *Audit Fees*

The audit fees for PricewaterhouseCoopers LLP for professional services rendered for the 2014 audit of our annual financial statements and the review of the financial statements included in our quarterly reports on Form 10-Q totaled \$448,000, of which \$308,000 was billed in 2014 and \$140,000 was billed in 2015.

The audit fees for PricewaterhouseCoopers LLP for professional services rendered for the 2013 audit of our annual financial statements and the review of the financial statements included in our quarterly reports on Form 10-Q totaled \$456,000, of which \$350,000 was billed in 2013 and \$106,000 was billed in 2014.

##### *Audit-Related Fees*

There were no audit-related fees for PricewaterhouseCoopers LLP in 2014 and 2013.

##### *All Other Fees*

Fees for PricewaterhouseCoopers LLP for services other than audit-related services were \$19,300 and \$16,800 for 2014 and 2013, respectively, and included annual fees of \$17,500 in 2014 and \$15,000 in 2013 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 2014 and 2013.

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

The Audit Committee approved all audit and non-audit services provided to us by PricewaterhouseCoopers LLP during the 2014 and 2013 fiscal years.

**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:

<b>Exhibit Number</b>	<b>Description</b>
2.1	Asset Purchase Agreement dated November 7, 2008 by and between NeuroMetrix, Inc. and Advanced Diagnostics, LLC <sup>(7)</sup>
3.1.1	Third Amended and Restated Certificate of Incorporation of NeuroMetrix, Inc. dated July 27, 2004 <sup>(6)</sup>
3.1.2	Certificate of Designations for Series A Junior Cumulative Preferred Stock, par value \$0.001 per share, dated March 7, 2007 <sup>(5)</sup>
3.1.3	Certificate of Amendment to Restated Certificate of Incorporation of NeuroMetrix, Inc. dated September 1, 2011 <sup>(14)</sup>
3.1.4	Certificate of Amendment to Restated Certificate of Incorporation of NeuroMetrix, Inc. dated February 15, 2013 <sup>(15)</sup>
3.1.5	Certificate of Designation of Preferences, Rights and Limitations of Series A-1 Convertible Preferred Stock, par value \$0.001 per share, dated June 5, 2013 <sup>(21)</sup>
3.1.6	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 <sup>(21)</sup>
3.1.7	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 <sup>(27)</sup>
3.1.8	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 <sup>(27)</sup>
3.2.1	Second Amended and Restated Bylaws of NeuroMetrix, Inc. <sup>(6)</sup>
3.2.2	Amendment No. 1 to Second Amended and Restated Bylaws of NeuroMetrix, Inc. <sup>(4)</sup>
4.1	Specimen Certificate for Shares of Common Stock <sup>(1)</sup>
4.2.1	Shareholder Rights Agreement, dated as of March 7, 2007, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent <sup>(5)</sup>
4.2.2	Amendment to Shareholder Rights Agreement, dated September 8, 2009, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent <sup>(9)</sup>
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 <sup>(21)</sup>
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 <sup>(27)</sup>
4.3	Form of Unit Warrant to purchase Common Stock <sup>(18)</sup>
4.4	Form of Placement Agent Warrant <sup>(18)</sup>
4.5	Form of Common Stock Purchase Warrant (June 2013) <sup>(22)</sup>

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<u>Exhibit Number</u>	<u>Description</u>
4.6	Form of Common Stock Purchase Warrant (June 2014)(27)
10.1.1	Lease Agreement, dated October 18, 2000, between Fourth Avenue LLC and NeuroMetrix, Inc.(1)
10.1.2	Amendment Number One to Lease, dated February 22, 2008, between Fourth Avenue LLC and NeuroMetrix, Inc.(11)
10.1.3	Amendment Number Two to Lease, dated June 6, 2012, between Fourth Avenue LLC and NeuroMetrix, Inc.(20)
10.1.4	Amendment Number Three to Lease, dated June 20, 2013, between Fourth Avenue LLC and NeuroMetrix, Inc.(23)
10.1.5	Lease Agreement, dated August 27, 2014, between Cummings Properties, LLC and NeuroMetrix, Inc.(28)
10.1.6	Lease Agreement, dated September 10, 2014, between Boston Properties, Inc. and NeuroMetrix, Inc.(28)
10.2.1	Loan and Security Agreement between NeuroMetrix, Inc. and Comerica Bank, dated March 5, 2010(12)
10.2.2	First Modification to Loan and Security Agreement between NeuroMetrix, Inc. and Comerica Bank, dated March 1, 2011(16)
10.2.3	Fifth Modification to Loan and Security Agreement between NeuroMetrix, Inc. and Comerica Bank, dated January 31, 2014(26)
10.3+	Amended and Restated 1996 Stock Option/Restricted Stock Plan(1)
10.4.1+	Amended and Restated 1998 Equity Incentive Plan(1)
10.4.2+	Second Amendment to Amended and Restated 1998 Equity Incentive Plan(1)
10.5.1+	Sixth Amended and Restated 2004 Stock Option and Incentive Plan(24)
10.5.2+	Form of Restricted Stock Agreement(12)
10.5.3+	Form of Incentive Stock Option Agreement(2)
10.5.4+	Form of Non-Qualified Stock Option Agreement For Company Employees(2)
10.5.5+	Form of Non-Qualified Stock Option Agreement For Non-Employee Directors(2)
10.6+	2010 Employee Stock Purchase Plan(13)
10.7+	Second Amended and Restated 2010 Employee Stock Purchase Plan(25)
10.8+	2009 Non-Qualified Inducement Stock Plan(17)
10.9+	Form of Indemnification Agreement between NeuroMetrix, Inc. and each of its directors(1)
10.10.1+	Employment Agreement, dated June 21, 2004, by and between NeuroMetrix, Inc. and Shai N. Gozani, M.D., Ph.D.(1)
10.10.2+	First Amendment to Employment Agreement dated December 31, 2008, by and between NeuroMetrix, Inc. and Shai N. Gozani, M.D., Ph.D.(8)
10.10.3+	Indemnification Agreement dated June 21, 2004, by and between Shai N. Gozani, M.D., Ph.D., and NeuroMetrix, Inc.(1)
10.10.4+	NeuroMetrix, Inc. Non-Statutory Stock Option Agreement (pursuant to the Amended and Restated 1998 Equity Incentive Plan), dated as of June 21, 2004, by and between Shai N. Gozani M.D., Ph.D., and NeuroMetrix, Inc.(1)
10.11.1+	Letter Agreement, dated August 31, 2009, between NeuroMetrix, Inc. and Thomas T. Higgins(10)
10.11.2+	Indemnification Agreement, dated September 10, 2009, by and between NeuroMetrix, Inc. and Thomas T. Higgins(10)
10.11.3+	Employment Agreement, dated October 27, 2014 by and between NeuroMetrix, Inc. and Thomas T. Higgins(28)



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<u>Exhibit Number</u>	<u>Description</u>
10.12.1+	Letter Agreement, dated August 14, 2014, between NeuroMetrix, Inc. and Frank McGillin <sup>(32)</sup>
10.13	Form of Securities Purchase Agreement, dated September 8, 2009 between the Company and each investor <sup>(9)</sup>
10.14†	Manufacturing and Supply Agreement, dated as of August 2, 2006, by and between Parlex Polymer Flexible Circuits, Inc. and NeuroMetrix, Inc. <sup>(3)</sup>
10.15.1	Engagement Letter by and between NeuroMetrix, Inc. and Dawson James Securities, Inc., dated December 30, 2011 <sup>(18)</sup>
10.15.2	First Amendment to Engagement Letter by and between NeuroMetrix, Inc. and Dawson James Securities, Inc., dated January 30, 2012 <sup>(18)</sup>
10.16	Engagement Letter by and between NeuroMetrix, Inc. and Dawson James Securities, Inc., dated June 4, 2013 <sup>(21)</sup>
10.17+	Amended and Restated 2010 Employee Stock Purchase Plan <sup>(19)</sup>
10.18+	Management Retention and Incentive Plan, as modified, dated October 27, 2014 <sup>(28)</sup>
10.19	Securities Purchase Agreement by and between NeuroMetrix, Inc. and the purchasers named therein, dated June 4, 2013 <sup>(21)</sup>
10.20	Securities Purchase Agreement by and between NeuroMetrix, Inc. and the purchasers named therein, as amended, dated June 24, 2014 <sup>(27)</sup>
10.21	Registration Rights Agreement by and between NeuroMetrix, Inc. and the purchasers named therein, dated June 4, 2013 <sup>(21)</sup>
10.22	Registration Rights Agreement by and between NeuroMetrix, Inc. and the purchasers named therein, dated June 24, 2014 <sup>(27)</sup>
*23.1	Consent of PricewaterhouseCoopers LLP, an independent registered public accounting firm
*31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
*31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
*32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following materials from NeuroMetrix, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2014, formatted in XBRL (eXtensible Business Reporting Language); (i) Balance Sheets as of December 31, 2014 and 2013, (ii) Statements of Operations for the years ended December 31, 2014, 2013, and 2012, (iii) Statements of Changes in Stockholders' Equity for the years ended December 31, 2014, 2013, and 2012, (iv) Statements of Cash Flows for the years ended December 31, 2014, 2013, and 2012, and (v) Notes to Financial Statements.

\* Filed herewith.

+ Indicates management contract or any compensatory plan, contract or arrangement.

† Confidential treatment has been granted with respect to certain portions of this Exhibit, which portions have been omitted and filed separately with the Securities and Exchange Commission as part of an application for confidential treatment pursuant to the Securities Exchange Act of 1934, as amended.

(1) Incorporated herein by reference to NeuroMetrix, Inc.'s Registration Statement on Form S-1 filed on May 13, 2004, as amended (Registration No. 333-115440).

(2) Incorporated herein by reference to NeuroMetrix, Inc.'s Quarterly Report on Form 10-Q filed on November 15, 2004 (File No. 000-50856).

(3) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on August 2, 2006 (File No. 000-50856).

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- (4) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on September 17, 2007 (File No. 001-33351).
- (5) Incorporated herein by reference to NeuroMetrix, Inc.'s Form 8-A12(b) filed on March 8, 2007 (File No. 001-33351).
- (6) Incorporated herein by reference to NeuroMetrix, Inc.'s Registration Statement on Form S-8 filed on August 9, 2004 (File No. 333-118059).
- (7) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on November 26, 2008 (File No. 001-33351).
- (8) Incorporated herein by reference to NeuroMetrix, Inc.'s Annual Report on Form 10-K filed on March 20, 2009 (File No. 001-33351).
- (9) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed September 14, 2009 (File No. 001-33351).
- (10) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed September 15, 2009 (File No. 001-33351).
- (11) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on February 27, 2008 (File No. 001-33351).
- (12) Incorporated herein by reference to NeuroMetrix, Inc.'s Quarterly Report on Form 10-Q filed on May 14, 2010 (File No. 001-33351).
- (13) Incorporated herein by reference to Appendix A to NeuroMetrix, Inc.'s Proxy Statement on Schedule 14A filed on April 8, 2010 (File No. 001-33351).
- (14) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on September 1, 2011 (File No. 001-33351).
- (15) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on February 15, 2013 (File No. 001-33351).
- (16) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on March 3, 2011 (File No. 001-33351).
- (17) Incorporated herein by reference to NeuroMetrix, Inc.'s Registration Statement on Form S-8 filed on June 3, 2009 (File No. 333-159712).
- (18) Incorporated herein by reference to NeuroMetrix, Inc.'s Registration Statement on Form S-1 filed on November 23, 2011, as amended (Registration No. 333-178165).
- (19) Incorporated herein by reference to Appendix B to NeuroMetrix, Inc.'s Proxy Statement on Schedule 14A filed on April 16, 2012 (File No. 001-33351).
- (20) Incorporated herein by reference to NeuroMetrix, Inc.'s Quarterly Report on Form 10-Q filed on August 3, 2012 (File No. 001-33351).
- (21) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on June 6, 2013 (File No. 001-33351).
- (22) Incorporated herein by reference to NeuroMetrix, Inc.'s Amendment No. 1 to its Current Report on Form 8-K filed on June 7, 2013 (File No. 001-33351).
- (23) Incorporated herein by reference to NeuroMetrix, Inc.'s Quarterly Report on Form 10-Q filed on July 26, 2013 (File No. 001-33351).
- (24) Incorporated herein by reference to Appendix A to NeuroMetrix, Inc.'s Proxy Statement on Schedule 14A filed on April 7, 2014 (File No. 001-33351).
- (25) Incorporated herein by reference to Appendix B to NeuroMetrix, Inc.'s Proxy Statement on Schedule 14A filed on April 7, 2014 (File No. 001-33351).
- (26) Incorporated herein by reference to NeuroMetrix, Inc.'s Quarterly Report on Form 10-Q filed on April 24, 2014 (File No. 001-33351).
- (27) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on June 25, 2014 (File No. 001-33351).
- (28) Incorporated herein by reference to NeuroMetrix, Inc.'s Quarterly Report on Form 10-Q filed on October 28, 2014 (File No. 001-33351).



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**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NEUROMETRIX, INC.

By: /s/ SHAI N. GOZANI, M.D., PH.D.

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

*Chairman, President and Chief Executive Officer*

Date: February 25, 2015

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant on February 25, 2015 in the capacities indicated below.

<u>Name</u>	<u>Title</u>
<u>/s/ SHAI N. GOZANI, M.D., PH.D.</u> Shai N. Gozani, M.D., Ph.D.	Chairman, President and Chief Executive Officer (Principal Executive Officer)
<u>/s/ THOMAS T. HIGGINS</u> Thomas T. Higgins	Senior Vice President, Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)
<u>/s/ DAVID E. GOODMAN, M.D.</u> David E. Goodman, M.D.	Director
<u>/s/ ALLEN J. HINKLE, M.D.</u> Allen J. Hinkle, M.D.	Director
<u>/s/ NANCY E. KATZ</u> Nancy E. Katz	Director
<u>/s/ TIMOTHY R. SURGENOR</u> Timothy R. Surgenor	Director
<u>/s/ DAVID VAN AVERMAETE</u> David Van Avermaete	Director

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**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of NeuroMetrix, Inc.

In our opinion, the accompanying balance sheets and the related statements of operations, of changes in stockholders' equity, and of cash flows present fairly, in all material respects, the financial position of NeuroMetrix, Inc. at December 31, 2014 and December 31, 2013, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2014 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 15(a)(2) presents fairly, in all material respects, the information set forth therein when read in conjunction with the related financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and negative cash flows from operating activities that raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts  
February 25, 2015

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## NeuroMetrix, Inc.

## Balance Sheets

	December 31,	
	2014	2013
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 9,221,985	\$ 9,195,753
Accounts receivable, net of allowances of \$39,966 and \$35,895 at December 31, 2014 and 2013, respectively	580,240	390,922
Inventories	679,740	563,036
Prepaid expenses and other current assets	608,160	416,816
Total current assets	11,090,125	10,566,527
Fixed assets, net	311,520	229,313
Other long-term assets	585	923
Total assets	<u>\$ 11,402,230</u>	<u>\$ 10,796,763</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 522,871	\$ 322,896
Accrued compensation	885,353	386,004
Accrued expenses	1,264,876	870,196
Current portion of deferred revenue	25,048	68,812
Total current liabilities	2,698,148	1,647,908
Deferred revenue, net of current portion	9,635	15,277
Common stock warrants	5,307,332	1,938,603
Total liabilities	8,015,115	3,601,788
Commitments and contingencies (Note 8)		
Stockholders' equity		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized at December 31, 2014 and 2013; no shares issued and outstanding at December 31, 2014 and 2013	—	—
Convertible preferred stock, 11,083 and 4,438 shares designated at December 31, 2014 and December 31, 2013, respectively, and 3,614.357 and 0 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively	4	—
Common stock, \$0.0001 par value; 50,000,000 authorized; 8,152,746 and 5,945,581 shares issued and outstanding at December 31, 2014 and 2013, respectively	815	595
Additional paid-in capital	157,764,598	153,806,460
Accumulated deficit	(154,378,302)	(146,612,080)
Total stockholders' equity	3,387,115	7,194,975
Total liabilities and stockholders' equity	<u>\$ 11,402,230</u>	<u>\$ 10,796,763</u>

The accompanying notes are an integral part of these financial statements.

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**NeuroMetrix, Inc.**

**Statements of Operations**

	Years Ended December 31,		
	2014	2013	2012
Revenues	\$ 5,512,764	\$ 5,278,806	\$ 7,575,289
Cost of revenues	<u>2,568,602</u>	<u>2,194,259</u>	<u>3,588,806</u>
Gross profit	2,944,162	3,084,547	3,986,483
Operating expenses:			
Research and development	4,075,976	3,438,218	3,545,790
Sales and marketing	2,913,112	2,779,695	5,727,482
General and administrative	4,725,123	4,225,474	4,735,238
Total operating expenses	<u>11,714,211</u>	<u>10,443,387</u>	<u>14,008,510</u>
Loss from operations	(8,770,049)	(7,358,840)	(10,022,027)
Interest income	4,606	5,666	14,474
Warrants offering costs	(50,874)	(376,306)	—
Change in fair value of warrant liability	<u>1,050,095</u>	<u>(289,657)</u>	<u>—</u>
Net loss	<u>\$ (7,766,222)</u>	<u>\$ (8,019,137)</u>	<u>\$ (10,007,553)</u>
Net loss per common share applicable to common stockholders, basic and diluted (See Note 2, Summary of Significant Accounting Policies)	<u>\$ (1.54)</u>	<u>\$ (3.07)</u>	<u>\$ (5.22)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>6,973,977</u>	<u>2,862,094</u>	<u>1,918,723</u>

The accompanying notes are an integral part of these financial statements.



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**NeuroMetrix, Inc.**

**Statements of Changes in Stockholders' Equity**

	Series A1 – A4 Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Number of Shares	Amount	Number of Shares	Amount			
Balance at December 31, 2011	—	\$ —	650,720	\$ 65	\$139,673,846	\$(128,585,390)	\$ 11,088,521
Stock-based compensation expense	—	—	—	—	319,368	—	319,368
Issuance of common stock and warrants in public offering	—	—	1,421,735	142	7,376,906	—	7,377,048
Issuance of common stock on redemption of warrants	—	—	23,127	2	(2)	—	—
Issuance of common stock under employee stock purchase plan	—	—	8,895	1	23,037	—	23,038
Other issuances of stock from option plan	—	—	36,394	4	(4)	—	—
Net loss	—	—	—	—	—	(10,007,553)	(10,007,553)
Balance at December 31, 2012	—	\$ —	2,140,871	\$ 214	\$147,393,151	\$(138,592,943)	\$ 8,800,422
Stock-based compensation expense	—	—	—	—	245,843	—	245,843
Issuance of common stock and Series A1 and A2 preferred stock under Securities Purchase Agreement	4,436.76	4	248,147	25	876,757	—	876,786
Issuance of common stock upon conversion of preferred stock	(4,436.76)	(4)	2,117,787	212	(208)	—	—
Issuance of common stock upon exercise of warrants	—	—	1,308,611	131	2,617,091	—	2,617,222
Reclassification of warrant liability to equity	—	—	—	—	2,362,259	—	2,362,259
Issuance of common stock under employee stock purchase plan	—	—	16,094	2	26,283	—	26,285
Common stock issued to settle incentive compensation obligations	—	—	114,071	11	285,284	—	285,295
Net loss	—	—	—	—	—	(8,019,137)	(8,019,137)
Balance at December 31, 2013	—	\$ —	5,945,581	\$ 595	\$153,806,460	\$(146,612,080)	\$ 7,194,975
Stock-based compensation expense	—	—	—	—	289,873	—	289,873
Issuance of common stock and Series A3 and A4 preferred stock under Securities Purchase Agreement	6,644.22	7	664,600	66	3,539,874	—	3,539,947
Issuance of common stock upon conversion of preferred stock	(3,029.86)	(3)	1,485,225	149	(146)	—	—
Issuance of common stock under employees stock purchase plan	—	—	14,725	1	24,136	—	24,137
Common stock issued to settle incentive compensation obligations	—	—	42,615	4	104,401	—	104,405
Net loss	—	—	—	—	—	(7,766,222)	(7,766,222)
Balance at December 31, 2014	<u>3,614.36</u>	<u>\$ 4</u>	<u>8,152,746</u>	<u>\$ 815</u>	<u>\$157,764,598</u>	<u>\$(154,378,302)</u>	<u>\$ 3,387,115</u>

The accompanying notes are an integral part of these financial statements.

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**NeuroMetrix, Inc.**

**Statements of Cash Flows**

	Years Ended December 31,		
	2014	2013	2012
<b>Cash flows for operating activities:</b>			
Net loss	\$ (7,766,222)	\$ (8,019,137)	\$ (10,007,553)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	145,100	150,663	297,097
Stock-based compensation	289,873	245,843	319,368
Inventory charges	—	151,558	234,848
Warrants offering costs	50,874	376,306	—
Change in fair value of warrant liability	(1,050,095)	289,657	—
Changes in operating assets and liabilities:			
Accounts receivable	(189,318)	175,529	343,267
Inventories	(116,704)	119,932	694,327
Prepaid expenses and other current assets	(195,454)	52,748	(76,880)
Accounts payable	199,975	65,535	(371,854)
Accrued expenses and compensation	998,434	(54,635)	(530,141)
Deferred revenue, deferred costs, and other	(44,956)	(108,907)	(78,046)
Net cash used in operating activities	(7,678,493)	(6,554,908)	(9,175,567)
<b>Cash flows for investing activities:</b>			
Purchases of fixed assets	(227,308)	(86,079)	(107,465)
Release of restricted cash	—	—	229,500
Net cash (used in) provided by investing activities	(227,308)	(86,079)	122,035
<b>Cash flows from financing activities:</b>			
Net proceeds from issuance of stock and warrants, including public offering and equity plans	7,932,033	7,155,191	7,482,884
Payments on capital lease	—	(17,929)	(20,320)
Net cash provided by financing activities	7,932,033	7,137,262	7,462,564
Net increase (decrease) in cash and cash equivalents	26,232	496,275	(1,590,968)
Cash and cash equivalents, beginning of year	9,195,753	8,699,478	10,290,446
Cash and cash equivalents, end of year	<u>\$ 9,221,985</u>	<u>\$ 9,195,753</u>	<u>\$ 8,699,478</u>
<b>Supplemental disclosure of cash flow information:</b>			
Common stock issued to settle incentive compensation obligation	<u>\$ 104,405</u>	<u>\$ 285,295</u>	<u>\$ —</u>
Warrants issued under Securities Purchase Agreement initially recorded as a non-current liability	<u>\$ 4,418,824</u>	<u>\$ 4,011,205</u>	<u>\$ —</u>
Common stock issued in exchange for warrants	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 127,885</u>
Warrants issued in public offering	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,373,267</u>
Warrants liability reclassified to additional paid-in capital upon exercise of warrants	<u>\$ —</u>	<u>\$ 2,362,259</u>	<u>\$ —</u>

The accompanying notes are an integral part of these financial statements.

**NeuroMetrix, Inc.**

**Notes to Financial Statements**

**1. Description of Business and Basis of Presentation**

NeuroMetrix, Inc., or the Company, a Delaware corporation, was founded in June 1996. The Company develops wearable medical technology and point-of-care tests that help patients and physicians better manage chronic pain, nerve diseases, and sleep disorders. The Company markets the SENSUS™ Pain Management System, or SENSUS, which is a wearable therapeutic device designed for relief of chronic, intractable pain. The Company also markets DPNCheck®, which is a quantitative nerve conduction test that is used by physicians and health care professionals to evaluate systemic neuropathies such as diabetic peripheral neuropathy, or DPN. The Company's historical neurodiagnostic business is based on the ADVANCE™ NCS/EMG System, or the ADVANCE System, which is a comprehensive platform for the performance of traditional nerve conduction studies and invasive electromyography procedures and which is primarily used in physician offices and clinics.

On June 26, 2014, the Company entered into a Securities Purchase Agreement, as amended providing for the issuance of (i) 664,600 shares of common stock at a price of \$2.04 per share, (ii) 2,621,859 shares of Series A-3 Preferred Stock at a price of \$1,000 per share, (iii) 4,022,357 shares of Series A-4 Preferred Stock at a price of \$1,000 per share, and (iv) five year warrants to purchase up to 3,921,569 shares of common stock with an exercise price of \$2.04 per share (the "2014 Offering"). The 2014 Offering resulted in approximately \$8.0 million in gross proceeds, before deducting expenses. Net proceeds from the 2014 Offering were approximately \$7.9 million. During the second and third quarter of 2014 all of the Series A-3 Preferred Stock was converted into a total of 1,285,225 shares of common stock. In addition, during the fourth quarter of 2014, a portion of the Series A-4 Preferred Stock was converted into a total of 200,000 shares of common stock. See Note 12, Stockholders' Equity, for further details.

The accompanying financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company has suffered recurring losses from operations and negative cash flows from operating activities. The Company's net losses for 2014, 2013 and 2012 were approximately \$7.8 million, \$8.0 million and \$10.0 million, respectively. At December 31, 2014, the Company has an accumulated deficit of \$154.4 million. The Company held cash and cash equivalents of \$9.2 million as of December 31, 2014. The Company believes that these resources and the cash to be generated from expected product sales will be sufficient to meet its projected operating requirements through the third quarter of 2015. The Company continues to face significant challenges and uncertainties and, as a result, the Company's available capital resources may be consumed more rapidly than currently expected due to (a) decreases in sales of the Company's products and the uncertainty of future revenues from new products; (b) changes the Company may make to the business that affect ongoing operating expenses; (c) changes the Company may make in its business strategy; (d) regulatory developments affecting the Company's existing products and delays in the FDA approval process for products under development; (e) changes the Company may make in its research and development spending plans; and (f) other items affecting the Company's forecasted level of expenditures and use of cash resources. Accordingly, the Company will need to raise additional funds to support its operating and capital needs in the fourth quarter of 2015 and beyond. These factors raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. The Company intends 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, the Company may not be able to secure such financing in a timely manner or on favorable terms, if at all. Furthermore, if the Company issues equity or debt securities to raise additional funds, its existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of the Company's existing stockholders. If the Company raises additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to its potential products or proprietary technologies, or grant licenses on terms that are not favorable to the Company. Without additional funds, the Company may be forced to delay, scale back

**NeuroMetrix, Inc.**

**Notes to Financial Statements**

**1. Description of Business and Basis of Presentation – (continued)**

or eliminate some of its 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 its operations. If any of these events occurs, the Company's ability to achieve its development and commercialization goals would be adversely affected.

**2. Summary of Significant Accounting Policies**

*Use of Estimates and Assumptions*

The preparation of financial statements in conformity with United States generally accepted accounting principles requires management to make significant estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during reporting periods. Actual results could differ from those estimates.

The Company bases its estimates on historical experience and various other assumptions that it believes to be reasonable under the circumstances and regularly assesses these estimates, but actual results could differ materially from these estimates. Effects of changes in estimates are recorded in the period in which they occur.

*Cash and Cash Equivalents*

The Company considers all highly liquid investments with an original maturity of ninety days or less to be cash equivalents. Cash equivalents are recorded at cost which approximates fair value. The Company invests cash primarily in a money market account and other investments which management believes are subject to minimal credit and market risk.

*Concentrations of Credit Risk*

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents in bank deposit accounts and trade receivables. The Company invests its funds in highly rated institutions and limits its investment in any individual account so that they do not exceed FDIC limits. The Company has not experienced significant losses related to cash and cash equivalents and does not believe it is exposed to any significant credit risks relating to its cash and cash equivalents.

At December 31, 2014, one customer accounted for 30% of accounts receivable. For the year ended December 31, 2014 one customer accounted for more than 10% of revenue. For the years ended December 31, 2013, and 2012, no single customer accounted for more than 10% of revenue.

The Company relies on in-house assembly and three third-party manufacturers to manufacture the major portion of its current products and product components. The disruption or termination of the supply of these products or a significant increase in the cost of these products from these sources could have an adverse effect on the Company's business, financial position, and results of operations.

*Inventories*

Inventories, consisting primarily of purchased components, are stated at the lower of cost or market. Cost is determined using the first-in, first-out method. The Company writes down inventory to its net realizable value for excess or obsolete inventory.

*Fair Value*

The carrying amounts of the Company's accounts receivable, accounts payable, and accrued expenses approximate their fair value at December 31, 2014 and 2013 due to the short-term nature of these assets and liabilities. The Company's cash equivalents and its warrant liability are carried at fair value determined according to the fair value hierarchy described in Note 9.

**NeuroMetrix, Inc.**

**Notes to Financial Statements**

**2. Summary of Significant Accounting Policies – (continued)**

***Revenue Recognition***

The Company recognizes 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 the sale of the ADVANCE devices to customers and distributors are recognized upon shipment, provided that the selling price is fixed or determinable, persuasive evidence of an arrangement exists, collection of receivables is reasonably assured, product returns are reasonably estimable, and no continuing obligations exist. The revenues from the sale of an ADVANCE communication hub together with access to NeuroMetrix information systems are considered one unit of accounting and deferred and recognized on a straight-line basis over the estimated period of time that the Company provides the service associated with the information systems of three years. The resulting deferred revenue and deferred costs are presented as separate line items on the accompanying balance sheet. Revenues related to extended service agreements for the devices are recognized ratably over the term of the extended service agreement. Revenues associated with the sale of the SENSUS and DPNCheck devices are recognized upon shipment, provided that the selling price is fixed or determinable, persuasive evidence of an arrangement exists, collection of receivables is reasonably assured, product returns are reasonably estimable, and no continuing obligations exist. Revenues also include sales of consumables, including single use nerve specific electrodes and other accessories. These revenues are recognized upon shipment provided that the selling price is fixed or determinable, persuasive evidence of an arrangement exists, collection of receivables is reasonably assured, and product returns are reasonably estimable.

When multiple elements are contained in a single arrangement, the Company allocates revenue between the elements based on their relative selling prices. The Company determines selling price using vendor specific objective evidence, or VSOE, if it is available, third-party evidence, or TPE, if VSOE is not available, and best estimate of selling price, or BEBP, if neither VSOE nor TPE are available. The Company generally expects that it will not be able to establish TPE due to the nature of the markets in which it competes, and, as such, it will typically determine selling price using VSOE or if not available, BEBP. The objective of BEBP is to determine the selling price of a deliverable on a standalone basis. The Company's determination of BEBP involves a weighting of several factors based on the specific facts and circumstances of an arrangement. Specifically, the Company considers the cost to produce the deliverable, the anticipated margin on that deliverable, the selling price and profit margin for similar parts, its ongoing pricing strategy, the value of any enhancements that have been built into the deliverable, and the characteristics of the varying markets in which the deliverable is sold.

Revenue recognition involves judgments, including assessments of expected returns and expected customer relationship periods. The Company analyzes various factors, including a review of specific transactions, its historical 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, the Company's actual return or bad debt experience could exceed its estimate. Certain product sales are made with a 30-day right of return. Since the Company can reasonably estimate future returns, it recognizes revenues associated with product sales that contain a right of return upon shipment and at the same time it records a sales return reserve, which reduces revenue and accounts receivable by the amount of estimated returns.

***Accounts Receivable***

Accounts receivable on the balance sheet are recorded net of the allowance for doubtful accounts receivable and the reserve for estimated returns. The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses in its existing accounts receivable. The Company reviews its

**NeuroMetrix, Inc.**

**Notes to Financial Statements**

**2. Summary of Significant Accounting Policies – (continued)**

allowance for doubtful accounts and determines the allowance based on an analysis of customer past payment history, product usage activity, and recent communications between the Company and the customer. Past due balances are reviewed individually for collectibility. Account balances are written-off against the allowance when the Company feels it is probable the receivable will not be recovered. The Company does not have any off-balance sheet credit exposure related to its customers.

***Income Taxes***

The Company records income taxes using the asset and liability method. Deferred income tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases, and operating loss and tax credit carryforwards. The Company's financial statements contain certain deferred tax assets, which have arisen primarily as a result of operating losses, as well as other temporary differences between financial and tax accounting. In accordance with the provisions of the Income Taxes topic of the Codification, the Company is required to establish a valuation allowance if the likelihood of realization of the deferred tax assets is reduced based on an evaluation of objective verifiable evidence. Significant management judgment is required in determining the Company's provision for income taxes, the Company's deferred tax assets and liabilities and any valuation allowance recorded against those net deferred tax assets. The Company evaluates the weight of all available evidence to determine whether it is more likely than not that some portion or all of the net deferred income tax assets will not be realized.

Utilization of the NOL and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future, as provided by Section 382 of the Internal Revenue Code of 1986, as well as similar state provisions. Ownership changes may limit the amount of NOL and tax credit carryforwards that can be utilized to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. If the Company has experienced a change of control, utilization of its NOL or tax credits carryforwards would be subject to an annual limitation under Section 382. Any limitation may result in expiration of a portion of the NOL or research and development credit carryforwards before utilization. Subsequent ownership changes could further impact the limitation in future years. Further, until a study is completed and any limitation known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's 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.

Management performed a two-step evaluation of all tax positions, ensuring that these tax return positions meet the "more likely than not" recognition threshold and can be measured with sufficient precision to determine the benefit recognized in the financial statements. These evaluations provide management with a comprehensive model for how a company should recognize, measure, present, and disclose in its financial statements certain tax positions that the Company has taken or expects to take on income tax returns.

***Research and Development***

Costs incurred in research and development are expensed as incurred. Included in research and development costs are wages, benefits, product design consulting, and other operating costs such as facilities, supplies, and overhead directly related to the Company's research and development efforts.

***Product Warranty Costs***

The Company accrues estimated product warranty costs at the time of sale which are included in cost of sales in the statements of operations. The amount of the accrued warranty liability is based on historical information such as past experience, product failure rates, number of units repaired, and estimated cost of

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**NeuroMetrix, Inc.**

**Notes to Financial Statements**

**2. Summary of Significant Accounting Policies – (continued)**

material and labor. The liabilities for product warranty costs of \$1,784 and \$4,719 at December 31, 2014 and 2013, respectively, are included in accrued expenses in the accompanying balance sheets.

***Fixed Assets and Long-Lived Assets***

Fixed assets are recorded at cost and depreciated using the straight-line method over the estimated useful life of each asset. Expenditures for repairs and maintenance are charged to expense as incurred. On disposal, the related assets and accumulated depreciation are eliminated from the accounts and any resulting gain or loss is included in the Company's statement of operations. Leasehold improvements are amortized over the shorter of the estimated useful life of the improvement or the remaining term of the lease.

The Company periodically evaluates the recoverability of its fixed assets and other long-lived assets whenever events or changes in circumstances indicate that an event of impairment may have occurred. This periodic review may result in an adjustment of estimated depreciable lives or asset impairment. When indicators of impairment are present, the carrying values of the asset are evaluated in relation to the assets operating performance and future undiscounted cash flows of the underlying assets. If the future undiscounted cash flows are less than their book value, an impairment may exist. The impairment is measured as the difference between the book value and the fair value of the underlying asset. Fair values are based on estimates of the market prices and assumptions concerning the amount and timing of estimated future cash flows and assumed discount rates, reflecting varying degrees of perceived risk.

***Accounting for Stock-Based Compensation***

Stock-based compensation cost is generally recognized ratably over the requisite service period. The Company uses the Black-Scholes option pricing model for determining the fair value of its stock options and amortizes its stock-based compensation expense using the straight-line method. The Black-Scholes model requires certain assumptions that involve judgment. Such assumptions are the expected share price volatility, expected life of options, expected annual dividend yield, and risk-free interest rate (See Note 3 — Stock-Based Compensation and Stockholders' Equity).

***Net Loss per Common Share***

Basic net loss per common share is computed by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the period. Unvested restricted shares, although legally issued and outstanding, are not considered outstanding for purposes of calculating basic net income per share. Diluted net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the period plus the dilutive effect of the weighted average number of outstanding instruments such as options, warrants, restricted stock, and preferred stock. Because the Company has reported a net loss for all periods presented, diluted loss per common share is the same as basic loss per common share, as the effect of utilizing the fully diluted share count would have reduced the net loss per common share. Therefore, in calculating net loss per share amounts, shares underlying the following potentially dilutive weighted average number of common stock equivalents were excluded from the calculation of diluted net loss per common share because their effect was anti-dilutive for each of the periods presented:

	Years Ended December 31,		
	2014	2013	2012
Options	500,826	161,391	53,999
Warrants	2,436,336	2,055,733	741,546
Unvested restricted stock	4,489	22,387	31,699
Convertible preferred stock	912,570	—	—
Total	<u>3,854,221</u>	<u>2,239,511</u>	<u>827,244</u>

**NeuroMetrix, Inc.****Notes to Financial Statements****2. Summary of Significant Accounting Policies – (continued)**

The Beneficial Conversion Feature, or BCF, recorded in both the 2014 Offering and 2013 Offering has been recognized as a deemed dividend attributable to the Preferred Stock and is reflected as an adjustment in the calculation of earnings per share. See Note 12, Stockholders' Equity, for further details.

Net loss per common share applicable to common stockholders, basic and diluted was determined as follows:

	Years Ended December 31,		
	2014	2013	2012
Net loss	<u>\$ (7,766,222)</u>	<u>\$(8,019,137)</u>	<u>\$(10,007,553)</u>
Deemed dividend attributable to preferred stockholders in connection with beneficial conversion features	<u>(2,955,668)</u>	<u>(766,872)</u>	<u>—</u>
Net loss applicable to common stockholders	<u>\$(10,721,890)</u>	<u>\$(8,786,009)</u>	<u>\$(10,007,553)</u>
Net loss per common share applicable to common stockholders, basic and diluted	<u>\$ (1.54)</u>	<u>\$ (3.07)</u>	<u>\$ (5.22)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>6,973,977</u>	<u>2,862,094</u>	<u>1,918,723</u>

***Advertising and Promotional Costs***

Advertising and promotional costs are expensed as incurred. Advertising and promotion expense was \$481,000, \$151,000, and \$242,000 in 2014, 2013, and 2012, respectively.

***Accumulated Other Comprehensive Items***

For 2014, 2013, and 2012, the Company had no components of other comprehensive income or loss other than net loss.

***Segments***

The Company operates in one segment for the sale of medical equipment and consumables. Substantially all of the Company's assets, revenues, and expenses for 2014, 2013, and 2012 were located at or derived from operations in the United States. Revenues from sales outside the United States accounted for approximately 19% of total revenues in 2014, 16% of total revenues in 2013, and 7% of total revenues in 2012.

***Risks and Uncertainties***

The Company is subject to risks common to companies in the medical device industry, including, but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, customers' reimbursement from third-party payers, protection of proprietary technology, and compliance with regulations of the FDA and other governmental agencies.

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

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. The Company is evaluating the provisions of ASU 2014-15 and assessing the impact, if any, it may have on financial position, results of operations or cash flows.



**NeuroMetrix, Inc.**

**Notes to Financial Statements**

**2. Summary of Significant Accounting Policies – (continued)**

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 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. The Company is in the process of evaluating the new standard and does not know the effect, if any, ASU 2014-09 will have on the Consolidated Financial Statements or which adoption method will be used.

**3. Stock-Based Compensation**

During 2004, the Company adopted the 2004 Stock Option and Incentive Plan, as amended and restated in 2006, 2008, 2009, 2012 and 2013. At the Annual Meeting of Stockholders held on May 6, 2014, the stockholders of the Company approved the Company’s Sixth Amended and Restated 2004 Stock Option and Incentive Plan (the “2004 Stock Plan”), which, among other things, increased the number of shares of the Company’s common stock authorized for issuance thereunder by 700,000 shares. The 2004 Stock Plan, among other things, provides for granting of incentive and nonqualified stock option and stock bonus awards to officers, employees and outside consultants. Outstanding options under the 2004 Stock Plan generally vest over three or four years and terminate 10 years after the grant date, or earlier if the option holder is no longer an executive officer, employee, consultant, advisor or director, as applicable, of the Company. As of December 31, 2014, 1,276,279 shares of common stock were authorized for issuance under the 2004 Stock Plan, of which 212,408 shares had been issued, 561,767 shares were subject to outstanding options at a weighted average exercise price of \$6.31 per share and 502,104 shares were available for future grant.

During May 2009, the Company adopted the 2009 Non-Qualified Inducement Stock Plan (the “2009 Inducement Plan”). The 2009 Inducement Plan is intended to encourage and enable employees, including prospective employees, of the Company upon whose judgment, initiative, and efforts the Company largely depends for the successful conduct of its business to acquire a proprietary interest in the Company. The 2009 Inducement Plan, among other things, provides for the granting of awards, including non-qualified stock options, restricted stock, and unrestricted stock. As of December 31, 2014, 400,000 shares of common stock were authorized for issuance under the 2009 Inducement Plan, of which 200,000 shares had been issued and were outstanding.

The exercise price of stock options awarded under the 2004 Stock Plan and the 2009 Inducement Plan may not be less than the fair market value of the common stock on the date of the option grant. For holders of more than 10% of the Company’s total combined voting power of all classes of stock, incentive stock options may not be granted at less than 110% of the fair market value of the Company’s common stock at the date of grant and for a term not to exceed five years.

In June 2004, the Company adopted the 2004 Employee Stock Purchase Plan (the “2004 ESPP”). All of the Company’s employees who had been employed by the Company for at least 60 days and whose customary employment is for more than 20 hours per week and for more than five months in any calendar year were eligible to participate and any employee who owned 5% or more of the voting power or value of the Company’s stock was not eligible to participate. The 2004 ESPP authorized the issuance of up to a total of 10,417 shares of the Company’s common stock to participating employees.

In May 2010, the Company adopted the 2010 Employee Stock Purchase Plan (the “2010 ESPP”). The 2010 ESPP initially authorized the issuance of up to a total of 6,945 shares, of the Company’s common stock to participating employees plus an annual increase on the first day of each of the Company’s fiscal years

**NeuroMetrix, Inc.**

**Notes to Financial Statements**

**3. Stock-Based Compensation – (continued)**

beginning in 2011, equal to the lesser of (i) 6,945 shares, (ii) 1 percent of the shares of common stock outstanding on the last day of the immediately preceding fiscal year, or (iii) such lesser number of shares as is determined by the Board. At the Company’s Annual Meeting of Stockholders held on May 14, 2012, the stockholders of the Company approved the Company’s Amended and Restated 2010 Employee Stock Purchase Plan (the “Amended and Restated 2010 ESPP”), which, among other things, increased the number of shares of the Company’s common stock authorized for issuance thereunder by 16,667 shares. All of the Company’s full-time employees and certain part-time employees are eligible to participate in the Amended and Restated 2010 ESPP. For part-time employees to be eligible, they must have customary employment of more than five months in any calendar year and more than 20 hours per week. Employees who, after exercising their rights to purchase shares under the Amended and Restated 2010 ESPP, would own shares representing 5% or more of the voting power of the Company’s common stock, are ineligible to participate.

Under the Amended and Restated 2010 ESPP, participating employees can authorize the Company to withhold up to 10% of their earnings during consecutive six-month payment periods for the purchase of the shares. At the conclusion of each period, participating employees can purchase shares at 85% of the lower of their fair market value at the beginning or end of the period. The Amended and Restated 2010 ESPP is regarded as a compensatory plan. For the years ended December 31, 2014 and 2013 the Company issued 14,725 and 16,094 shares of its common stock, respectively, under the Amended and Restated 2010 ESPP and the 2010 ESPP, respectively. As of December 31, 2014, there were 124,280 remaining shares to be issued under the Amended and Restated 2010 ESPP.

The Company uses the Black-Scholes option pricing model for determining the fair value of shares of common stock issued or to be issued under the 2010 ESPP and the Amended and Restated 2010 ESPP. The following assumptions are used in determining fair value: The risk-free interest rate assumption is based on the United States Treasury’s constant maturity rate for a six month term (corresponding to the expected option term) on the date the option was granted. The expected dividend yield is zero because the Company does not currently pay dividends nor expects to do so during the expected option term. An expected term of six months is used based on the duration of each plan offering period. The volatility assumption is based on a consideration of stock price volatility over the most recent period of time corresponding to the expected term and is also based on expected future stock price volatility.

The weighted average grant-date fair value of stock options used in the calculation of stock-based compensation expense in the accompanying statement of operations for the years ended December 31, 2014, 2013, and 2012 is calculated using the following assumptions:

	Years Ended December 31,		
	2014	2013	2012
Risk-free interest rate	1.4% – 1.8%	1.4% – 1.7%	0.6% – 0.9%
Expected dividend yield	—	—	—
Expected option term	5 years	5 years	5 years
Volatility	70.0%	70.0%	70.0%

The risk-free interest rate assumption is based on the United States Treasury’s constant maturity rate for a five year term (corresponding to the expected option term) on the date the option was granted. The expected dividend yield is zero as the Company does not currently pay dividends nor expects to do so during the expected option term. The expected option term of five years is estimated based on an analysis of actual option exercises and a review of comparable medical device companies. The volatility assumption is based on weekly historical volatility during the time period that corresponds to the expected option term, a review of comparable medical device companies and expected future stock price volatility. The pre-vesting forfeiture rate is based on the historical and projected average turnover rate of employees.

**NeuroMetrix, Inc.**

**Notes to Financial Statements**

**3. Stock-Based Compensation – (continued)**

A summary of option activity for the year ended December 31, 2014 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2013	310,146	\$ 13.20		
Granted	537,300	1.82		
Exercised	—	—		
Forfeited	(84,554)	10.30		
Expired	(1,125)	249.68		
Outstanding at December 31, 2014	<u>761,767</u>	5.15	9.15	\$ 109,460
Vested or expected to vest at December 31, 2014	<u>691,404</u>	5.49	9.11	100,761
Exercisable at December 31, 2014	<u>146,646</u>	19.10	7.83	21,586

Expected to vest options are determined by applying the pre-vesting forfeiture rate to the total outstanding options. Aggregate intrinsic value represents the total pre-tax intrinsic value (the aggregate difference between the closing stock price of the Company's common stock as of December 31, 2014, as applicable, and the exercise price for the in-the-money options) that would have been received by the option holders if all the in-the-money options had been exercised on December 31, 2014.

The weighted average per share grant-date fair values of options granted during 2014, 2013, and 2012 was \$1.06, \$1.02, and \$2.67, respectively.

The aggregate intrinsic value of options issued or exercised during 2014, 2013, and 2012 was \$0.

Total unrecognized stock-based compensation costs related to non-vested stock options was \$538,188, which related to 615,953 shares with a per share weighted fair value of \$0.87 as of December 31, 2014. This unrecognized cost is expected to be recognized over a weighted average period of approximately 2.3 years.

Stock options granted to non-employees are recorded at fair value and adjusted to market over the vesting period. The Company determines fair value using the Black-Scholes option pricing model, an expected term equal to the option term, a risk-free interest rate corresponding to the expected term, a stock price volatility over the most recent period of time corresponding to the expected term and also based on expected future stock price volatility, and a dividend yield of zero. There were no options granted to non-employees during the years ended December 31, 2014, 2013 or 2012.

Beginning in 2010, certain employees have been granted restricted stock. There were no restricted stock grants in 2014. During 2013, and 2012, the Company granted 2,000, and 37,167 shares of restricted stock, respectively. The restricted stock vests based on continuing employment. The fair value of restricted stock is calculated based on the closing sale price of the Company's common stock on the date of issuance.

A summary of restricted stock activity for the year ended December 31, 2014 is presented below:

	Restricted Shares	Weighted Average Grant Date Fair Value
Restricted shares at December 31, 2013	17,476	\$ 4.62
Granted	—	—
Vested	(16,644)	(4.75)
Canceled	—	—
Restricted shares at December 31, 2014	<u>832</u>	<u>\$ 1.90</u>

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**NeuroMetrix, Inc.**

**Notes to Financial Statements**

**3. Stock-Based Compensation – (continued)**

During 2014, 2013 and 2012, certain employees, in lieu of paying withholding taxes on the vesting of restricted stock, authorized the withholding of an aggregate of 0, 4,214 and 721 shares, respectively, of common stock to satisfy the minimum tax withholding requirements related to such vesting. Shares withheld were calculated using the market price of the common stock.

Cash received from option exercises and purchases under the 2004 ESPP and the 2010 ESPP for the years 2014, 2013, and 2012 was \$24,000, \$26,000, and \$23,000, respectively. The Company issues new shares upon option exercises, purchases under the Company's ESPPs, and vesting of restricted stock.

The Company recorded stock-based compensation expense of \$290,000, \$246,000, and \$319,000 for 2014, 2013, and 2012, respectively.

**4. Inventories**

Inventories consist of the following:

	<u>December 31,</u>	
	<u>2014</u>	<u>2013</u>
Purchased components	\$ 209,426	\$ 205,320
Finished goods	470,314	357,716
	<u>\$ 679,740</u>	<u>\$ 563,036</u>

**5. Fixed Assets**

Fixed assets consist of the following:

	<u>Estimated Useful Life (Years)</u>	<u>December 31,</u>	
		<u>2014</u>	<u>2013</u>
Construction in process		\$ 182,755	—
Computer and laboratory equipment	3	1,782,330	\$ 1,748,566
Furniture and equipment	3	109,617	249,377
Production equipment	7	745,596	997,297
Leasehold improvements	*	7,268	185,255
		<u>2,827,566</u>	<u>3,180,495</u>
Less – accumulated depreciation		<u>(2,516,046)</u>	<u>(2,951,182)</u>
		<u>\$ 311,520</u>	<u>\$ 229,313</u>

\* Lesser of life of lease or estimated useful life.

Depreciation expense was \$145,100, \$150,663, and \$239,168 for 2014, 2013, and 2012, respectively.

**NeuroMetrix, Inc.**

**Notes to Financial Statements**

**6. Accrued Compensation and Expenses**

The following table provides a rollforward of the liability balance for severance obligations which was recorded as research and development and sales and marketing expense in the Company's Statement of Operations for 2014 and 2013. The balance as of December 31, 2014 which is included as a component of accrued compensation on the balance sheet will be paid by June 30, 2015.

	<b>December 31,</b>	
	<b>2014</b>	<b>2013</b>
Balance – beginning	\$ 110,608	\$ —
Accrual for severance	302,758	532,115
Severance payments made	(264,445)	(421,507)
Balance – ending	<u>\$ 148,921</u>	<u>\$ 110,608</u>

Accrued expenses consist of the following for the years ended December 31, 2014 and 2013:

	<b>December 31,</b>	
	<b>2014</b>	<b>2013</b>
Technology fees	\$ 450,000	\$ 450,000
Professional services	257,024	263,642
Consulting fees	173,759	—
Clinical study obligations	74,000	51,424
Sales taxes	34,206	32,688
Personnel related obligations	37,761	12,322
Federal excise tax	25,989	24,600
Other	212,137	35,520
	<u>\$1,264,876</u>	<u>\$ 870,196</u>

**7. Income Taxes**

Current income tax expense (benefit) attributable to continuing operations consists of the following for the years ended December 31, 2014, 2013, and 2012.

	<b>Years Ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
Federal	—	—	—
State	—	—	—
Total	<u>—</u>	<u>—</u>	<u>—</u>

The Company's effective income tax rate differs from the statutory federal income tax rate as follows for the years ended December 31, 2014, 2013, and 2012.

	<b>Years Ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
Federal tax provision (benefit) rate	(34.0)%	(34.0)%	(34.0)%
State tax provision, net of federal provision	(7.0)	(4.8)	(3.5)
Permanent items	(3.6)	3.4	0.8
Federal research and development credits	(1.0)	(1.7)	—
Expiration of tax attribute	10.9	—	—
Valuation allowance	34.7	37.1	36.7
Effective income tax rate	<u>—%</u>	<u>—%</u>	<u>—%</u>

**NeuroMetrix, Inc.**

**Notes to Financial Statements**

**7. Income Taxes – (continued)**

The Company's deferred tax assets consist of the following:

	December 31,	
	2014	2013
Deferred tax assets:		
Net operating loss carryforwards	\$ 35,449,695	\$ 32,253,602
Research and development credit carryforwards	1,855,586	1,735,265
Accrued expenses	657,132	493,075
Stock-based compensation	590,006	565,077
Other	13,506	1,061,212
Total gross deferred tax assets	38,565,925	36,108,231
Valuation allowance	(38,565,925)	(36,108,231)
Net deferred tax assets	\$ —	\$ —

At December 31, 2014, the Company has federal and state net operating loss carryforwards ("NOL") of \$105.4 million and \$24 million, respectively, as well as federal and state tax credits of \$1.2 million and \$1.0 million, respectively, which may be available to reduce future taxable income and the related taxes thereon. This amount includes tax benefits of \$3.9 million and \$71,000 attributable to NOL and tax credit carryforwards, respectively, that result from the exercise of employee stock options. The tax benefit of these items will be recorded as a credit to additional paid-in capital upon realization of the deferred tax asset or reduction in income taxes payable. The federal NOL's begin to expire in 2019 and the state NOL's begin to expire in 2015. The federal and state research and development credits both begin to expire in 2018.

In accordance with the provisions of the Income Taxes topic of the Codification, the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating losses. Management has determined that it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets and, as a result, a valuation allowance of approximately \$38.6 million and \$36.1 million has been established at December 31, 2014 and 2013, respectively. Utilization of the NOL and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future, as provided by Section 382 of the Internal Revenue Code of 1986, as well as similar state provisions. Ownership changes may limit the amount of NOL and tax credit carryforwards that can be utilized to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. If the Company has experienced a change of control, utilization of its NOL or tax credits carryforwards would be subject to an annual limitation under Section 382. Any limitation may result in expiration of a portion of the NOL or research and development credit carryforwards before utilization. Subsequent ownership changes could further impact the limitation in future years. Further, until a study is completed and any limitation known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's 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.

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**Notes to Financial Statements**

**8. Commitments and Contingencies**

*Operating Leases*

In June 2013, the Company amended the lease agreement dated October 18, 2000 between Fourth Avenue LLC and the Company for office and engineering laboratory space to extend the term of the lease through March 31, 2015. Base rent for the period from January 2014 through March 2015 is \$52,917 per month.

The Company plans to relocate its corporate headquarters and operations facilities. In August 2014, the Company entered into a 5-year operating lease agreement with one 5-year extension option for manufacturing and order fulfillment facilities in Woburn, Massachusetts (the "Woburn Lease"). The Woburn Lease commenced December 15, 2014 and has a monthly base rent of \$7,350. In September 2014, the Company entered into a 7-year operating lease agreement with one 5-year extension option for its corporate office and product development activities in Waltham, Massachusetts (the "Waltham Lease"). The term of the Waltham Lease commences on February 20, 2015 and includes fixed payment obligations that escalate over the initial lease term. Average monthly base rent under the 7-year lease is approximately \$37,792. These payment obligations will be accrued and recognized over the term of occupancy such that rent expense is recognized on a straight-line basis. Under the Waltham Lease, the landlord is responsible for making certain improvements to the leased space at an agreed upon cost to the landlord. If the landlord and the Company mutually agree to make improvements that cost in excess of the agreed upon landlord cost, the landlord will bill that excess cost to the Company as additional rent. This additional rent, if and when incurred, will be included in the net calculation of lease payments, so that rent expense will be recognized on a straight-line basis over the remaining term of occupancy.

Future minimum lease payments under non-cancellable operating leases as of December 31, 2014 are as follows:

2015	\$ 594,906
2016	515,722
2017	527,693
2018	539,665
2019	544,285
2020	475,408
2021	487,380
2022	81,562
Total minimum lease payments	<u>\$ 3,766,621</u>

Total recorded rent expense was \$638,679, \$635,004, and \$709,164 for the 2014, 2013, and 2012, respectively. The Company records rent expense on its facility lease on a straight-line basis over the lease term.

*Other Commitments*

At December 31, 2014, other commitments, comprised of purchase orders, totaled approximately \$76,338.

**9. Fair Value Measurements**

The Fair Value Measurements and Disclosures Topic of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification (the "Codification") defines fair value, establishes a framework for measuring fair value in applying generally accepted accounting principles, and expands disclosures about fair value measurements. This Codification topic identifies two kinds of inputs that are used to determine the fair value of assets and liabilities: observable and unobservable. Observable inputs are based on market data or independent sources while unobservable inputs are based on the Company's own market assumptions. Once

**NeuroMetrix, Inc.**

**Notes to Financial Statements**

**9. Fair Value Measurements – (continued)**

inputs have been characterized, this Codification topic requires companies to prioritize the inputs used to measure fair value into one of three broad levels. Fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values identified by Level 2 inputs utilize observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities. Fair values identified by Level 3 inputs are unobservable data points and are used to measure fair value to the extent that observable inputs are not available. Unobservable inputs reflect the Company’s own assumptions about the assumptions that market participants would use at pricing the asset or liability.

The following tables present information about the Company’s assets and liabilities that are measured at fair value on a recurring basis for the periods presented and indicates the fair value hierarchy of the valuation techniques it utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable such as quoted prices, interest rates, and yield curves. Fair values determined by Level 3 inputs are unobservable data points for the asset or liability, and include situations where there is little, if any, market activity for the asset or liability.

	December 31, 2014	Fair Value Measurements at December 31, 2014 Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Cash equivalents	\$ 4,107,478	\$ 4,107,478	\$ —	\$ —
Total	\$ 4,107,478	\$ 4,107,478	\$ —	\$ —
<b>Liabilities:</b>				
Common stock warrants	\$ 5,307,332	\$ —	\$ —	\$ 5,307,332
Total	\$ 5,307,332	\$ —	\$ —	\$ 5,307,332

Due to the lack of market quotes relating to our common stock warrants, the fair value of the common stock warrants was determined at December 31, 2014 using the Black-Scholes model, which is based on Level 3 inputs. As of December 31, 2014, inputs used in the Black-Scholes model are presented below. The assumptions used may change as the underlying sources of these assumptions and market conditions change. Based on the Black-Scholes model, the Company recorded a common stock warrants liability of \$5.3 million at December 31, 2014.

	Black-Scholes Inputs to Warrant Liability Valuation at December 31, 2014					
	Stock Price	Exercise Price	Expected Volatility	Risk-Free Interest	Expected Term	Dividends
<b>Warrants:</b>						
2014 Offering	\$ 1.95	\$ 2.04	71.11%	1.51%	4yr 6mo	none
2013 Offering	\$ 1.95	\$ 2.00	75.71%	1.24%	3yr 5mo	none

The following table provides a summary of changes in the fair value of the Company’s Level 3 financial liabilities between the initial warrant issuances in June 2013 and December 31, 2014.

	2014 Offering	2013 Offering	Total
Balance at December 31, 2012	\$ —	\$ —	\$ —
Initial fair value of warrants at issuance in June 2013	—	4,011,205	4,011,205
Change in fair value of warrant liability	—	289,657	289,657



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**NeuroMetrix, Inc.**

**Notes to Financial Statements**

**9. Fair Value Measurements – (continued)**

	2014 Offering	2013 Offering	Total
Reclassification of liability to additional paid-in capital upon exercise of warrants	—	(2,362,259)	(2,362,259)
Balance at December 31, 2013	\$ —	\$ 1,938,603	\$ 1,938,603
Initial fair value of warrants at issuance in June 2014	4,418,824	—	4,418,824
Change in fair value of warrant liability	(185,095)	(865,000)	(1,050,095)
Balance at December 31, 2014	<u>\$4,233,729</u>	<u>\$ 1,073,603</u>	<u>\$ 5,307,332</u>

	December 31, 2013	Fair Value Measurements at December 31, 2013 Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Cash equivalents	\$ 3,926,600	\$ 3,926,600	\$ —	\$ —
Total	<u>\$ 3,926,600</u>	<u>\$ 3,926,600</u>	<u>\$ —</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Common stock warrants	\$ 1,938,603	\$ —	\$ —	\$ 1,938,603
Total	<u>\$ 1,938,603</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,938,603</u>

Due to the lack of market quotes relating to our common stock warrants, the fair value of the common stock warrants was determined at December 31, 2013 using the Black-Scholes model, which is based on Level 3 inputs. As of December 31, 2013, inputs used in the Black-Scholes model are presented below. The assumptions used may change as the underlying sources of these assumptions and market conditions change. Based on the Black-Scholes model, the Company recorded a common stock warrants liability of \$1.9 million at December 31, 2013.

**Black-Scholes Inputs to Warrant Liability Valuation at December 31, 2013**

	Stock Price	Exercise Price	Expected Volatility	Risk-Free Interest	Expected Term	Dividends
Warrants:						
2013 Offering	\$ 2.92	\$ 2.00	67.60%	1.71%	4yr 5mo	none

**10. Retirement Plan**

The Company has established a 401(k) defined contribution savings plan for its employees who meet certain service period and age requirements. Contributions are permitted up to the maximum allowed under the Internal Revenue Code of each covered employee's salary. The savings plan permits the Company to contribute at its discretion. In 2014, 2013 and 2012 the Company made no contributions to the plan.

**11. Credit Facility**

The Company is party to a Loan and Security Agreement, or the Credit Facility, with a bank. As of December 31, 2014 the Credit Facility permitted the Company to borrow up to \$2.5 million on a revolving basis. The Credit Facility was subsequently amended and extended until January 15, 2016. 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 the Company's cash, accounts receivable, inventory, and equipment. The Credit Facility includes traditional lending and reporting covenants. These include certain financial covenants applicable to liquidity that are to be maintained by the Company. As of December 31, 2014, the Company was in compliance with these covenants and had not borrowed any funds under the Credit Facility. However, \$451,731 of the amount available under the Credit Facility is restricted to support letters of credit issued in

**NeuroMetrix, Inc.**

**Notes to Financial Statements**

**11. Credit Facility – (continued)**

favor of the Company's landlords for its existing premise and the premises leased in September 2014 for its future corporate offices. Consequently, the amount available for borrowing under the Credit Facility as of December 31, 2014 was \$2.0 million.

**12. Stockholders' Equity**

*Public Offerings of Common Stock and Warrants*

During June 2014 and June 2013 the Company entered into securities purchase agreements for two equity offerings that were similar in structure and in terms. The purchase agreement entered into in the 2014 Offering") provided for the issuance of (i) 664,600 shares of common stock at a price of \$2.04 per share, (ii) 2,621,859 shares of Series A-3 Preferred Stock at a price of \$1,000 per share, (iii) 4,022,357 shares of Series A-4 Preferred Stock at a price of \$1,000 per share, and (iv) five year warrants to purchase up to 3,921,569 shares of common stock with an exercise price of \$2.04 per share. The 2014 Offering resulted in approximately \$8.0 million in gross proceeds, before deducting expenses. Net proceeds from the 2014 Offering were approximately \$7.9 million.

The purchase agreement entered into in June 2013 (the "2013 Offering") provided for the issuance of (i) 248,147 shares of common stock at a price of \$2.095 per share, (ii) 1,066,254 shares of Series A-1 Preferred Stock at a price of \$1,000 per share, (iii) 3,370,510 shares of Series A-2 Preferred Stock at a price of \$1,000 per share, and (iv) five year warrants to purchase up to 2,365,934 shares of common stock with an exercise price of \$2.00 per share. The 2013 Offering resulted in approximately \$5.0 million in gross proceeds, before deducting placement agent fees and other expenses. Net proceeds from the 2013 Offering were approximately \$4.5 million.

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

The terms and conditions of the Preferred Stock were evaluated based on the guidance of the Derivatives and Hedging topic of the Codification to determine if the conversion feature was an embedded derivative requiring bifurcation. It was concluded for both equity offerings that bifurcation was not required because the conversion feature was clearly and closely related to the Preferred Stock. The conversion price at which shares of Preferred Stock were convertible into shares of common stock was determined to be lower than the fair value of common stock at the date of the Purchase Agreement. This "in-the-money" beneficial conversion feature, or BCF, required separate recognition and measurement of its intrinsic value (i.e., the amount of the increase in value that holders of Preferred Stock would realize upon conversion based on the value of the conversion shares on the date of the Purchase Agreement). For both equity offerings, the BCF measurement was limited by the transaction proceeds which had been allocated to the Preferred Stock. Because there was not a stated redemption date for the shares of Preferred Stock, the BCF was recognized as a deemed dividend attributable to the Preferred Stock and reflected as an adjustment in the calculation of earnings per share. The amounts of the BCF totaled \$2,955,668 and \$766,900, respectively, for the 2014 Offering and the 2013 Offering.

The Series A-4 Preferred Stock outstanding as of December 31, 2014 is convertible into an aggregate of 1,771,744 shares of common stock. During June and July 2014, all of the shares of the Series A-3 Preferred Stock were converted into 1,285,225 shares of common stock and in October 2014 a portion of the Series A-4 Preferred Stock were converted into 200,000 shares of common stock. All of the Series A-1 Preferred Stock and the Series A-2 Preferred Stock issued in the 2013 Offering was converted in 2013 into a total of 2,117,787 shares of common stock.

**NeuroMetrix, Inc.****Notes to Financial Statements****12. Stockholders' Equity – (continued)**

The Company will continue to revalue unexercised warrants from both the 2014 and 2013 offerings at each reporting period over the life of the warrants using the Black-Scholes model and the changes in the fair value of the warrants will be recognized in the Company's statement of operations. The warrants issued in connection with the 2013 Offering and the 2014 Offering are within the scope of the Derivatives and Hedging topic of the Codification. This Codification topic requires issuers to classify as liabilities (or assets under certain circumstances) financial instruments which require an issuer to settle in registered shares. As the warrants are required to be settled in registered shares when exercised and since the Company is required to pay cash in the event it does not make timely filings with the SEC, the Company reflected the warrants as a liability in the balance sheet.

The fair value of the warrants issued in connection with the 2014 Offering was estimated to be \$4.4 million on the offering date using a Black-Scholes model with the following assumptions: stock price of \$2.00, exercise price of \$2.04, expected volatility of 67.5%, risk free interest rate of 1.64%, expected term of five years, and no dividends. These warrants remain outstanding. They were revalued at December 31, 2014 in the amount of \$4.2 million using the same Black-Scholes model and the liability was reflected in the December 31, 2014 balance sheet.

The 2013 Offering warrants were estimated at a fair value of \$4.0 million on the offering date using a Black-Scholes model with the following assumptions: stock price of \$2.60, exercise price of \$2.00, expected volatility of 73.6%, risk free interest rate of 1.05%, expected term of five years, and no dividends. These warrants were revalued at each subsequent reporting period using the same Black-Scholes model. The liability for the remaining 1,057,323 warrants from the 2013 Offering was reflected in the balance sheet at December 31, 2014 in the amount of \$1.1 million.

In 2014 and 2013, the Company issued shares of fully vested common stock in partial settlement of management incentive compensation. The 2014 issuance totaled 42,615 shares with a value of \$104,400 reflecting the \$2.45 closing price of the Company's common stock as reported on the NASDAQ Capital Market on February 25, 2014. The 2013 issuance totaled 119,370 shares with a value of \$285,300 reflecting the \$2.39 NASDAQ Capital Market closing price on June 4, 2013.

As of December 31, 2014, the Company had 50,000,000 shares of common stock authorized and 8,152,746 shares issued and outstanding. Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are not entitled to receive dividends unless declared by the Board of Directors.

At December 31, 2014, the Company has reserved authorized shares of common stock for future issuance as follows:

Warrants	5,760,847
Outstanding stock options	761,767
Possible future issuance under inducement plan	200,000
Possible future issuance under stock option plans	502,104
Possible future issuance under employee stock purchase plan	124,280
Total	<u>7,348,998</u>

**13. Management Retention and Incentive Plan**

The Company has adopted the Management Retention and Incentive Plan (the "Plan"), under which a portion of the consideration payable upon a change in control transaction, as defined in the Plan and its amendments, would be paid in cash to certain executive officers and key employees and recorded as compensation expense within the Statement of Operations during the period in which the change of control transaction occurs. The Plan is structured to work in conjunction with, and not replace, the Company's other incentive programs and is designed to provide market-based incentives which will be reduced over time by any future equity grants to participants.

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NeuroMetrix, Inc.

Notes to Financial Statements

13. Management Retention and Incentive Plan – (continued)

NeuroMetrix, Inc.

Schedule II — Valuation and Qualifying Accounts

Description	Balance at Beginning of Period	Charged to costs and expenses	Charged to other accounts	Recoveries/ (Deductions)	Balance at End of Period
<b>December 31, 2014</b>					
Allowance for Doubtful Accounts	\$ 35,000	\$ 26,042	\$ —	\$ (23,042)	\$ 38,000
Sales Returns Reserve	895	—	49,114	(48,043)	1,966
Deferred Tax Asset Valuation Allowance	36,108,231	3,280,605	—	(822,911) <sup>(2)</sup>	38,565,925
<b>December 31, 2013</b>					
Allowance for Doubtful Accounts	\$ 130,000	\$ 111,296	\$ —	\$ (206,296) <sup>(1)</sup>	\$ 35,000
Sales Returns Reserve	21,616	—	38,278	(58,999) <sup>(1)</sup>	895
Deferred Tax Asset Valuation Allowance	34,347,467	2,976,809	—	(1,216,045) <sup>(2)</sup>	36,108,231
<b>December 31, 2012</b>					
Allowance for Doubtful Accounts	\$ 286,612	\$ (12,999)	\$ —	\$ (143,613) <sup>(1)</sup>	\$ 130,000
Sales Returns Reserve	13,302	—	180,066	(171,752) <sup>(1)</sup>	21,616
Deferred Tax Asset Valuation Allowance	30,487,085	3,900,388	—	(40,006) <sup>(2)</sup>	34,347,467

(1) Net write-offs.

(2) Expiration of Federal and State Net Operating Loss Carryforwards and other reductions.

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-118059, 333-135242, 333-151195, 333-159712, 333-159713, 333-167180, 333-173769, 333-183071, 333-186827, 333-189383, 333-190177, and 333-197407) and on Form S-3 (Nos. 333-150087, 333-162303, 333-178165, 333-186855, 333-189392, 333-197405 and 333-199359) of NeuroMetrix, Inc. of our report dated February 25, 2015 relating to the financial statements and financial statement schedule, which appears in this Form 10-K. We also consent to the reference to us under the heading "Selected Financial Data" in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts  
February 25, 2015

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**CERTIFICATION**

I, Shai N. Gozani, certify that:

1. I have reviewed this Annual Report on Form 10-K of NeuroMetrix, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2015

/s/ SHAI N. GOZANI, M.D., PH.D.

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

*Chairman, President and Chief Executive Officer*

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## CERTIFICATION

I, Thomas T. Higgins, certify that:

1. I have reviewed this Annual Report on Form 10-K of NeuroMetrix, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2015

/s/ THOMAS T. HIGGINS

Thomas T. Higgins

*Senior Vice President, Chief Financial Officer and Treasurer*

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**CERTIFICATION**

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of NeuroMetrix, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2014 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 25, 2015

/s/ SHAI N. GOZANI, M.D., PH.D.

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

*Chairman, President and Chief Executive Officer*

Date: February 25, 2015

/s/ THOMAS T. HIGGINS

Thomas T. Higgins

*Senior Vice President, Chief Financial Officer and Treasurer*

This certification is being furnished and not filed, and shall not be incorporated into any document for any purpose, under the Securities Exchange Act of 1934 or the Securities Act of 1933.

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