

NeuroMetrix, Inc.  
Form S-1  
April 25, 2013

As filed with the Securities and Exchange Commission on April 25, 2013

**Registration No. 333-**

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

**FORM S-1  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

**NEUROMETRIX, INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

3841  
(Primary Standard Industrial  
Classification Code Number)

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

**62 Fourth Avenue  
Waltham, Massachusetts 02451  
(781) 890-9989**

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

**Shai N. Gozani, M.D., Ph.D.  
Chief Executive Officer  
NeuroMetrix, Inc.  
62 Fourth Avenue  
Waltham, Massachusetts 02451  
(781) 890-9989**

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

*Copies to:*

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

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

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

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

Megan N. Gates, Esq. Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. One Financial Center Boston, MA 02111

offering.

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

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

## CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered <sup>(1)</sup>	Proposed Maximum Aggregate Offering Price <sup>(2)</sup>	Amount of Registration Fee <sup>(3)</sup>
Units consisting of Common Stock and Warrants <sup>(4)(5)(6)</sup>	\$ 15,000,000	\$ 2,046
Common Stock Underlying Units <sup>(4)(5)</sup>		
Warrants Underlying Units <sup>(5)</sup>		
Common Stock Issuable Upon Exercise of Warrants in the Units <sup>(4)</sup>		
<b>Total</b>	<b>\$ 15,000,000</b>	<b>\$ 2,046</b>

The securities registered also include such indeterminate amounts and numbers of shares of common stock issuable (1) to cover additional securities that may be offered or issued to prevent dilution resulting stock splits, stock dividends or similar transactions.

(2) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(o) under the Securities Act of 1933.

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

Pursuant to a shareholder rights agreement, dated as of March 7, 2007, between the Company and American Stock (4) Transfer & Trust Company, as amended, each share of common stock has an attached right to purchase our Series A Junior Cumulative Preferred Stock, which rights are not currently exercisable.

(5) No fee required pursuant to Rule 457 under the Securities Act of 1933.

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

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

**Subject to Completion, Dated April 25, 2013**

**Up to \$10,000,000**

**Units, each consisting of  
Common Stock and Warrants**

We are offering up to \_\_\_\_\_ units, each consisting of \_\_\_\_\_ share(s) of common stock and \_\_\_\_\_ warrant(s). Each warrant entitles the holder to purchase \_\_\_\_\_ share(s) of our common stock. The shares of common stock and warrants will immediately separate after purchase and will be issued separately. The warrants are exercisable at an exercise price of \$ \_\_\_\_\_ per share ( \_\_\_\_\_ % of the aggregate offering price for a unit) for a five year term. We are not required to sell any specific dollar amount or number of units but will use our best efforts to sell all of the units being offered.

Our common stock is listed on the NASDAQ Capital Market under the symbol NURO. We do not intend to apply to list the warrants on any securities exchange. The last reported sale price of our common stock on the NASDAQ Capital Market on April 24, 2013 was \$2.12 per share.

**Investing in our common stock and warrants involves risks. See Risk Factors beginning on page 11.**

	Per Unit	Total
Offering price per unit	\$	\$
Placement agent's fees	\$	\$
Offering proceeds, before expenses, to NeuroMetrix	\$	\$

We intend to engage a placement agent for this offering. We anticipate that such placement agent will not purchase or sell any units, nor will they be required to arrange for the purchase and sale of any specific number or dollar amount of units, other than to use their best efforts to arrange for the sale of units by us. We have not arranged to place the funds in an escrow, trust or similar account.

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

We expect to deliver the securities to investors on or about \_\_\_\_\_, 2013.

**The date of this prospectus is , 2013.**

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You should rely only on the information contained or incorporated by reference in this prospectus and any free-writing prospectus prepared by or on behalf of us or to which we have referred you. Neither we nor the placement agent have authorized anyone to provide you with additional or different information. We are offering to sell, and are seeking offers to buy these securities only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our securities.

**Registered Trademarks and Trademark Applications:** NEUROMETRIX , NC-STAT , ADVANCE , SENSUS , 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 prospectus are the property of their respective owners. Solely for convenience, the trademarks, service marks and trade names referred to in this prospectus are without the ® and ™ symbols, but such references are not intended to indicate, in any way, that the owner thereof will not assert, to the fullest extent under applicable law, such owner's rights to these trademarks, service marks and trade names. This prospectus contains additional trade names, trademarks and service marks of other companies, which, to our knowledge, are the property of their respective owners.

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

On February 15, 2013 we completed a 1-for-6 reverse split of our common stock. Throughout this prospectus we have adjusted historical per share data, as well as data related to common stock, options and warrants to reflect the effects of this reverse split.

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## PROSPECTUS SUMMARY

*This summary highlights selected information contained in greater detail elsewhere in this prospectus or incorporated by reference into this prospectus. This summary may not contain all of the information that you should consider before investing in the units and the common stock and warrants included in the units. You should carefully read the entire prospectus, including Risk Factors beginning on page 11 and the financial statements and related notes and other documents incorporated by reference into this prospectus, before making an investment decision. As used in this prospectus, references to we, our, us and NeuroMetrix refer to NeuroMetrix, Inc. unless the context requires otherwise.*

### Our Business and Opportunity

We are a medical device company focused on the treatment of the neurological complications of diabetes. People with diabetes do not effectively regulate their blood glucose, or sugar, levels leading to chronically high levels of glucose in the blood, called hyperglycemia, and occasionally bouts of low glucose in the blood, called hypoglycemia. The primary reason that glucose levels are not effectively regulated in people with diabetes is that those with the disease do not produce insulin (Type I diabetes) or are resistant to the normal physiological action of insulin (Type II diabetes). Many Type II diabetics eventually require insulin because production of the hormone by their pancreas decreases with time. Type I diabetes usually affects children and teenagers whereas Type II diabetes has typically been a disease of adults over the age of 50. However, over the past decade, Type II diabetes is occurring in younger adults, which can probably be attributed to higher levels of obesity in this age group.

Diabetes is a worldwide epidemic. Recent studies estimate the worldwide prevalence of diabetes to be over 350 million people, of which approximately 90% are of the Type II variety. Within the United States, there are over 25 million people with diabetes and another 80 million people with pre-diabetes, which represents a constellation of conditions such as obesity and high triglyceride levels that are likely to progress to diabetes. In the United States, the annual cost of treating diabetes is over \$100 billion. Although there are dangerous acute manifestations of diabetes, the primary burden of the disease is in the long term complications of chronic hyperglycemia. These complications include among other things cardiovascular disease, nerve disease and resulting pathological conditions such as foot ulcers and amputation, eye disease leading to blindness, and kidney failure.

The most common long-term complication of diabetes, which affects over 50% of the diabetic population, is nerve disease or diabetic neuropathy. There are different forms of diabetic neuropathy; the most common are diabetic peripheral neuropathy, or DPN, carpal tunnel syndrome, or CTS, and autonomic neuropathy. DPN is a systemic nerve disease that is worse in the feet and lower legs. It may lead to loss of sensation in the feet, severe pain in the feet and legs, and increased risk of falling. DPN is the primary trigger for diabetic foot ulcers which may progress to the point where amputation is required. People with diabetes have a 15% to 25% lifetime risk of developing a foot ulcer and 15% of foot ulcers lead to amputation. Foot ulcers are among the most expensive complications of diabetes, with a typical cost of \$5,000 to \$50,000 per episode. Between 16% and 26% of people with diabetes suffer from pain of the feet and lower legs due to painful diabetic neuropathy, or PDN, which is caused by DPN. In addition to causing pain that is often severe, PDN may interfere with sleep and is also associated with anxiety and depression. Loss of sleep is particularly concerning because sleep deprivation is associated with insulin resistance and worse glycemic control, and thereby exacerbates diabetes severity. CTS is caused by focal damage to the median nerve as it passes from the forearm into the hand, through the wrist. When the median nerve is compressed it can lead to symptoms in the hand including pain, numbness, and loss of strength. Autonomic neuropathy is a systemic disease of the autonomic nerves, which regulate the heart, digestion, sexual function, and other essential bodily functions. Damage to these nerves leads

to a host of clinical complications that include an increased risk of sudden death, elevated risk of stroke, digestion difficulties and impotence.

Most people with diabetes receive health care attention in primary care settings where physicians have limited access to sophisticated diagnostic tools to detect diabetic neuropathy early and monitor its progress and response to treatment. As a result, they rely primarily on clinical examination of patients which, although it is an important part of the evaluation of a patient with diabetes, has limited sensitivity and specificity and can usually only detect later stage disease where treatment options and efficacy are compromised.

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Early detection of DPN is particularly important because there are no treatment options once the nerves have degenerated. At the present time, the most widely used and recommended diagnostic method for DPN is the 5.07/10-g monofilament test. This test assesses the patient's ability to detect focal pressure application in the foot. The inability to detect a monofilament indicates that the patient lacks adequate sensation to protect their feet from mechanical insults that can lead to foot ulcers; a condition known as loss of protection sensation, or LOPS. Although the monofilament is an important clinical test, it is insensitive to early DPN where interventions may slow or even halt further nerve damage. Nerve conduction studies, or NCS, are objective electrical tests of nerve function. They are considered the gold standard diagnostic method for DPN and can detect mild nerve damage before it is expressed as clinical symptoms. NCS have typically been provided by specialists using expensive equipment and therefore access has been limited, particularly for common conditions such as DPN.

Currently, there are limited treatment options for diabetic neuropathies. There are no approved disease modifying treatments for DPN, although a few pharmacological candidates are in clinical trials. One such drug is Ranirestat, an aldose reductase inhibitor being developed in the United States by Eisai Co., Ltd., which has recently completed a large scale Phase III clinical trial. If trial results are successful, Eisai could submit a FDA new drug application as early as 2014. If Ranirestat becomes commercially available, it may expand the demand for early detection and monitoring of DPN. In the absence of targeted therapies, several large studies have shown that reducing hyperglycemia lowers the risk of developing DPN and decreases its severity. There is also observational data that suggests that a reduction in triglyceride levels slows the progression of DPN. Several drugs, such as duloxetine and pregabalin, have been approved to provide pain relief in patients with PDN. Unfortunately, these drugs, which are also anti-depressants or anti-seizure medications, have systemic effects and are therefore often associated with side effects. In the case of PDN and/or DPN, it is essential to intervene before extensive nerve degeneration has occurred.

## **Our Strategy**

We believe that there are large and important unmet needs in the treatment of diabetic neuropathies. As a medical device company with both unique and substantial experience in devices to measure and alter peripheral nerve function, we believe we are in the unique position to address these unmet needs through the development of novel proprietary medical devices. Therefore, we are focused on developing and marketing medical devices for the diagnosis and treatment of diabetic neuropathies. We believe that we are the only medical device company with a strategic focus on the diabetic neuropathy market and our goal is to be the dominant player in this field.

Our key business strategies for 2013 by which we intend to advance our objectives in the diabetic neuropathy market include:

***Driving Commercial Adoption of Our Proprietary Products for Diabetic Neuropathy in the United States.*** Our two primary products that target the diabetic neuropathy market are the following:

**SENSUS**, our therapeutic device for relief of chronic, intractable pain, was launched in January 2013. We believe this product will be attractive to pain medicine physicians, neurologists, endocrinologists, podiatrists, primary care physicians, and other physicians that are challenged with trying to manage pain in their patients with PDN and other forms of neuropathic pain. The prevalence of PDN indicates a patient group of 3 to 5 million in the United States alone. We estimate the wholesale market for SENSUS is characterized by the 50% of patients with either severe pain or sleep interference due to PDN. This represents an annual revenue potential in excess of \$300 million. We also believe that there are international market opportunities, particularly in Europe and Japan. In the US, SENSUS is a prescription product and our initial challenge will be to obtain broad, national exposure and acceptance among physicians as well as a broad distribution channel to fulfill prescriptions. We are working to create demand in several

distinct channels: independent regional and national durable medical equipment, or DME, suppliers that employ sales representatives who detail physicians, large direct sale customers such as orthotic and prosthetic clinics and chronic pain treatment centers, and national diabetes mail order DME s. As of April 25, 2013, we had ten regional DME suppliers. We believe there may be future opportunities to expand the SENSUS revenue and gross margin potential by developing a direct sales channel.

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**NC-stat DPNCheck**, our diagnostic test for DPN, has now been on the market for over eighteen months since its launch in late 2011. Revenues for fiscal year 2012 were nearly \$1.5 million, an increase from \$0.1 million in fiscal year 2011. Importantly, we tested product acceptance in several domestic market segments and have focused on the managed care market as the most attractive near-term revenue opportunity. Within managed care, we are specifically targeting Medicare Advantage providers. Medicare Advantage providers assume financial responsibility and the associated risks for the health care costs of their patients. For Medicare Advantage providers, we believe that NC-stat DPNCheck presents a compelling 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 NC-stat 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. The Medicare Advantage market encompasses approximately 15 million covered lives or about 27% of the total Medicare population. We believe that about one-third of these patients have diabetes and that up to 25% of that sub-population could be tested in a given year. This represents an annual potential market of approximately \$20 million. We also believe that there are attractive international market opportunities, particularly in Europe, Japan, South Korea and in some developing countries. We have a small, senior level commercial operations team focused on developing this market.

***Continuing the Productivity of Our Research and Development Pipeline.*** During the past eighteen months we have established a new presence in DPN and PDN through the launch of NC-stat DPNCheck in late 2011 followed by the SENSUS launch in early 2013. We believe that we can enhance SENSUS market penetration by providing unique functionality related to use of the device during nighttime sleep, as half of people with PDN report that the condition interferes with their sleep. Sleep impairment is associated with insulin resistance, worsening of glycemic control, and exacerbation of the severity of diabetes. We are developing and intend to launch a sleep-enabled version of SENSUS. We have also started to develop a second generation version of SENSUS that will have a lower profile and will utilize radio frequency identification (RFID) tags in the disposable electrodes. The RFID tags will help patients manage the electrode replacement cycle and prevent other manufacturers from selling electrodes for the SENSUS device. Additionally, we believe there are opportunities to develop a second generation version of NC-stat DPNCheck. This device would improve on the first generation device by incorporating a larger and more intuitive display and by incorporation of RFID tags in the disposable biosensors. The RFID tags would allow us to precisely control biosensor reuse and to lock out biosensors from other manufacturers should such competition emerge in the future.

***Commercializing NC-stat DPNCheck in Select International Markets Using a Distribution Network.*** We are targeting select international markets where we believe that the combination of a high prevalence of diabetes plus support from the local payer system will support NC-stat DPNCheck and, eventually, SENSUS. This includes countries in Western Europe, including Germany and the Netherlands, where we have both CE marking for NC-stat DPNCheck and established distribution, as well as East Asia, where we recently entered into distribution partnerships with Handok Pharmaceuticals for South Korea and Omron Healthcare Company, Ltd. for Japan. While our resources committed to this effort are modest, we believe that this approach could contribute meaningful revenue in 2013 while positioning us for international growth in subsequent years.

***Leveraging a More Efficient Operating Structure with Future Revenue Growth.*** During 2012, we modified our operating structure to focus more narrowly on the high-value opportunities for SENSUS and NC-stat DPNCheck that can be pursued via independent distributors and a small commercial operations team. This has reduced our operating expenses and, more significantly, improved our future flexibility to generate increased sales volume without the cost of adding sales representatives and field clinical support. Our operating expenses during 2012 totaled \$14.0 million and we forecast 2013 operating expenses to be in the range of \$11 to \$12 million, a reduction of 14% to 21%. We believe we can maintain and leverage this approximate operating expense level over the next several years as our diabetes business grows.

***Managing Our Legacy Neurodiagnostics Business to Optimize Cash Flow.*** Our historical neurodiagnostics business generated \$6.1 million in revenue during 2012 with gross margins exceeding 50%.

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There are few direct cash operating expenses of our neurodiagnostics business. Two years ago we shifted our strategic focus toward more attractive opportunities in diabetes care and we determined that we would manage this legacy neurodiagnostic business for its cash contribution rather than growth. This decision was primarily due to changes in the reimbursement environment which were challenging and presented few practical alternatives. We see the legacy business continuing to decline as we operate it for cash flow. See Legacy Neurodiagnostics Business.

## **Our Business Model**

We develop and market neurodiagnostic systems which typically consist of a medical device plus single patient-use biosensors or electrodes. Other accessories are also offered to our customers. Our goal for these systems is to build an installed base of active customer accounts and distributors that regularly reorder consumables 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 and, more recently, to the ADVANCE NCS/EMG System. The planning for our diabetes care pipeline, including SENSUS, NC-stat DPNCheck, and other products in development, is based on the device plus consumables business model.

## **Marketed Products**

### SENSUS

The SENSUS Pain Management System is a transcutaneous electrical nerve stimulator, or TENS, designed for relief of chronic, intractable pain, such as PDN. We believe that SENSUS will be attractive to pain medicine physicians, neurologists, endocrinologists, podiatrists, and primary care physicians that are challenged with trying to manage pain in their patients with PDN. We have used our unique expertise in peripheral nerve stimulation in the development of SENSUS which incorporates several proprietary features for ease of patient use and physician reporting. 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.

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**NC-stat DPNCheck**

NC-stat 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. NC-stat 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.

**ADVANCE System**

The ADVANCE NCS/EMG System, or the ADVANCE System, 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 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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## **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 clinical trials sanctioned by the Food and Drug Administration, or FDA, for pharmacological agents and large scale epidemiological studies sponsored by the National Institute of Health, or NIH, the 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 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, the U.S. Centers for Medicare and Medicaid Services, or CMS, included in the Physician Fee Schedule a new Category 1CPT Code (95905) for nerve conduction studies performed using preconfigured electrodes 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 products. This experience was reflected in our revenues which peaked in 2006 at \$55.3 million. We have reported revenue from this business of \$13.9 million in 2010, \$10.3 million in 2011, \$6.1 million in 2012, and for the three month periods ended March 31, 2012 and 2013, reported revenue of \$1.9 million and \$1.1 million, respectively.

As we managed our general purpose neurodiagnostic business to improve reimbursement and minimize customer erosion, we increasingly became aware of the unmet medical need for improved diagnostic tools and therapies in the specific area of diabetic neuropathy. Diabetes care is one of the fastest growing sectors of health care as discussed above. We believe that our tools and therapies for addressing diabetic neuropathy represent a significant market opportunity. Consequently, in January 2011 we announced a shift to diabetes care as our primary business focus. We also restructured our neurodiagnostics business to consolidate functions and to eliminate our direct sales force. We emphasized our commitment to supporting our neurodiagnostic products and installed base of physician accounts. Our objective for our legacy neurodiagnostics business is to maintain a high standard of product support while managing the business to optimize cash flow.

## **Risks Affecting Us**

Our business is subject to numerous risks, as discussed more fully in the section entitled "Risk Factors" immediately following this prospectus summary. At March 31, 2013 we had an accumulated deficit of \$140.8 million and held cash

and cash equivalents of \$6.9 million. We believe that these resources and the cash to be generated from expected product sales will be sufficient to meet our projected operating requirements at least into the first quarter of 2014. We continue to face significant challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected. Accordingly, we will need to raise additional funds to support our operating and capital needs in the first quarter of 2014 and beyond. However, we may not be able to secure such financing in a timely manner or on



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favorable terms, if at all. Without additional funds, we may be forced to delay, scale back or eliminate some of our sales and marketing efforts, research and development activities, or other operations and potentially delay product development in an effort to provide sufficient funds to continue our operations.

## **Our Corporate Information**

Our President and Chief Executive Officer, Shai N. Gozani, M.D., Ph.D. founded NeuroMetrix in June 1996. We originally were incorporated in Massachusetts in 1996, and we reincorporated in Delaware in 2001. Our common stock is listed on the NASDAQ Capital Market under the ticker symbol NURO. Our principal offices are located at 62

Fourth Avenue, Waltham, Massachusetts 02451 and our telephone number is (781) 890-9989. Our web site is [www.neurometrix.com](http://www.neurometrix.com). We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this document. Our web site address is included in this document as an inactive textual reference only. The NeuroMetrix name and logo and the names of products and services offered by NeuroMetrix are trademarks, registered trademarks, service marks or registered service marks of NeuroMetrix.

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## The Offering

### Securities offered

Up to units. Each unit will consist of share(s) of common stock and warrant(s). Each warrant entitles its holder to purchase shares of our common stock. The shares of common stock and warrants will immediately separate upon issuance.

### Offering price

An assumed price of \$ per unit, which is the closing price of our common stock on , 2013. This assumed offering price per unit is used throughout this prospectus each time the price per unit is stated.

### Description of the warrants

The warrants will be exercisable at any time until the fifth anniversary of the closing date at an exercise price of \$ per share ( % of the aggregate offering price for a unit).

### Common stock outstanding before this offering

2,260,195 shares

### Common stock to be outstanding after this offering

shares, assuming shares are issued in this offering, which does not include shares of common stock issuable upon exercise of the warrants included in the offering units.

### Use of proceeds

We intend to use the net proceeds of this offering for general corporate purposes, including continuing our commercialization efforts for NC-stat DPNCheck and SENSUS and development of our product candidates. See Use of Proceeds for additional information.

### Risk factors

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

### NASDAQ Capital Market symbol

NURO

The number of shares of our common stock that will be outstanding immediately after this offering is based on 2,260,195 shares outstanding as of March 31, 2013 and excludes the following:

781,955 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2013, at a weighted average exercise price of \$6.95 per share;

50,834 shares of common stock issuable upon the exercise of options outstanding as of March 31, 2013, at a weighted average exercise price of \$73.99 per share;

177,494 shares of common stock available for future issuance under our 2004 Stock Option and Incentive Plan as of March 31, 2013;

11,806 shares of common stock available for future issuance under our 2009 Non-qualified Inducement Stock Plan as of March 31, 2013;

21,765 shares of common stock available for future issuance under our 2010 Employee Stock Purchase Plan as of March 31, 2013; and

up to shares of common stock issuable upon the exercise of the warrants included in the units to be sold in this offering.

The information in this prospectus reflects a 1-for-6 reverse stock split completed on February 15, 2013.

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The following tables summarize our financial data for the periods presented. The summary statement of operations data and balance sheet data for each of the years ended December 31, 2012, 2011, 2010, 2009, and 2008 have been derived from our audited financial statements. The audited financial statements for the years ended December 31, 2012, 2011, and 2010, and the report thereon, were included in our Annual Report on Form 10-K for the year ended December 31, 2012, which is incorporated by reference into this prospectus. The summary statement of operations data for the three months ended March 31, 2013 and 2012 and summary balance sheet data as of March 31, 2013 have been derived from our unaudited financial statements, which were included in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, which is incorporated by reference into this prospectus. The pro forma balance sheet data gives effect to the sale of units offered by this prospectus at an assumed aggregate offering amount of \$ , based on an assumed offering price of \$ per unit and after deducting estimated placement agent fees and offering expenses payable by us. Our historical results are not necessarily indicative of the results to be expected for any future periods.

You should read this data together with the financial statements and related notes incorporated by reference into this prospectus, as well as Management's Discussion and Analysis of Financial Condition and Results of Operations and the other financial information in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, which are incorporated by reference into this prospectus.

	Years Ended December 31,					Three Months Ended March 31,	
	2012	2011	2010	2009	2008	2013	2012
	(In thousands, except per share data)						
Statement of operations data:							
Revenues	\$7,575	\$10,397	\$13,900	\$26,137	\$31,121	\$1,401	\$2,082
Cost of revenues	3,589	4,722	7,050	7,536	9,012	570	1,135
Gross profit	3,986	5,675	6,850	18,601	22,109	831	947
Loss from continuing operations <sup>(1)</sup>	(10,008)	(9,981)	(17,012)	(11,918)	(21,129)	(2,253)	(2,752)
Loss from discontinued operations <sup>(2)</sup>					(6,601)		
Net loss <sup>(1)</sup>	\$(10,008)	\$(9,981)	\$(16,891)	\$(11,918)	\$(27,730)	\$(2,253)	\$(2,752)
Net loss per common share from continuing operations, basic and diluted <sup>(3)</sup> :							
Net loss per common share from discontinued operations, basic and diluted <sup>(3)</sup> :							
Net loss per common share, basic and diluted <sup>(3)</sup> :							
	\$(5.22)	\$(15.53)	\$(26.41)	\$(25.56)	\$(55.38)	\$(1.06)	\$(1.99)
	\$	\$	\$	\$	\$(17.28)	\$	\$
Net loss per common share, basic and diluted <sup>(3)</sup> :	\$(5.22)	\$(15.53)	\$(26.41)	\$(25.56)	\$(72.66)	\$(1.06)	\$(1.99)

Includes a \$5,175 warrants fair value adjustment expense in 2009. Includes the following unusual items in 2008:  
(1) goodwill impairment (\$5,833); legal settlement (\$3,706); intangible asset impairment (\$1,768); gain from deconsolidation of joint venture (\$2,100); and loss on available-for-sale investment (\$2,500).

In December 2007, we acquired substantially all of the assets of EyeTel Imaging, Inc., or EyeTel, and their product, the DigiScope, a product used for the detection of eye disorders such as diabetic retinopathy. On  
(2) September 30, 2008, we approved a plan to discontinue sales and support of DigiScopes and DigiScope related services, effective November 1, 2008. On November 7, 2008, we sold substantially

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all of the assets related to the DigiScope business to Advanced Diagnostics, LLC in exchange for assuming certain identified commitments of approximately \$400 and a cash payment of \$50.

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

	As of December 31,					As of
	2012	2011	2010	2009	2008	March 31, 2013
	(In thousands)					
Balance sheet data:						
Cash, cash equivalents, and short-term investments	\$8,699	\$10,290	\$16,987	\$30,432	\$19,797	\$6,886
Working capital <sup>(4)</sup>	8,567	10,482	19,020	34,374	21,632	6,688
Total assets	10,877	14,221	23,066	40,567	31,147	8,891
Total liabilities	2,077	3,132	2,867	4,857	8,314	1,996
Total stockholders equity	8,800	11,089	20,199	35,710	22,833	6,895

	As of March 31, 2013	
	Actual	Pro forma
	(In thousands)	
Pro forma balance sheet effects of this offering:		
Cash, cash equivalents, and short-term investments	\$6,886	\$
Working capital <sup>(4)</sup>	6,688	
Total assets	8,891	
Total liabilities	1,996	
Total stockholders equity	6,895	

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

The following table represents certain unaudited quarterly information for each of the four quarters in the years ended December 31, 2012 and 2011 and the quarter in the interim period ended March 31, 2013. In our opinion, this information has been prepared on the same basis as the audited financial statements incorporated by reference into this prospectus and includes all the adjustments necessary for a fair statement of the unaudited quarterly results of operations (in thousands, except per share data).

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2013:				
Net loss	\$(2,253)	N/A	N/A	N/A
Basic and diluted net loss per share	\$(1.06 )	N/A	N/A	N/A
2012:				
Net loss	\$(2,752)	\$(2,772)	\$(2,610)	\$(1,873)
Basic and diluted net loss per share <sup>(1)</sup>	\$(1.99 )	\$(1.32 )	\$(1.24 )	\$(0.89 )
2011:				
Net loss	\$(2,697)	\$(2,437)	\$(2,431)	\$(2,416)
Basic and diluted net loss per share <sup>(1)</sup>	\$(4.20 )	\$(3.80 )	\$(3.78 )	\$(3.76 )

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

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## RISK FACTORS

*Investing in our units, common stock and warrants involves a high degree of risk. You should carefully consider the following risk factors and all other information contained in or incorporated by reference into this prospectus before purchasing our units, common stock and warrants. If any of the following risks were to occur, our business, financial condition or results of operations could be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose some or all of your investment.*

### Risks Related to Our Business

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

We have incurred significant cumulative net losses since our inception. Our net losses for the three month period ended March 31, 2013 and for the years ended December 31, 2012, 2011, and 2010 were approximately \$2.3 million, \$10.0 million, \$10.0 million, and \$16.9 million, respectively, reflecting a decline in revenues. At March 31, 2013, we had an accumulated deficit of approximately \$140.8 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.

**We will be required to raise additional funds to finance our operations and remain a going concern; we may not be able to do so when necessary, and/or the terms of any financings may not be advantageous to us.**

We held cash and cash equivalents of \$6.9 million as of March 31, 2013. We believe that these resources and the cash to be generated from expected product sales will be sufficient to meet our projected operating requirements at least into the first quarter of 2014. 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 in the first quarter of 2014 and beyond. We may attempt to obtain additional funding through public or private financing, collaborative arrangements with strategic partners, or through additional credit lines or other debt financing sources to increase the funds available to fund operations. However, we may not be able to secure such financing in a timely manner or on favorable terms, if at all. Furthermore, if we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges 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.

**In January 2011, we shifted our business focus to diabetes care. We cannot assure you that we will be successful in this field or that our initial commercial products for diabetes care, NC-stat DPNCheck and SENSUS, or the**

**products in our development pipeline, will be successful.**

Our strategic focus is diabetes care. Our initial diabetes care product, NC-stat DPNCheck which was launched in late 2011, is a fast, accurate, and quantitative nerve conduction test for systemic neuropathies, such as DPN. In January 2013, we launched SENSUS, our pain management therapeutic device for relief of chronic, intractable pain. We also have other products in our development pipeline. Our future prospects are closely tied to our success with our NC-stat DPNCheck and SENSUS devices which, in turn, depends upon market acceptance and growth in future revenues. We cannot assure you that our diabetes care strategy,



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including the commercialization of our current products and other products in our development pipeline, will be successful. If our diabetes care 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 secure broad, national distribution for SENSUS among independent DME suppliers;  
inability to increase adoption of NC-stat DPNCheck within the Medicare Advantage market;  
decreased rates of patient visits to physicians;  
unfavorable changes to current Medicare and commercial payer payment policies;  
unfavorable experiences by patients and physicians using SENSUS; and  
physicians' reluctance to alter their existing practices.

If we are unable to expand exposure and penetrate the market for NC-stat DPNCheck and SENSUS, our ability to increase our revenues will be limited and our business prospects will be adversely affected.

**We currently rely on sales of the products that comprise the ADVANCE System to generate a substantial 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 sophisticated nerve conduction testing system, in June 2008. For the year ended December 31, 2012, \$6.1 million of our \$7.6 million in total revenue was attributed to the ADVANCE System.

We continue to derive a substantial portion of our revenues from sales of the products that comprise this system, particularly from electrodes. We expect that sales of ADVANCE System products will constitute more than half of our sales during 2013. Accordingly, our ability to generate revenues in the short-term is dependent on our ability to market and sell the products that comprise the ADVANCE System, particularly electrodes. Our sales of these products may be negatively impacted by many factors, including:

changes in reimbursement rates or policies relating to our products 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, our ability to generate revenues from the ADVANCE System could be significantly reduced.

**If health care providers are unable to obtain sufficient reimbursement or adjustment to capitated premium payments 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 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 our products, if managed care organizations do not receive improved capitated payments due to more accurate patient risk assessment using our products, and if DME suppliers are not adequately reimbursed for supplying our therapeutic products, we may be unable to sell our products at levels that are sufficient to allow us to achieve and maintain profitability, and our business would suffer significantly. Additionally, even if these products and procedures are adequately reimbursed by third-party payers today, adverse changes in payers' future policies toward payment would harm our ability to market and sell our products. Third-party payers include those governmental programs such as Medicare and Medicaid, private health insurers, workers' compensation

programs and other organizations.

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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, 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, cannot be predicted.

**We are subject to extensive regulation by the FDA which could restrict the sales and marketing of the NC-stat DPNCheck and SENSUS 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 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;



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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 NC-stat DPNCheck and SENSUS 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 entered into exclusive manufacturing and supply agreements with Parlex Polymer Flexible Circuits, Inc. for the manufacture of the biosensors for nerve conduction testing for our domestic market. Katecho, Inc. manufactures biosensors for use with our NC-stat DPNCheck devices in international markets and also manufactures electrodes for SENSUS, and Sunburst EMS, Inc. manufactures electronic boards and other components of our NC-stat DPNCheck and SENSUS products, which we assemble at our corporate headquarters 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.

**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.

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**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.**

In January 2011, we shifted our strategy to focus on diabetes care, specifically unmet medical needs related to DPN which is the most common complication of diabetes. Since then, we have advanced SENSUS and NC-stat DPNCheck through our product development pipeline to the market. We plan to introduce improvements to both SENSUS and to NC-stat DPNCheck in future periods. 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.

**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;

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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.  
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:

the agreements may be breached or not enforced in a particular jurisdiction;  
we may have inadequate remedies for any breach;  
trade secrets and other proprietary information could be disclosed to our competitors; or  
others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technologies.  
If, for any of the above reasons, our intellectual property is disclosed or misappropriated, it would harm our ability to protect our rights and our competitive position.

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

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

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

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

valuable. The occurrence of any of these events could harm our business, our ability to compete in the market or our reputation.

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

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

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

A federal law commonly known as the federal anti-kickback law, and several similar state laws, prohibit the payment of any remuneration that is intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of health care products or services. These laws constrain a medical device company's sales, marketing and other promotional activities by limiting the kinds of business relationships and financial arrangements, including sales programs we may have with hospitals, physicians or other potential purchasers of medical devices. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment to Medicare, Medicaid or other third-party payers that are false or fraudulent, or for items or services that were not provided as claimed. From time to time, we may provide coding and billing information as product support to purchasers of our products. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance, which can be quite substantial including exclusion from participation in federal health care programs. A number of states have enacted laws that require pharmaceutical and medical device companies to monitor and report payments, gifts and other remuneration made to physicians and other health care professionals and health care organizations. Some state statutes, such as the one in Massachusetts, impose an outright ban on gifts to physicians. These laws are often referred to as gift ban or aggregate spend laws and carry substantial fines if they are violated. Similar legislation, known as the Physician Payments Sunshine Act, has been introduced in Congress each year for the past several years but has not yet been enacted. 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.

In February 2009, we announced that we had reached a resolution with the United States Department of Justice, or DOJ, and the Office of Inspector General, or OIG, 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. As part of the resolution with the DOJ and OIG, we entered into a three-year Deferred Prosecution Agreement with the DOJ and a five-year Corporate Integrity Agreement with the OIG. The Deferred Prosecution

Agreement has now expired. However, failure to comply with the terms of the Corporate Integrity Agreement could result in substantial civil or criminal penalties and being excluded from government health care programs, which could materially reduce our sales and adversely affect our financial condition and results of operations.

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**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 NC-stat and ADVANCE systems, NC-stat DPNCheck, and SENSUS products may be susceptible to claims of injury because their use involves the electric stimulation of a patient's nerves. Although we maintain product liability insurance for our products and other commercial insurance, the coverage limits of these policies may not be adequate to cover future claims. As sales and use of our products increase, we may be unable to maintain sufficient product liability or other commercial insurance on acceptable terms or at reasonable costs, and this insurance may not provide us with adequate coverage against potential liabilities. A successful claim brought against us in excess of, or outside of, our insurance coverage could have a material adverse effect on our financial condition and results of operations. A product liability claim, regardless of its merit or eventual outcome, could result in substantial costs to us, a substantial diversion of management attention and adverse publicity. A product liability claim could also harm our reputation and result in a decline in revenues and an increase in expenses.

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

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

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

- loss of customer orders and delay in order fulfillment;
- damage to our brand reputation;
- increased cost of our warranty program due to product repair or replacement;
- inability to attract new customers;

diversion of resources from our manufacturing and research and development departments into our service department; and

legal action.

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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 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; Krishnamurthy Balachandran, our Senior Vice President and Chief Operating Officer, Commercial; Guy Daniello, our Senior Vice President of Information Technology; and Michael Williams, Ph.D., our Senior Vice President of Engineering and Chief Technology Officer. We do not maintain key person life insurance policies covering any of our employees. The loss of any of our 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 35 employees as of March 31, 2013, 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 our business has recently faced. 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 SENSUS and NC-stat 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.

**We currently compete, and may in the future need to compete, against other medical device companies with potentially 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. We 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.

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As we develop the market for diagnosis and treatment of diabetic neuropathy, we may be faced with competition from these companies or others that decide and are able to enter this market. Some or all of our future competitors in the diabetes care market 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.

**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 7% of our revenues in 2012. We are working to expand market penetration, particularly in Europe and 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;

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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 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;



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difficulties in transitioning and maintaining key customer, distributor and supplier relationships; risks associated with entering markets in which we have no or limited prior experience; and unanticipated costs.

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

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

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

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

## **Risks Relating to Owning Our Common Stock**

**As 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 February 2012 and any additional sales of shares of our common stock and other securities exercisable into our common stock are likely to have a dilutive effect on some or all of our then existing stockholders. Resales of newly issued shares in the open market could also have the effect of lowering our stock price, thereby increasing the number of shares we may need to issue in the future to raise the same dollar amount and consequently further diluting our outstanding shares.

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

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

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

The trading price of our common stock has been highly volatile. Since our public offering in July 2004 through March 31, 2013 our stock price has fluctuated from a low of \$1.98 to a high of \$1,450.34. 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;

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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.

**We have previously failed to satisfy certain continued listing requirements on NASDAQ and 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. We have previously 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 March 31, 2013 as reported by NASDAQ was approximately 24,000 shares. Limited trading volume may subject our common stock to greater price volatility and may make it difficult for investors to sell shares at a price that is attractive to them.

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**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.

**We do not intend to pay cash dividends.**

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

## **Risks Related To This Offering**

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

Substantially all of our net proceeds from this offering will be used, as determined by management in its sole discretion, to continue work toward commercialization of our SENSUS and NC-stat DPNCheck products, for research and development activities and for working capital and other general corporate purposes. Our management will have broad discretion over the use and investment of the net proceeds of this offering. The failure of our management to



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

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**There is no public market for the warrants to purchase common stock in this offering.**

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

Without an active market, the liquidity of the warrants will be limited.

If the registration statement covering the shares issuable upon exercise of the warrants contained in the units is no longer effective, the unit warrants may only be exercised on a cashless basis and will be issued with restrictive legends unless such shares are eligible for sale under Rule 144 of the Securities Act of 1933, as amended.

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

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

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## **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

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

Risk Factors and Business, as well as other sections in this prospectus or incorporated by reference into this prospectus, discuss some of the factors that could contribute to these differences.

The forward-looking statements made in this prospectus relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events.

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



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## **USE OF PROCEEDS**

We estimate that we will receive up to approximately \$      in net proceeds from the sale of units in this offering, based on an assumed offering price of \$      per unit and after deducting estimated placement agent fees and estimated offering expenses payable by us.

We intend to use the net proceeds of this offering for general corporate purposes, including continuing our commercialization efforts for our NC-stat DPNCheck product launched in September 2011 and our SENSUS product launched in January 2013, enhancing our SENSUS and NC-stat DPNCheck products, and developing other product candidates. We have not yet determined with certainty the manner in which we will allocate these net proceeds. Accordingly, our management will have broad discretion in the application of the net proceeds, and investors will be relying on the judgment of our management regarding the application of the proceeds of this offering.

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

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Our common stock has been traded on NASDAQ under the symbol NURO since our initial public offering in July 2004. Our common stock was traded on the NASDAQ Global Market from its initial listing until March 23, 2011. As a part of our plan to cure our deficiencies with the continued listing requirements of the NASDAQ Global Market, we requested and were approved to transfer our listing to the NASDAQ Capital Market, effective March 24, 2011, where our stock now trades. The following table sets forth, for the periods indicated, the high and low sales prices of our common stock (rounded to the nearest penny) as reported by NASDAQ. Prices have been adjusted for all periods to reflect the impact of two 1-for-6 reverse splits of our common stock completed on September 1, 2011 and February 15, 2013, respectively.

	High	Low
Fiscal Year 2013		
First Quarter	\$ 3.24	\$ 1.98
Second Quarter (through April 24, 2013)	\$ 2.68	\$ 2.04
Fiscal Year 2012		
First Quarter	\$ 9.48	\$ 3.96
Second Quarter	\$ 4.98	\$ 3.66
Third Quarter	\$ 5.10	\$ 3.12
Fourth Quarter	\$ 3.66	\$ 2.40
Fiscal Year 2011		
First Quarter	\$ 24.84	\$ 15.48
Second Quarter	\$ 22.68	\$ 14.76
Third Quarter	\$ 19.80	\$ 9.60
Fourth Quarter	\$ 12.30	\$ 6.90

As of April 22, 2013, there were approximately 119 stockholders of record of our common stock. Because many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

**DIVIDEND POLICY**

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

TABLE OF CONTENTS**CAPITALIZATION**

The following table describes our capitalization and cash and cash equivalents as of March 31, 2013 on an actual basis and on a pro forma basis to reflect our assumed sale of units consisting of shares of common stock together with warrants to purchase shares of common stock in this offering at an assumed offering price of \$ per unit, and the placement agent fees and estimated offering expenses payable by us.

You should read this capitalization table together with the financial statements and related notes that are incorporated by reference into this prospectus, as well as Management's Discussion and Analysis of Financial Condition and Results of Operations and the other financial information contained in our Annual Report on Form 10-K for the year ended December 31, 2012 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2013 and incorporated by reference into this prospectus.

	As of March 31, 2013	
	Actual	Pro forma <sup>(1)</sup>
Cash and cash equivalents	\$6,886,191	\$
Stockholders' equity:		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized, actual and pro forma; none issued and outstanding, actual and pro forma		
Common stock, \$0.0001 par value: 50,000,000 shares authorized, actual; 2,260,195 shares issued and outstanding, actual; 50,000,000 shares authorized, pro forma; and shares issued and outstanding, pro forma	\$226	
Additional paid-in capital	147,741,590	
Accumulated deficit	(140,846,358)	
Total stockholders' equity	6,895,458	
Total capitalization	\$6,895,458	\$

- (1) A \$0.50 increase (decrease) in the assumed aggregate public offering price of \$ for each unit issued in this offering would increase (decrease) cash and cash equivalents, and total capitalization by \$ million, assuming that the number of securities offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions.

The preceding table excludes 781,955 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2013 at a weighted average exercise price of \$6.95 per share, 50,834 shares of common stock issuable upon the exercise of options outstanding as of March 31, 2013 at a weighted average exercise price of \$73.99 per share, 177,494 shares of common stock available for future issuance under our 2004 Stock Option and Incentive Plan, 11,806 shares of common stock available for future issuance under our 2009 Non-qualified Inducement Stock Plan, and 21,765 shares of our common stock available for future issuance under our 2010 Employee Stock Purchase Plan. The preceding table also excludes up to shares of common stock issuable upon the exercise of the warrants sold in this offering.

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## **BUSINESS**

### **Our Business-An Overview**

We are a medical device company focused on the treatment of the neurological complications of diabetes. People with diabetes do not effectively regulate their blood glucose, or sugar, levels leading to chronically high levels of glucose in the blood, called hyperglycemia, and occasionally bouts of low glucose in the blood, called hypoglycemia. The primary reason that glucose levels are not effectively regulated in people with diabetes is that those with the disease do not produce insulin (Type I diabetes) or are resistant to the normal physiological action of insulin (Type II diabetes). Many Type II diabetics eventually require insulin because production of the hormone by their pancreas decreases with time. Type I diabetes usually affects children and teenagers whereas Type II diabetes has typically been a disease of adults over the age of 50. However, over the past decade, Type II diabetes is occurring in younger adults, which can probably be attributed to higher levels of obesity in this age group.

Diabetes is a worldwide epidemic. Recent studies estimate the worldwide prevalence of diabetes to be over 350 million people, of which approximately 90% are of the Type II variety. Within the United States, there are over 25 million people with diabetes and another 80 million people with pre-diabetes, which represents a constellation of conditions such as obesity and high triglyceride levels that are likely to progress to diabetes. In the United States, the annual cost of treating diabetes is over \$100 billion. Although there are dangerous acute manifestations of diabetes, the primary burden of the disease is in the long term complications of chronic hyperglycemia. These complications include among other things cardiovascular disease, nerve disease and resulting pathological conditions such as foot ulcers and amputation, eye disease leading to blindness, and kidney failure.

The most common long-term complication of diabetes, which affects over 50% of the diabetic population, is nerve disease or diabetic neuropathy. There are different forms of diabetic neuropathy; the most common are diabetic peripheral neuropathy, or DPN, carpal tunnel syndrome, or CTS, and autonomic neuropathy. DPN is a systemic nerve disease that is worse in the feet and lower legs. It may lead to loss of sensation in the feet, severe pain in the feet and legs, and increased risk of falling. DPN is the primary trigger for diabetic foot ulcers which may progress to the point where amputation is required. People with diabetes have a 15% to 25% lifetime risk of developing a foot ulcer and 15% of foot ulcers lead to amputation. Foot ulcers are among the most expensive complications of diabetes, with a typical cost of \$5,000 to \$50,000 per episode. Between 16% and 26% of people with diabetes suffer from pain of the feet and lower legs due to painful diabetic neuropathy, or PDN, which is caused by DPN. In addition to causing pain that is often severe, PDN may interfere with sleep and is also associated with anxiety and depression. Loss of sleep is particularly concerning because sleep deprivation is associated with insulin resistance and worse glycemic control, and thereby exacerbates diabetes severity. CTS is caused by focal damage to the median nerve as it passes from the forearm into the hand, through the wrist. When the median nerve is compressed it can lead to symptoms in the hand including pain, numbness, and loss of strength. Autonomic neuropathy is a systemic disease of the autonomic nerves, which regulate the heart, digestion, sexual function, and other essential bodily functions. Damage to these nerves leads to a host of clinical complications that include an increased risk of sudden death, elevated risk of stroke, digestion difficulties and impotence.

Most people with diabetes receive health care attention in primary care settings where physicians have limited access to sophisticated diagnostic tools to detect diabetic neuropathy early and monitor its progress and response to treatment. As a result, they rely primarily on clinical examination of patients which, although it is an important part of the evaluation of a patient with diabetes, has limited sensitivity and specificity and can usually only detect later stage disease where treatment options and efficacy are compromised.



Early detection of DPN is particularly important because there are no treatment options once the nerves have degenerated. At the present time, the most widely used and recommended diagnostic method for DPN is the 5.07/10-g monofilament test. This test assesses the patient's ability to detect focal pressure application in the foot. The inability to detect a monofilament indicates that the patient lacks adequate sensation to protect their feet from mechanical insults that can lead to foot ulcers; a condition known as loss of protection sensation, or LOPS. Although the monofilament is an important clinical test, it is insensitive to early DPN where interventions may slow or even halt further nerve damage. Nerve conduction studies, or NCS, are

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objective electrical tests of nerve function. They are considered the gold standard diagnostic method for DPN and can detect mild nerve damage before it is expressed as clinical symptoms. NCS have typically been provided by specialists using expensive equipment and therefore access has been limited, particularly for common conditions such as DPN.

Currently, there are limited treatment options for diabetic neuropathies. There are no approved disease modifying treatments for DPN, although a few pharmacological candidates are in clinical trials. One such drug is Ranirestat, an aldose reductase inhibitor being developed in the United States by Eisai Co., Ltd., which has recently completed a large scale Phase III clinical trial. If trial results are successful, Eisai could submit a FDA new drug application as early as 2014. If Ranirestat becomes commercially available, it may expand the demand for early detection and monitoring of DPN. In the absence of targeted therapies, several large studies have shown that reducing hyperglycemia lowers the risk of developing DPN and decreases its severity. There is also observational data that suggests that a reduction in triglyceride levels slows the progression of DPN. Several drugs, such as duloxetine and pregabalin, have been approved to provide pain relief in patients with PDN. Unfortunately, these drugs, which are also anti-depressants or anti-seizure medications, have systemic effects and are therefore often associated with side effects.

In the case of PDN and/or DPN, it is essential to intervene before extensive nerve degeneration has occurred.

## **Our Strategy**

We believe that there are large and important unmet needs in the treatment of diabetic neuropathies. As a medical device company with both unique and substantial experience in devices to measure and alter peripheral nerve function, we believe we are in the unique position to address these unmet needs through the development of novel proprietary medical devices. Therefore, we are focused on developing and marketing medical devices for the diagnosis and treatment of diabetic neuropathies. We believe that we are the only medical device company with a strategic focus on the diabetic neuropathy market and our goal is to be the dominant player in this field.

Our key business strategies for 2013 by which we intend to advance our objectives in the diabetic neuropathy market include:

***Driving Commercial Adoption of Our Proprietary Products for Diabetic Neuropathy in the United States.*** Our two primary products that target the diabetic neuropathy market are the following:

**SENSUS**, our therapeutic device for relief of chronic, intractable pain, was launched in January 2013. We believe this product will be attractive to pain medicine physicians, neurologists, endocrinologists, podiatrists, primary care physicians, and other physicians that are challenged with trying to manage pain in their patients with PDN and other forms of neuropathic pain. The prevalence of PDN indicates a patient group of 3 to 5 million in the United States alone. We estimate the wholesale market for SENSUS is characterized by the 50% of patients with either severe pain or sleep interference due to PDN. This represents an annual revenue potential of \$300 million. We also believe that there are international market opportunities, particularly in Europe and Japan. In the US, SENSUS is a prescription product and our initial challenge will be to obtain broad, national exposure and acceptance among physicians as well as a broad distribution channel to fulfill prescriptions. We are working to create demand in several distinct channels: independent regional and national durable medical equipment, or DME, suppliers that employ sales representatives who detail physicians, large direct sale customers such as orthotic and prosthetic clinics and chronic pain treatment centers, and national diabetes mail order DME s. As of April 25, 2013, we had ten regional DME suppliers. We believe there may be future opportunities to expand the SENSUS revenue and gross margin potential by developing a direct sales channel.

**NC-stat DPNCheck**, our diagnostic test for DPN, has now been on the market for over eighteen months since its launch in late 2011. Revenues for fiscal year 2012 were nearly \$1.5 million, an increase from \$0.1 million in fiscal year 2011. Importantly, we tested product acceptance in several domestic market segments and have focused on the managed care market as the most attractive near-term revenue opportunity. Within managed care, we are specifically targeting Medicare Advantage providers. Medicare Advantage providers assume financial responsibility and the associated risks for the health care costs of their patients. For Medicare Advantage providers, we

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believe that NC-stat DPNCheck presents a compelling 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 NC-stat 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. The Medicare Advantage market encompasses approximately 15 million covered lives or about 27% of the total Medicare population. We believe that about one-third of these patients have diabetes and that up to 25% of that sub-population could be tested in a given year. This represents an annual potential market of approximately \$20 million. We also believe that there are attractive international market opportunities, particularly in Europe, Japan, South Korea and in some developing countries. We have a small, senior level commercial operations team focused on developing this market.

***Continuing the Productivity of Our Research and Development Pipeline.*** During the past eighteen months we have established a new presence in DPN and PDN through the launch of NC-stat DPNCheck in late 2011 followed by the SENSUS launch in early 2013. We believe that we can enhance SENSUS market penetration by providing unique functionality related to use of the device during nighttime sleep, as half of people with PDN report that the condition interferes with their sleep. Sleep impairment is associated with insulin resistance, worsening of glycemic control, and exacerbation of the severity of diabetes. We are developing and intend to launch a sleep-enabled version of SENSUS. We have also started to develop a second generation version of SENSUS that will have a lower profile and will utilize radio frequency identification (RFID) tags in the disposable electrodes. The RFID tags will help patients manage the electrode replacement cycle and prevent other manufacturers from selling electrodes for the SENSUS device. Additionally, we believe there are opportunities to develop a second generation version of NC-stat DPNCheck. This device would improve on the first generation device by incorporating a larger and more intuitive display and by incorporation of RFID tags in the disposable biosensors. The RFID tags would allow us to precisely control biosensor reuse and to lock out biosensors from other manufacturers should such competition emerge in the future.

***Commercializing NC-stat DPNCheck in Select International Markets Using a Distribution Network.*** We are targeting select international markets where we believe that the combination of a high prevalence of diabetes plus support from the local payer system will support NC-stat DPNCheck and, eventually, SENSUS. This includes countries in Western Europe, including Germany and the Netherlands, where we have both CE marking for NC-stat DPNCheck and established distribution, as well as East Asia, where we recently entered into distribution partnerships with Handok Pharmaceuticals for South Korea and Omron Healthcare Company, Ltd. for Japan. While our resources committed to this effort are modest, we believe that this approach could contribute meaningful revenue in 2013 while positioning us for international growth in subsequent years.

***Leveraging a More Efficient Operating Structure with Future Revenue Growth.*** During 2012, we modified our operating structure to focus more narrowly on the high-value opportunities for SENSUS and NC-stat DPNCheck that can be pursued via independent distributors and a small commercial operations team. This has reduced our operating expenses and, more significantly, improved our future flexibility to generate increased sales volume without the cost of adding sales representatives and field clinical support. Our operating expenses during 2012 totaled \$14.0 million and we forecast 2013 operating expenses to be in the range of \$11 to \$12 million, a reduction of 14% to 21%. We believe we can maintain and leverage this approximate operating expense level over the next several years as our diabetes business grows.

***Managing Our Legacy Neurodiagnostics Business to Optimize Cash Flow.*** Our historical neurodiagnostics business generated \$6.1 million in revenue during 2012 with gross margins exceeding 50%. There are few direct cash operating expenses of our neurodiagnostics business. Two years ago we shifted our strategic focus toward more attractive opportunities in diabetes care and we determined that we would manage this legacy neurodiagnostic business for its cash contribution rather than growth. This decision was primarily due to changes in the reimbursement environment which were challenging and presented few practical alternatives. We see the legacy business continuing to decline as

we operate it for cash flow. See Legacy Neurodiagnostics Business.

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## **Our Business Model**

We develop and market neurodiagnostic systems which typically consist of a medical device plus single patient-use biosensors or electrodes. Other accessories are also offered to our customers. Our goal for these systems is to build an installed base of active customer accounts and distributors that regularly reorder consumables 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 and, more recently, to the ADVANCE NCS/EMG System. The planning for our diabetes care pipeline, including SENSUS, NC-stat DPNCheck, and other products in development, is based on the device plus consumables business model.

## **Marketed Products**

### SENSUS

The SENSUS pain therapy device is a transcutaneous electrical nerve stimulator, or TENS, designed for relief of chronic, intractable pain, such as PDN. We believe that SENSUS will be attractive to pain medicine physicians, neurologists, endocrinologists, podiatrists, and primary care physicians that are challenged with trying to manage pain in their patients with PDN and other forms of neuropathic pain. We have used our unique expertise in peripheral nerve stimulation in the development of SENSUS which incorporates several proprietary features for ease of patient use and physician reporting. 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.

A recent 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 the devices currently on the market do not meet the needs of patients with PDN because they are not optimized for PDN but are instead targeted at low back pain, sports medicine, and rehabilitation applications. Furthermore, they are difficult to administer and tend to be complicated for clinicians and patients.

Our SENSUS device and electrodes were cleared by the FDA for commercial distribution during 2012. When medically indicated and supported by proper documentation, TENS are generally reimbursed by Medicare and many commercial insurance companies under the DME benefit.

### NC-stat DPNCheck

NC-stat 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.

NC-stat 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.

NC-stat 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 1.7 million patient studies have been performed using our NC-stat technology and there have been approximately 6.3 million nerve tests, including nearly 700,000 sural nerve tests. It has been the subject of many published studies, including several studies specifically addressing the accuracy and clinical utility of the device in assessment of DPN.

**ADVANCE System**

Our legacy neurodiagnostics business is based on the ADVANCE NCS/EMG System, or the ADVANCE System, which is a comprehensive platform for the performance of traditional nerve conduction studies and invasive electromyography procedures. The ADVANCE System is comprised of: (1) various types of

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electrodes and needles, (2) the ADVANCE device and related modules, 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 CTS, low back and leg pain, and DPN. It is most commonly used in the assessment of CTS. Numerous papers have been published on the use of this technology in this clinical application.

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

Product	Time on Market		Technology	Primary Clinical Indications	No. Patients Tested/Treated
NC-stat*	Q2 1999	Q3 2010	Nerve Conduction	Diagnosis and evaluation of CTS, low back pain, peripheral neuropathies (including DPN)	~ 1,750,000
ADVANCE	Q2 2008	present	Nerve Conduction Invasive Needle EMG	Diagnosis and evaluation of CTS, low back pain, peripheral neuropathies (including DPN)	
NC-stat DPNCheck	Q3 2011	present	Nerve Conduction	Diagnosis and evaluation of peripheral neuropathies, such as DPN	est. >60,000
SENSUS	Q1 2013	present	Transcutaneous Electrical Nerve Stimulation	Relief for chronic, intractable pain, such as PDN	~150

\* 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 suppliers. Our SENSUS device was launched in January 2013 and is being sold to DME suppliers who, in turn, distribute the product along with consumables directly to patients. As of March 31, 2013, we had ten DME suppliers stocking SENSUS and they had purchased 145 SENSUS devices during the first quarter of 2013. We are working to develop large direct customers such as pain centers and national diabetes mail order DME s. Our NC-stat DPNCheck device was launched in late 2011 and approximately 1,100 devices had been placed with customers through March 31, 2013. These customers include managed care organizations, retail health businesses, endocrinologists, podiatrists and primary care physicians. As of March 31, 2013, we had an installed base of approximately 1,500 active customers using our ADVANCE System. These customers include primary care, internal medicine, orthopedic and hand surgeons, pain medicine physicians, neurologists, physical medicine and rehabilitation, or PM&R, physicians, and neurosurgeons. At



March 31, 2013, one customer accounted for 11.7% of accounts receivable. No single customer has accounted for more than 10% of our revenues in the fiscal years ended December 31, 2012, 2011, and 2010, or for the three month period ended March 31, 2013.

## **Geographic Information**

Substantially all of our assets, revenues, and expenses for the years ended December 31, 2012, 2011, and 2010 were located at or derived from operations in the United States. In addition, we have had limited sales through distributors in the United Kingdom, the Netherlands, India, and various other countries. For each of

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the years ended December 31, 2012, 2011, and 2010, international revenues accounted for approximately 7%, 6%, and 2%, respectively, of our total revenues. For the three month period ended March 31, 2013, international revenues accounted for approximately 22% of our total revenues.

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

We believe SENSUS will be attractive to endocrinologists, podiatrists, and primary care physicians that are challenged with trying to manage pain in their patients with diabetes. The prevalence of PDN suggests that there is a significant market for SENSUS in the United States. As of March 31, 2013, we had ten regional DME distributors in place in the United States with 40 sales representatives. Our goal is to have broad national coverage in place by the end of 2013. We also believe that there are international market opportunities, particularly in Europe and Japan.

In late 2011, we launched NC-stat DPNCheck into the United States market for endocrinology and podiatry, followed by market evaluations and/or sales efforts in primary care, retail health, and managed care. While we believe that all of these segments hold potential, we have narrowed our focus to managed care, and specifically Medicare Advantage providers, which we believe represent the most attractive near-term opportunity. We believe the Medicare Advantage market represents an annual potential market of about \$20 million. We also believe that there are attractive international market opportunities, particularly in Europe, Japan, South Korea and in some developing countries. We have a four person senior level commercial operations team led by our Chief Operating Officer that is focused on developing the Medicare Advantage market.

Our installed base of ADVANCE accounts is supported by our customer service department which consists of three representatives. 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 who are directed by our European Sales Manager.

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

We invest significant effort 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 new SENSUS and NC-stat DPNCheck devices at our corporate headquarters facility. We rely on an outside contractor for the manufacture and servicing of our ADVANCE device and also for the components that we use in the buildup for SENSUS and NC-stat DPNCheck. We rely on outside contractors for the manufacture of our consumable biosensor/electrodes. With the exception of the biosensors for use with our NC-stat DPNCheck devices, which we acquire from two manufacturers, we do not currently maintain alternative manufacturing sources for our SENSUS, NC-stat 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, kitting, packaging, and labeling at our corporate headquarters facility. We believe these manufacturing relationships minimize our capital investment, provide us with manufacturing expertise, and help control costs.

Sunburst EMS, Inc., or Sunburst, has been manufacturing our NC-stat devices since November 2005. We entered into a supply agreement with Sunburst during 2006 for the manufacturing and supply of our

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neurodiagnostic devices. Sunburst manufactures the current generation of our ADVANCE device as well as the NC-stat 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 2011 Parlex began manufacturing the NC-stat DPNCheck biosensors. In August 2006, we entered into a mutually exclusive manufacturing and supply agreement with Parlex pursuant to which Parlex will manufacture and supply to us, and we will purchase from Parlex, at agreed upon prices per unit, all of 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 NC-stat DPNCheck devices in international markets and initiated manufacturing SENSUS electrodes during 2012 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 NC-stat DPNCheck are cleared for marketing within the United States, Canada, and the European Union. In addition, our SENSUS Pain Management System is 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. Key members of our R&D management team have worked together for over a decade. This team includes the extensive involvement of our founder and Chief Executive Officer who holds both M.D. and Ph.D. degrees. The R&D group consists of 11 people, including two who hold M.D. degrees and three who hold Ph.D. degrees. The group has extensive experience in neurophysiology, biomedical instrumentation, signal processing, biomedical sensors, and information systems. The R&D group works closely with our marketing group and our customers to design new and modified products that are focused on improving clinical outcomes. Our clinical programs are led by our Chief Medical Officer who is a board-certified endocrinologist with extensive diabetes management experience.

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Our research and development efforts are primarily focused in the following areas:

*Enhancements to our first generation SENSUS pain therapy device.* With the recent launch of our SENSUS device, we anticipate customer requests to enhance usability. We believe that we can enhance SENSUS market penetration by providing unique functionality related to use of the device during nighttime sleep, as half of people with PDN report that the condition interferes with their sleep. Sleep impairment is associated with insulin resistance, worsening of glycemic control, and exacerbation of the severity of diabetes. Also, we have begun to identify improvements that we intend to make in designing a second generation SENSUS device.

*Enhancements to our first generation NC-stat DPNCheck device.* We are focused on improving NC-stat DPNCheck's clinical utility, enhancing device usability, integrating into customer electronic medical records, and lowering manufacturing costs. We are also in the process of evaluating the design of a second generation NC-stat DPNCheck device.

*Oversee our support to clinical studies that employ our NC-stat DPNCheck and SENSUS products.* We presently are involved in seven studies that use NC-stat DPNCheck in the evaluation of neuropathy in persons with diabetes under various study conditions. We are presently planning a 6 week open label multisite study evaluating the efficacy of SENSUS in a total of 40 subjects with PDN. These studies will expand the clinical foundation for use of NC-stat DPNCheck and SENSUS which, in turn, should support future adoption of these products.

In addition to these core areas of research and development focus, we are also exploring additional clinical applications within the diagnosis and treatment of diabetic neuropathy for our core technology and expertise.

Research and development expenses were approximately \$3.5 million, \$3.9 million, and \$5.9 million for the years ended December 31, 2012, 2011, and 2010, respectively, and \$1.1 million and \$978,000 for the three months ended March 31, 2013 and 2012, respectively.

## **Clinical Programs**

We maintain a clinical program under the direction of our Chief Medical Officer, who is a board certified endocrinologist with extensive experience in diabetes. Our clinical programs are 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.

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

Institution	Initiated	Study Focus	Product	Duration	Subjects
Ipswich Diabetes Centre, Ipswich Hospital (UK)	Fall 2011	Evaluation of small fiber neuropathy in patients with diabetes	NC-stat DPNCheck	4 years	400
Royal Hallamshire Hospital University of Sheffield (UK)	Mid 2012	Evaluation of DPN based on severity of diabetes	NC-stat DPNCheck	1 year	120
Joslin Diabetes Center	Mid 2012	Effect of weight loss on DPN	NC-stat DPNCheck	1 year	50
Toronto General Hospital, University of Toronto	Mid 2012	Assessment of various neuropathy measurement modalities	NC-stat DPNCheck	1 year	140
Institute for Clinical Diabetology, Heinrich Heine University	Mid 2012	Assessment of DPN in newly diagnosed Type 2 diabetes patients	NC-stat DPNCheck	1 year	150
Department of Diabetes, Poole Hospital (UK)	Fall 2012	Comparison of DPNCheck with Vibratory Perception Testing	NC-stat DPNCheck	6 months	100
Institute for Clinical Diabetology, Heinrich Heine University	Early 2013	Assessment of DPN in prediabetes and newly diagnosed Type 2 diabetes patients	NC-stat DPNCheck	2 years	1,000
First Vitals Health	Early 2013	Effect of aggressive intervention on foot disease for high risk patients	NC-stat DPNCheck	3 years	600

## Competition

With respect to SENSUS, 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 further believe that most of the current manufacturers are focused on low back pain, sports medicine, and rehabilitation rather than on PDN. As a result, we are not aware of any devices that are uniquely optimized for use in treating PDN. There are a few companies that claim that their devices have specific utility for PDN; however, we do not believe that these claims have been widely validated through adequate clinical studies.

Other than NC-stat DPNCheck, we believe that there is currently no 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 NC-stat, SENSUS, ADVANCE, and NC-stat DPNCheck 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

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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 March 31, 2013, we had 38 issued U.S. patents, one issued foreign patent, and 17 pending patent applications, including nine U.S. applications, five international PCT applications, and three foreign national applications. We have filed a utility patent application for NC-stat DPNCheck and another utility patent application for SENSUS.

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

## **Third-Party Reimbursement**

Procedures performed with our neurodiagnostic medical devices including ADVANCE and NC-stat DPNCheck may be paid for by third-party payers, including government health programs, such as Medicare, and private insurance and managed care organizations. The 2013 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 NC-stat DPNCheck device and the ADVANCE System.

We believe that physicians are generally receiving reimbursement under CPT 95905 from Medicare for nerve conduction studies performed 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 NC-stat DPNCheck.

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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 NC-stat DPNCheck is attractive to Medicare Advantage insurers and risk bearing provider organizations. We are focusing our sales effort for NC-stat DPNCheck on the Medicare Advantage managed care market segment.

We believe that the SENSUS pain management therapeutic system is considered a durable medical equipment (DME) benefit and is reimbursed for chronic pain by Medicare and many commercial insurers under HCPCS code EO730 for the device and under HCPCS code A4595 for the consumable electrodes. These pre-existing codes apply to DME benefits employing transcutaneous electrical nerve stimulation equipment.

We believe that 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 NC-stat 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 Risk Factors *We are subject to extensive regulation by*

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*the FDA which could restrict the sales and marketing of the NC-stat DPNCheck and SENSUS 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 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

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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;

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 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 NC-stat DPNCheck.

As a transcutaneous electrical nerve stimulator, the SENSUS pain therapy device is a Class II medical device which received 510(k) clearance from the FDA in August 2012. In November 2012 the FDA provided 510(k) clearance for the disposable electrode used in conjunction with the SENSUS device. The intended use of the SENSUS pain management therapeutic system is the symptomatic relief and management of chronic intractable pain.



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### **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 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;

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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 \$6.1 million, \$10.3 million, and \$13.9 million for the fiscal years ended December 31, 2012, 2011, and 2010, respectively, and \$1.1 million and \$1.9 million for the three month periods ended March 31, 2013 and 2012, respectively.

As we managed our general purpose neurodiagnostic business to improve reimbursement and minimize customer erosion, we increasingly became aware of the unmet medical need for improved diagnostic tools and therapies in the specific area of diabetic neuropathy, or nerve damage caused by diabetes. Diabetes care is one of the fastest growing sectors of health care as discussed above. We believe that our tools and therapies for addressing diabetic neuropathy represent a significant market opportunity. Consequently, in January 2011 we announced a shift to diabetes care as our primary business focus. We also restructured our neurodiagnostics business to consolidate functions and to eliminate our direct sales force. We emphasized our commitment to supporting our neurodiagnostic products and installed base of physician accounts. Our objective for our legacy neurodiagnostics business is to maintain a high standard of product support while managing the business to optimize cash flow.

## **Employees**

As of March 31, 2013, we had a total of 35 employees, 34 of which were full-time employees. Of these employees, 11 were in research and development, 12 in sales and marketing, five in production/distribution, and seven in general and administrative services. One employee holds both M.D. and Ph.D. degrees, two additional employees hold M.D. degrees, and three additional employees hold Ph.D. degrees.

Our employees are not represented by a labor union and are not subject to a collective bargaining agreement. We have never experienced a work stoppage. We believe that we have good relations with our employees.

## **Properties**

Our headquarters is located in an approximately 30,000 square foot facility in Waltham, Massachusetts, which we occupy under an office lease expiring in March 2014. We believe that our existing facilities are adequate for our current needs.

## **Legal Proceedings**

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

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

The following table sets forth information regarding our executive officers and directors, including their ages, as of March 31, 2013.

Name	Age	Position
Shai N. Gozani, M.D., Ph.D.	48	Chairman of the Board, Chief Executive Officer, President and Secretary
Thomas T. Higgins	61	Senior Vice President, Chief Financial Officer and Treasurer
Guy Daniello	68	Senior Vice President of Information Technology
Krishnamurthy Balachandran	55	Senior Vice President, Chief Operating Officer, Commercial
Michael Williams, Ph.D.	56	Senior Vice President, Chief Technical Officer
David E. Goodman, M.D. <sup>(1)(2)</sup>	57	Director
Allen J. Hinkle, M.D. <sup>(2)(3)</sup>	62	Director
Nancy E. Katz <sup>(1)</sup>	53	Director
Timothy R. Surgenor <sup>(1)(3)</sup>	53	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 Vice President and General Manager 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.

**Guy Daniello** has served as our Senior Vice President of Information Technology since July 2003 and, prior to that time, as our Vice President of Information Technology and Director of Information Technology since 1998. Prior to joining NeuroMetrix, Mr. Daniello was an independent software consultant, the Senior Vice President of Engineering at Shiva Corporation from 1996 to 1997, and the Chief Technology Officer and Vice President of Product Development at Gandalf Technologies from 1993 to 1996. In 1991 he founded Network Architects, a software company. Prior to starting Network Architects, he served as President and

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Chief Executive Officer of Datamedia Corp. and the Director of Small Systems Development at Honeywell Information Systems. Mr. Daniello holds a B.S. in business administration from Northeastern University.

**Krishnamurthy Balachandran** has served as our Senior Vice President and General Manager, International since April 2010. In January 2011 he assumed additional responsibilities as our Chief Operating Officer. Prior to joining NeuroMetrix, from November 2007 to April 2010, Mr. Balachandran was Vice President and General Manager of Cardinal Health's NeuroCare Division, a provider of technology and services to the neurophysiology industry. Before joining Cardinal Health, Mr. Balachandran worked at with Hewlett Packard as Senior Director, Global Alliances from April 1999 to December 2006. Prior to joining Hewlett Packard, Mr. Balachandran was Vice President, International Sales and Marketing for Nicolet Biomedical, the leading business in EMG and nerve conduction testing which was subsequently acquired by Cardinal Health and became its NeuroCare division. Mr. Balachandran started his career in sales with Blue Star, Ltd of India. Mr. Balachandran, an electrical engineer from the National Institute of Technology in India, holds an MBA in Marketing from the Indian Institute of Management in Ahmedabad, India.

**Michael Williams, Ph.D.** has served as our Senior Vice President of Engineering and Chief Technology Officer since September 2011 and, prior to that time, as our Senior Vice President of Engineering since July 2003 and as Vice President of Engineering since May 2000. From March 1996 to January 2000, Dr. Williams served as Division President at Radionics, where he was responsible for all software-based products, including treatment planning and image-guided surgery. Prior to Radionics, he served as an engineer at Hughes Aircraft Space & Communications Group. Dr. Williams received a B.S. in physics and mathematics from University of Puget Sound and an M.S. and Ph.D. in Physics from Brown University.

**David E. Goodman, M.D.** has served as a member of our Board of Directors since June 2004. Dr. Goodman is the Chief Medical Officer and co-founder of FirstVitals Health and Wellness, a personalized online health portal and also serves as an independent consultant and practicing physician. During 2010, Dr. Goodman 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 serves as a director of Sound Surgical Technologies LLC, a private manufacturer of aesthetic surgical tools. 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. 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

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Thornton Plan, health insurance provider organizations. Dr. Hinkle has over 30 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 of Anesthesiology and Pediatrics 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. Since May 2011, Ms. Katz has served as Vice President, Consumer Marketing at Medtronic, Inc., a medical technology company. From July 2005 to July 2010, Ms. Katz was Senior Vice President, Bayer Diabetes Care North America. Prior to this position, she was President and Chief Executive Officer of Calypte Biomedical Corporation, a manufacturer of HIV diagnostics, President of Zila Pharmaceutical, Inc, a manufacturer of oral care products, and held senior marketing positions with the Lifescan division of Johnson & Johnson (blood glucose diabetes products), Schering-Plough Healthcare Products, and with American Home Products. She has previously served on the Boards of Directors of Neoprobe Corporation (AMEX: NEOP), Calypte Biomedical Corporation, LXN Corporation and Pepgen Corporation. She received a B.S. in business from the University of South Florida. The Board has concluded that Ms. Katz should serve as a director because her experience in diabetes care and marketing into the diabetes sector provides valuable insight to the Board and management in our diabetes strategy.

**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.

## **Board Independence**

Our Board of Directors has determined that Dr. Goodman, Dr. Hinkle, Mr. Surgenor, and Ms. Katz are independent directors for purposes of the corporate governance rules contained in the NASDAQ Marketplace Rules, or the NASDAQ rules. In making the independence determination with respect to Mr. Surgenor, our Board of Directors considered Mr. Surgenor's service to the Company as a consultant described below under the heading *Transactions with Related Persons*.

## **Committee Independence**

Our Board of Directors has an Audit Committee currently consisting of Mr. Surgenor, Chairman, and Dr. Goodman and Ms. Katz. Dr. Goodman, Ms. Katz, and Mr. Surgenor are all independent as that term is defined in the rules of the

SEC and the applicable NASDAQ Marketplace Rules relating to audit committee membership. Our Board of Directors has determined that Mr. Surgenor qualifies as an audit committee financial expert as such term is defined in the rules of the SEC.

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

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

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

The following table sets forth compensation information with respect to services rendered to us in all capacities during the fiscal years ended December 31, 2012 and 2011 for (i) the individual who served as the Chief Executive Officer during the year ended December 31, 2011, (ii) the individual who served as the Chief Financial Officer during the year ended December 31, 2012, and (iii) each of the three other most highly compensated executive officers who were serving as executive officers at December 31, 2012 (we refer to these individuals, collectively, as the named executive officers ):

**Summary Compensation Table**

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards <sup>(1)</sup> (\$)	Option Awards <sup>(1)</sup> (\$)	All Other Compensation (\$)	Total Compensation (\$)
Shai N. Gozani, M.D. Ph.D. Chairman of the Board, Chief Executive Officer, President and Secretary	2012	375,000	(2)	165,138			540,138
Thomas T. Higgins Senior Vice President, Chief Financial Officer and Treasurer	2011	375,000	178,125	22,688	55,983		631,796
Krishnamurthy Balachandran Chief Operating Officer, Commercial	2012	275,000	(2)	87,300			362,300
Guy Daniello Senior Vice President of Information Technology	2011	275,000	104,500	9,529	23,513		412,542
Michael Williams, Ph.D. Senior Vice President of Engineering, Chief Technology Officer	2012	275,000	(2)	87,300			362,300
	2011	275,000	100,375	9,529	23,616		408,520
	2012	239,532	(2)	58,912			298,444
	2011	239,532	68,267	6,806	16,795		331,400
	2012	260,201	(2)	67,338			327,539
	2011	246,773	69,303	6,806	22,607		345,489

(1) These amounts include the aggregate grant date fair value for option and stock awards granted during fiscal years 2012 and 2011 computed in accordance with FASB ASC Topic 718. The 2012 stock awards presented above also include 2012 bonuses paid in stock in March 2013 as described in (2) below. The amount of each grant is set forth below under Discussion of Summary Compensation Table Long-Term Incentive Compensation. A discussion of the assumptions used in determining grant date fair value may be found in Note 3 to our Financial Statements, included in our Annual Report on Form 10-K for fiscal year 2012.

(2) The named executive officer received his 2012 bonus, net of applicable taxes, in shares of our common stock at a price per share of \$2.39, which represented the closing price of our common stock as reported on the NASDAQ Capital Market on March 4, 2013, the date of the grant. Therefore, this amount is included in the Stock Awards column.

## Discussion of Summary Compensation Table

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

### Cash Compensation

We pay our executive officers a base salary, which we review and determine annually. We have not increased the base salaries of our executive officers since 2009 with the exception of Dr. Williams who was promoted to Senior Vice President, Chief Technology Officer during 2011 and received a 9.5% increase in base salary to \$260,201.

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### **Bonus Payments**

Each executive officer has an annual bonus target which is expressed as a percentage of base salary. The annual bonus targets for executive officers were increased by 25% in 2012 reflecting the intention of the Compensation Committee to shift total executive compensation over time toward a higher percentage of annual performance-based awards. Consideration was also given to the fact that in most cases, executive officer base salary had not been increased for several years. For 2012, executive officer bonus targets as a percentage of base salary were as follows: Dr. Gozani 62.5%; Mr. Higgins 50%; Mr. Balachandran 50%; Mr. Daniello 37.5%; and Dr. Williams 37.5%.

The Compensation Committee has established a process for annual assessment of corporate performance which is the foundation for decisions regarding bonus payments to executive officers. Quantitative metrics are established following approval by the Board of Directors of the annual operating budget. These are monitored quarterly during the year and assessed after the end of the year. The Compensation Committee evaluates performance against metrics and also applies qualitative judgment in arriving at an overall corporate performance percentage. This process was followed for 2012 as in previous years. The most significant performance metrics for 2012 were:

Secure new equity funding of \$7 million-\$10 million. This metric was achieved in the February 2012 equity offering which raised \$8.5 million in gross proceeds.

Manage cash usage below \$10 million for the year. This metric was achieved with our 2012 cash usage totaling \$9.1 million.

Advance the commercialization of NC-stat DPNCheck by achieving \$1 million revenue, 1,000 device placements, and 100,000 biosensor sales in the first full year following launch. This metric was partly achieved with \$1.5 million revenue, 939 device placements, and 107,000 biosensor sales.

Commercialize the SENSUS pain management system by completing product development, filing device and biosensor 510(k) premarket clearance applications with FDA, managing the FDA review and launching the product before the end of 2012. This metric was partially achieved with final FDA clearance in November 2012 and launch of SENSUS in January 2013.

Initiate five clinical studies by independent researchers which incorporate the NC-stat DPNCheck. This metric was achieved with five studies underway at the end of 2012.

The Compensation Committee enlisted the counsel of an independent compensation expert, Radford, in their 2012 review. They considered performance against metrics and other qualitative factors including our product and business positioning going into 2013, and our market capitalization in arriving at their decision that a corporate performance factor of 50% would be used for the executive officer bonuses. Further, as a means to incentivize and retain our current executive officers, the Compensation Committee decided that each of the executive officers would receive fully vested stock in lieu of his cash bonus or any long-term incentive stock awards. This decision of the Compensation Committee was reviewed and approved by the Board of Directors. As a result, the following shares of our common stock were issued to the executive officers in lieu of their 2012 cash bonus and any long-term incentive compensation, after the appropriate tax withholding: Dr. Gozani 32,947 shares; Mr. Higgins 17,048 shares; Mr. Balachandran 18,473 shares; Mr. Daniello 11,660 shares; and Dr. Williams 12,691 shares. For 2011, the Compensation Committee followed a similar evaluation process and decided that the corporate performance factor was 95%. The 2011 bonuses were paid to the executive officers in cash in the amounts set forth in the Summary Compensation Table.

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

We grant long-term equity incentive awards in the form of stock options and restricted shares to executives as part of our total compensation package. The Compensation Committee decided not to grant long-term equity incentive

awards to our executive officers for 2012.

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We made equity grants in March 2012, comprised of restricted shares, to our named executive officers under our 2004 Stock Plan: Dr. Gozani 11,416 restricted shares; Mr. Higgins 4,416 restricted shares; Mr. Balachandran 4,416 restricted shares; Mr. Daniello 3,333 restricted shares; and Dr. Williams 4,416 restricted shares.

On February 1, 2011, we made the following equity grants, comprised of time-based stock options and restricted shares, to our named executive officers under our 2004 Stock Plan with an exercise price of \$19.80 per share for the stock options: Dr. Gozani 1,861 stock options and 1,146 restricted shares; Mr. Higgins 782 stock options and 481 restricted shares; Mr. Balachandran 782 stock options and 481 restricted shares; Mr. Daniello 558 stock options and 344 restricted shares; and Dr. Williams 558 stock options and 344 restricted shares. In addition, on the same date, we made the following equity grants, comprised of performance-based stock options, to our named executive officers under our 2004 Stock Plan with an exercise price of \$19.80 per share: Dr. Gozani 2,792 stock options; Mr. Higgins 1,173 stock options; Mr. Balachandran 1,172 stock options; Mr. Daniello 838 stock options; and Dr. Williams 837 stock options. The performance-based options fully vested on the achievement of certain revenue-related and cash flow targets, all of which were achieved in 2011. Accordingly, as of December 31, 2011, all performance-based stock options had vested. Dr. Williams also received a grant of 556 stock options on July 25, 2011 in connection with his promotion to Senior Vice President and Chief Technology Officer.

Stock options referred to above have a term of ten years and, other than the performance-based stock options, vest over four years with 25% of the total award vesting after one year and the remainder vesting in equal quarterly installments thereafter. Generally, to the extent vested, each stock option is exercisable during the term of the option while the grantee is employed by us and for a period of three months thereafter, unless such termination is upon death or disability, in which case the grantee may continue to exercise the option for a period of 12 months, or for cause, in which case the option terminates immediately. Vesting of stock options is also subject to acceleration in some certain circumstances in connection with a change-in-control as described below in Employment Agreements and Potential Payments upon Termination or Change-in-Control. The restricted shares granted in 2011 are subject to forfeiture provisions which expire with continuing service to us at the rate of 50% one year following the date of grant and 12.5% quarterly thereafter. The restricted shares granted in 2012 are subject to forfeiture provisions which expire with continuing service to us at the rate of 50% one year following the date of grant and 50% two years following the date of grant.

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The table below sets forth information with respect to our named executive officers concerning the outstanding equity awards as of December 31, 2012.

	Option Awards				Option Expiration Date	Stock Awards	
	Number of Securities Underlying Unexercised Options		Option Exercise Price (\$)	Option Expiration Date		Number of	Market Value
	Exercisable (#)	Unexercisable (#)				Units of Stock That Have Not Vested (#)	of Shares or Units of Stock That Have Not Vested (\$) <sup>(16)</sup>
Shai N. Gozani, M.D., Ph.D.	972			71.64	4/01/18		
	5,208	347	(1)	61.20	2/12/19		
	1,454	873	(2)	60.84	4/02/20		
	2,792			19.80	2/01/21		
	814	1,047	(3)	19.80	2/01/21		
						215	(13) 554
						143	(14) 370
						11,417	(15) 29,455
Thomas T. Higgins	1,173			19.80	2/01/21		
	342	440	(4)	19.80	2/01/21		
						121	(13) 311
						60	(14) 156
						4,417	(15) 11,395
Krishnamurthy Balachandran	1,172			19.80	2/01/21		
	342	440	(5)	19.80	2/01/21		
						60	(14) 156