NeuroMetrix, Inc.
Form 10-K
February 24, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

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

x

For the fiscal year ended December 31, 2011

OR

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

..

For the transition period from ____ to ____

Commission File Number 001-33351

NEUROMETRIX, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or Other Jurisdiction of Incorporation or Organization)	04-3308180 (I.R.S. Employer Identification No.)
62 Fourth Avenue, Waltham, Massachusetts (Address of Principal Executive Offices)	**02451** (Zip Code)

(781) 890-9989
(Registrant's Telephone Number, Including Area Code)

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

Title of each class	Name of exchange on which registered
Common Stock, $0.0001 par value per share	The NASDAQ Stock Market LLC
Preferred Stock Purchase Rights	The NASDAQ Stock Market LLC

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

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

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

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

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

As of June 30, 2011, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $9,138,841 based on the closing sale price of the common stock as reported on the NASDAQ Capital Market on June 30, 2011.

As of February 15, 2012, there were 12,430,905 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K: Certain information required by Item 11 in Part III of this Annual Report on Form 10-K is incorporated from the Registrant's Proxy Statement for the Annual Meeting of Stockholders to be held on May 14, 2012, or the 2012 Annual Meeting of Stockholders.

NEUROMETRIX, INC.

ANNUAL REPORT ON FORM 10-K

FOR THE YEAR ENDED DECEMBER 31, 2011

TABLE OF CONTENTS

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

PART I

The statements contained in this Annual Report on Form 10-K, including under the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other sections of this Annual Report, include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including, without limitation, statements regarding our or our management's expectations, hopes, beliefs, intentions or strategies regarding the future, such as our estimates regarding anticipated operating losses, future revenues and projected expenses; our 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 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 reimbursement methods used by private or governmental third-party payers; and other factors discussed elsewhere in this Annual Report on Form 10-K or any document incorporated by reference herein or therein. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "plan" and similar expressions m forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. The forward-looking statements contained in this annual report are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in the section titled "Risk Factors." Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. Unless the context otherwise requires, all references to "we", "us", the "Company", or "NeuroMetrix" in this Annual Report on Form 10-K refer to NeuroMetrix, Inc.

ITEM 1. BUSINESS

Our Business-An Overview

We are a medical device company focused on the diagnosis and 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% of such population is 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 high blood sugar, or 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. 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 objective electrical tests of nerve function. They are widely considered the gold standard diagnostic method for DPN and can even 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. 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 reductions in triglyceride levels slows the progression of DPN. Several drugs, such as duloxetine, gabepentin, and pregabalin, have been approved to treat the pain associated with DPN, which is referred to as painful diabetic neuropathy. Unfortunately, these drugs, which are also anti-depressants or anti-seizure medications, have systemic effects and are therefore often associated with intolerable side effects. Like DPN, autonomic neuropathies are difficult to manage, however early identification may allow physicians to lower cardiovascular risk. Mild to moderate CTS is effectively treated with conservative measures such as splinting and local steroid injections. More advanced CTS is usually managed surgically. In either case, it is essential to intervene before extensive nerve degeneration has occurred.

Our Strategy

We believe that there are large and important unmet needs in both the diagnosis and 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 vertical market and our goal is to be the dominant player in this field.

Our key business strategies by which we intend to meet our objectives in diabetic neuropathy include:

Drive Adoption of NC-stat DPNCheck, Our Initial Product for Diabetic Neuropathy, in the United States. NC-stat DPNCheck was launched in September 2011. Our initial target market is endocrinologists and podiatrists in the United States. We believe that this market represents approximately 15,000 physicians who are viewed as leaders in the detection and management of DPN. We initiated sales into this market through a direct, specialty sales force that we hired, trained and deployed during the third quarter of 2011.

Over 100,000 primary care physicians provide front-line care to approximately 85% of people with diabetes in the United States. We believe this is the most attractive sector of the United States market for NC-stat DPNCheck. Due to the size of the market and the large number of potential call points, we believe that the most effective sales approach is through national and/or regional third party distributors. Our strategy is to first establish product credibility in the endocrinology/podiatry market before negotiating arrangements with distributors to address the United States primary care market.

We believe that there may be an opportunity to sell NC-stat DPNCheck for use in retail medical clinics such as those in chain drug stores and department store pharmacies. There are approximately 1,200 retail medical clinics in the United States, a number growing at a double digit rate.

We believe that corporate accounts, including managed care organizations, companies that self-insure the health care risks of their employee populations, and governmental entities represent an attractive opportunity because of their focus on prevention and on health care costs over long durations. We plan to hire internal sales resources to market NC-stat DPNCheck directly to these corporate accounts.

Commercialize NC-stat DPNCheck in Select International Markets Using a Distribution Network. We have gained some experience in international markets with our ADVANCE System, which is currently used in the United Kingdom, Netherlands and India, among other countries, and which we sell through a distribution network. While international markets are a secondary priority at present, we believe we can leverage our distribution network to either sell NC-stat DPNCheck or to help us identify more appropriate distributors.

Expand Our Diabetic Neuropathy Products in the Near Term to Include SENSUS, a Pain Therapy Device. We are developing SENSUS, a pain therapy device which is a transcutaneous electrical nerve stimulator designed specifically for use in treating painful diabetic neuropathy. We believe that our unique expertise in peripheral nerve stimulation will expedite product development resulting in a product that is attractive to endocrinologists, podiatrists, and primary care physicians that are challenged with trying to manage pain in their patients with diabetes.

Initiate Clinical Studies to Further Validate the Clinical and Economic Benefits of Our Diabetes Products. We appointed a Chief Medical Officer in September 2011 who is responsible for developing and managing our diabetes-related clinical programs. These include studies to further validate the clinical and economic benefits of NC-stat DPNCheck testing, and various clinical and research and development activities in support of new diabetic neuropathy focused products, including SENSUS. This work should provide important support to our commercialization efforts and our efforts to obtain third party reimbursement for physicians using our products.

Obtain Coverage and Payment for NC-stat DPNCheck. While payers are not our direct customers, their coverage and reimbursement policies influence medical practice. We believe that NC-stat DPNCheck is appropriately described under the existing Category I CPT Code 95905; however, we expect only limited third-party reimbursement for health care providers using the device to detect and monitor diabetic neuropathy. We believe that the low cost of testing with NC-stat DPNCheck combined with its clinical utility will result in the development of an out-of-pocket payment model. We intend to initiate the type of clinical studies that may lead to expanded third party coverage over time.

Manage Our Legacy Neurodiagnostics Business to Optimize Cash Flow. Our neurodiagnostics business currently accounts for nearly all of our revenue. We restructured this portion of our business in January 2011 when we shifted our strategic focus toward more attractive opportunities in diabetes care. Accordingly, the legacy business is managed for cash and not growth and it is our intention to continue to carefully manage this business in order to optimize its future cash contribution.

Our Business Model

We develop and market neurodiagnostic systems which typically consist of a medical device plus single-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 that regularly reorder consumables to meet their clinical practice needs. We successfully implemented this model when we started our business with the NC-stat System, applied it to subsequent product generations and, more recently, to the ADVANCE System. The planning for our diabetes care pipeline including NC-stat DPNCheck and products in development such as SENSUS**,** is based on the device plus consumables business model.

Marketed Products

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 have been reduced by approximately 50%. The original NC-stat System was launched in 1999, and new sales of the device were discontinued in the third quarter of 2010. It will not be supported beyond the first quarter of 2012. Nearly 1.7 million patient studies have been performed with the NC-stat technology, 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

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) various types of 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. With our focus on diabetic neuropathies, we intend to target new sales of ADVANCE Systems for use by endocrinologists and primary care physicians who evaluate patients with diabetes and upper extremity symptoms suggestive of CTS.

Products in Development

SENSUS™

The SENSUS pain therapy device is a transcutaneous electrical nerve stimulator, or TENS, designed specifically for use in treating painful diabetic neuropathy, or PDN. A recent evidence based review by the American Academy of Neurology determined that TENS was a useful modality for managing this form of pain. TENS may reduce pain in patients with PDN without significant side effects and we believe that a PDN-specific TENS device that is effective,

easy to use and low cost could improve management of pain in patients with PDN. We further believe that currently available TENS devices do not meet this need 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.

We are using our unique expertise in peripheral nerve stimulation to develop a PDN optimized TENS device with several proprietary features that we believe will make it attractive to endocrinologists, podiatrists, and primary care physicians that are challenged with trying to manage pain in their patients with diabetes.

TENS devices are regulated as Class II devices and require a 510(k) premarket notification prior to commercial distribution. When medically indicated and supported by proper documentation, TENS are generally reimbursed by Medicare and many commercial insurance companies under the durable medical equipment, or DME, benefit.

ADVANCE™ CTS

We are currently exploring the market for a version of the ADVANCE device dedicated to detection of CTS in people with diabetes. The second most common form of diabetic neuropathy is focal damage to the median nerve, or CTS. We are currently investigating this market opportunity by creating a “diabetes CTS” package consisting of the ADVANCE NCS/EMG device and the combined median and ulnar nerve specific electrode, both of which are commercially available. If we determine that an attractive market exists for this clinical indication, then we will invest in development of an easier to use and lower cost version of the ADVANCE system dedicated specifically to detection of CTS in diabetes. This effort will consist primarily of modifying the device hardware and form factor to lower costs and enhance manufacturability. We also expect to simplify the software to eliminate support for non-CTS related functions. We believe that these modifications will not require a new 510(k), under the guidance issued by the Food and Drug Administration, or the FDA, on when new 510(k) submissions are required for modified devices. However, we will make a final determination on whether to file a 510(k) when the engineering work has been completed. We do not believe that these modifications will alter the appropriateness of billing for studies performed with ADVANCE CTS under CPT 95905 or the likelihood of obtaining reimbursement from Medicare and other third party insurers.

The following chart summarizes our marketed products and products in development as of December 31, 2011.

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)	nearly 1,700,000
ADVANCE	Q2 2008 - present	Nerve Conduction Invasive Needle EMG	Diagnosis and evaluation of CTS, low back pain, peripheral neuropathies (including DPN)	>103,000
NC-stat DPNCheck	Q3 2011 - present	Nerve Conduction	Diagnosis and evaluation of peripheral neuropathies, such as DPN	1,000 - 3,000
SENSUS	Target Q4 2012	Transcutaneous Electrical Nerve Stimulation	Relief for chronic, intractable pain, such as painful diabetic neuropathy	N/A
ADVANCE CTS	Target Q4 2012	Nerve Conduction	Diagnosis and evaluation of CTS	N/A

* Support to be discontinued in the first quarter of 2012.

Customers

Our customers include physicians, clinics, and hospitals. As of December 31, 2011, we had an installed base of approximately 3,000 active customers using our ADVANCE and NC-stat Systems. 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. Our NC-stat DPNCheck device was launched into the endocrinology/podiatry market in the third quarter of 2011. No single customer accounted for more than 10% of our revenues in 2011, 2010, or 2009.

Geographic Information

Substantially all of our assets, revenues, and expenses for the years ended December 31, 2011, 2010, and 2009 were located at or derived from operations in the United States. In addition, we have had limited but growing sales through distributors in the United Kingdom, the Netherlands, India, and various other countries. For each of the years ended December 31, 2011, 2010, and 2009, international revenues accounted for approximately 6%, 2%, and 2%, respectively, of our total revenues.

Sales, Marketing, and Distribution

NC-stat DPNCheck was launched in September 2011. Our initial target market is the United States endocrinology/podiatry market. We initiated sales into that market through a direct, specialty sales force that we hired, trained and deployed during the third quarter of 2011. This specialty sales organization consists of a Sales Director and eight field sales representatives who cover thirty states selected on the basis of diabetes population, number of endocrinologists and podiatrists, and income levels. Sales in the remaining states are covered by our team of field-based clinical educators.

Our installed base of ADVANCE and NC-stat accounts in the United States are supported by our clinical educators which include a Director of Clinical Education and nine field clinical educators. Our direct sales force which targeted new accounts was discontinued in January 2011 and we are not actively pursuing new ADVANCE customers. Interest expressed in new ADVANCE systems by potential customers is handled by our clinical educators 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 and our Chief Operating Officer.

Our marketing support for NC-stat DPNCheck and for ADVANCE is provided by our Vice President, Marketing, our Marketing Manager, Diabetes and two marketing staff.

We invest significant effort in technical, clinical, and business practices training for our sales organization, clinical educators, 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 Federal Trade Commission and, outside the United States, by other international bodies, and are subject to federal and state fraud and abuse enforcement activities.

Manufacturing and Supply

We rely on outside contractors for the manufacture and servicing of our products and their components, and we do not currently maintain alternative manufacturing sources for our NC-stat DPNCheck and 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. We believe these manufacturing relationships minimize our capital investment, provide us with manufacturing expertise, and help control costs.

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 may consider manufacturing certain products or product components internally, if and when demand or quality requirements make it appropriate to do so. We currently have no plans to manufacture any products or product components internally.

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

Polymer Flexible Circuits, Inc., or Parlex, has been manufacturing our nerve specific electrodes since early 1999. In the second quarter of 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. Either party may terminate the agreement at any time upon not less than 18 months prior written notice. 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.

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 is cleared for marketing within the United States, Canada, and the European Union. Our facility and the facility of our contract device manufacturer are 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 and our manufacturer 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 capability that is unique to the industry. Key members of our research and development, or 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 15 people, including 5 who hold Ph.D. or M.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 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.

Our research and development efforts are primarily focused in two areas:

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

- *Development of a first generation version of our SENSUS pain therapy device.* This device is based on many of the same electronic and neurophysiological principles as our neurodiagnostic devices and therefore we believe that we can efficiently develop a commercial product that may be useful in the treatment of painful diabetic neuropathy.

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. We believe that we are well positioned to develop additional point-of-care diagnostic devices such as for autonomic neuropathy and therapies that aid in the management of both mild and advanced forms of DPN.

Research and development expenses were approximately $3.9 million, $5.9 million, and $5.6 million for the years ended December 31, 2011, 2010, and 2009, respectively.

Clinical Programs

We maintain an active 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. For example, the National Institute of Health, or NIH, has funded large scale epidemiological studies of occupational carpal tunnel syndrome using our NC-stat device as a key component of the case definition.

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.

Competition

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 a number of companies that sell neurodiagnostic devices. These companies include CareFusion Corporation, Cadwell Laboratories, Inc., and Natus Medical Incorporated. CareFusion Corporation has substantially greater financial resources than we do. CareFusion Corporation and Cadwell Laboratories, Inc. have established a reputation as having effective worldwide distribution channels for medical instruments to neurologists and PM&R physicians.

With respect to SENSUS, there are numerous manufactures of transcutaneous electrical nerve stimulation devices. We believe that the largest 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 painful diabetic neuropathy. As a result, we are not aware of any devices that are uniquely optimized for use in treating painful diabetic neuropathy. There are a few companies that claim that their devices have specific utility for painful diabetic neuropathy, however we do not believe that these claims have been widely validated through adequate clinical studies.

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, ADVANCE, and NC-stat DPNCheck. We believe that in order to have a competitive advantage, we must develop and maintain the proprietary aspects of our technologies. We also require our employees, consultants and advisors, whom we expect to work on our products, to agree to disclose and assign to us all inventions conceived, developed using our property, or which relate to our business. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain and use information that we regard as proprietary.

Patents

As of December 31, 2011, we had 34 issued U.S. patents, 11 issued foreign patents, and 24 pending patent applications, including 17 U.S. applications, 3 international PCT applications, and 4 foreign national applications. We have filed a utility patent application for NC-stat DPNCheck and a provisional patent 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, NC-STAT and onCall. We use a trademark for ADVANCE and NC-stat DPNCHECK. We hold certain foreign trademark registrations for the marks NEUROMETRIX and NC-STAT.

Third-Party Reimbursement

Procedures performed with our neurodiagnostic medical devices may be paid for by third-party payers, including government health programs, such as Medicare, and private insurance and managed care organizations. The 2012 Physicians Fee Schedule published by the U.S. Centers for Medicare and Medicaid Services, or 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. We also believe that physicians are receiving reimbursement for CPT 95905 from a few commercial insurers. We are working with reimbursement experts to expand coverage for CPT 95905 and with physicians for their adoption of patient advance beneficiary notices where they believe that nerve conduction testing may not be covered by commercial insurers. 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 our neurodiagnostic devices.

NC-stat DPNCheck was launched in September 2011. Although we believe that NC-stat DPNCheck is appropriately described by CPT 95905, we expect only limited third-party reimbursement for health care providers using the device to diagnose and evaluate DPN. However, given the anticipated low costs involved combined with clinical upside of this test to people with diabetes and to physicians caring for them, we believe that an out-of-pocket payment model will develop. We intend to initiate the type of clinical studies that will lead to broad third party coverage. We do not expect this coverage to develop in the near term and cannot be sure of our eventual success in obtaining such coverage.

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, which puts the providers at financial risk for the services provided to their patients by paying these providers a predetermined payment per member per month, and consequently, may limit the willingness of these providers to use our products.

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 device and ADVANCE System, however, will depend upon, among other things, our customers receiving, and our potential customers' expectation that they will receive sufficient reimbursement from third-party payers or directly from patients for performing procedures using these products. See Item 1A, "Risk Factors," *"If physicians or other health care providers are unable to obtain sufficient reimbursement from third-party health care payers for procedures performed using our products, the adoption of our products and our future product sales will continue to be materially adversely affected."*

FDA and Other Governmental Regulation

FDA Regulation

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

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

Before being introduced into the market, our products must obtain market clearance or approval through the 510(k) pre-market notification process, the *de novo* review process or the PMA process, unless they qualify for an exemption from these processes. See Item 1A, "Risk Factors," *"We are subject to extensive regulation by the FDA which could restrict the sales and marketing of ADVANCE and NC-stat DPNCheck, 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 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.

During the fourth quarter of 2006, at the request of the FDA, we submitted a 510(k) relating to portions of our onCall Information System, or onCall, that are currently in use in the NC-stat System. In June 2010 we received a not substantially equivalent, or NSE, determination from the FDA regarding this 510(k) submission. We appealed the decision to the FDA's next level supervisor who upheld the NSE determination. In February 2011 we notified the FDA that we have implemented a program to transition users of NC-stat devices to our 510(k) cleared ADVANCE System that does not use the portions of onCall referenced in the NSE decision. This transition program will be completed by February 2012, after which we will no longer provide NC-stat customers with access to onCall. The NC-stat DPNCheck device does not use those portions of onCall referenced in the NSE decision.

We believe that as a transcutaneous electrical nerve stimulator, the SENSUS pain therapy device is a Class II medical device which will require a 510(k) premarket notification prior to commercial distribution. The FDA has issued a draft special controls guidance document for transcutaneous electrical nerve stimulators for pain relief. This document outlines the FDA's expectations with respect to the 510(k) submission, including requirements for bench top and clinical data.

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 and the facility utilized by our contract manufacturer will be inspected again as required by the FDA. If the FDA finds significant violations, we or our contract device manufacturer 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 lead to our initial public offering in 2004. The health market, particularly the physician office segment, embraced the opportunity to perform nerve conduction tests which previously had always required referral to specialists. Point-of-care nerve testing was seen to provide a combination of improved patient care and patient convenience. The success of point-of-care nerve testing, a market which we created, was met with resistance in some sectors of the medical community, particularly by neurologists and physical medicine and rehabilitation physicians, both of which had traditionally provided nerve testing services. As a consequence of successful lobbying by these specialists, physicians using our technology experienced increased denials of coverage by third party payers resulting in their discontinuing usage and our difficulty in accruing new customer accounts. In late 2009 CMS included in the Physician Fee Schedule a new Category I CPT Code, CPT 95905, for nerve conduction studies performed using preconfigured electrode such as those employed with our products. During 2010 most Medicare fiscal intermediaries assumed coverage for CPT 95905 for at least some clinical indications; however, the health care environment has been such that we have been unable to secure broad coverage among private payers, which is essential to the success of our products. This experience was reflected in our revenues for the legacy Neurodiagnostics business, which peaked in 2006 at $55.3 million. We reported revenue of $10.3 million, $13.9 million, and $26.1 million in 2011, 2010, and 2009, respectively, for the legacy Neurodiagnostics business.

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 fasted 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 December 31, 2011, we had a total of 58 employees, 55 of which were full-time employees. Of these employees, 15 were in research and development, 31 in sales and marketing, 2 in distribution and 10 in general and administrative services. One employee holds both M.D. and Ph.D. degrees, three additional employees hold a Ph.D. degree, and two additional employees hold an M.D. degree.

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

Available Information

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

Corporate Information

NeuroMetrix was founded in June 1996 by our President and Chief Executive Officer, Shai N. Gozani, M.D., Ph.D. We originally were incorporated in Massachusetts in 1996, and we reincorporated in Delaware in 2001. Our principal offices are located at 62 Fourth Avenue, Waltham, Massachusetts 02451.

ITEM 1A. Risk Factors

You should carefully consider the following risks and all other information contained in this Annual Report on Form 10-K and our other public filings before making any investment decisions with respect to our common stock. If any of the following risks occurs, our business, prospects, reputation, results of operations, or financial condition could be harmed. In that case, the trading price of our common stock could decline, and our stockholders could lose all or part of their investment. This Annual Report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of specific factors, including the risks described below and elsewhere in this Annual Report on Form 10-K.

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

The extent of our future operating income or losses is highly uncertain, and we may not be able to reach and sustain profitability. We have incurred significant cumulative net losses since our inception. Our net losses for the years ended December 31, 2011, 2010, and 2009 were approximately $10.0 million, $16.9 million, and $11.9 million, respectively, reflecting a decline in revenues. At December 31, 2011, we had an accumulated deficit of approximately $128.6 million. We cannot assure you that we will be able to reach or sustain profitability.

We have shifted our business focus to diabetes care. We cannot assure you that we will be successful in diabetes care or that our initial commercial product, NC-stat DPNCheck, for diagnosis and evaluation of systemic neuropathies, such as DPN, will be successful.

Our strategic focus is now on diabetes care. Our initial diabetes care product, NC-stat DPNCheck, is a rapid, cost-effective, quantitative test for systemic neuropathies, such as DPN. NC-stat DPNCheck is a modified version of our existing NC-stat device, designed specifically for the assessment of sural nerve conduction, a biomarker for DPN, at the point of care. We initiated commercial shipments of NC-stat DPNCheck in the third quarter of 2011. Our future prospects are closely tied to our success with NC-stat DPNCheck which, in turn, depends upon market acceptance and growth in future revenues. We cannot assure you that our diabetes care strategy, including the commercialization of NC-stat DPNCheck 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 of physicians to obtain patient payment for nerve testing using NC-stat DPNCheck;
- inability to secure broad-based third party reimbursement to physicians for nerve testing using NC-stat DPNCheck;
- decreased rates of patient visits to physicians;
- unfavorable experiences by physicians using NC-stat DPNCheck;
- physicians' reluctance to alter their existing practices; and
- the failure of other companies' existing drug development programs to produce an effective treatment for large fiber diabetic peripheral neuropathy, which may limit the perceived need for and the actual use of NC-stat DPNCheck and thereby limit or delay our growth in the diabetes market.

If we are unable to expand the market for the NC-stat DPNCheck product, 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 and NC-stat Systems to generate substantially all of our revenues. Any factors that negatively impact our sales of these products, including our plans to discontinue support of NC-stat in the first quarter of 2012, could significantly reduce our ability to generate revenues.

We launched the NC-stat System in May 1999 and introduced the ADVANCE System, our next generation nerve conduction testing system, in June 2008. We have derived, and continue to derive, substantially all of our revenues from sales of the products that comprise these two systems, particularly from electrodes. The NC-stat System is being phased out and will not be supported beyond the first quarter of 2012. We expect that sales of the ADVANCE System will continue to constitute the majority of our sales for the next year and beyond. Accordingly, our ability to generate revenues 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:

- the failure of the market to accept our products;
- 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 could be significantly reduced.

If physicians or other health care providers are unable to obtain sufficient reimbursement from third-party health care payers for procedures performed using our products, the adoption of our products and our future product sales will continue to be materially adversely affected.

Widespread adoption of our products by the medical community is unlikely to occur if physicians do not receive sufficient reimbursement from third-party payers for performing procedures using our products. If physicians are unable to obtain adequate reimbursement for procedures performed using our 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 procedures are reimbursed by third-party payers, adverse changes in payers' policies toward reimbursement for the procedures would harm our ability to market and sell our products. Third-party payers include those governmental programs such as Medicare and Medicaid, workers' compensation programs,

private health insurers and other organizations. These organizations may deny coverage if they determine that a procedure was not reasonable or necessary, for example, if its use was not considered medically appropriate, or was experimental, or was performed for an unapproved indication.

In addition, some health care systems are moving towards managed care arrangements in which they contract to provide comprehensive health care for a fixed cost per person, irrespective of the amount of care actually provided. These providers, in an effort to control health care costs, are increasingly challenging the prices charged for medical products and services and, in some instances, have pressured medical suppliers to lower their prices. Guidelines of the U.S. Centers for Medicare and Medicaid Services, or CMS, set the reimbursement rates for procedures covered by Medicare.

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.

The CMS Physician Fee Schedule includes the category I CPT code 95905, or CPT 95905, for nerve conduction studies performed with preconfigured electrode arrays, such as those utilized with our ADVANCE System and with our NC-stat DPNCheck device. This code has been adopted throughout the Medicare system. Although Medicare now provides coverage for nerve testing using our proprietary pre-configured electrodes under CPT 95905 for at least some clinical indications, most commercial insurance companies have not revised their coverage policies. We generally do not foresee a significant near-term improvement in reimbursement for procedures performed with our neurodiagnostic devices. Additionally, we do not expect broad third-party reimbursement coverage for NC-stat DPNCheck to develop in the near term and cannot be sure of our eventual success in obtaining such coverage. We cannot assure you that third-party coverage will be available, that the amounts paid for procedures performed with our medical devices will be adequate, or that future legislation, regulation, or reimbursement policies of third-party payers will not adversely affect the demand for our products or our ability to sell these products on a profitable basis. Uncertain physician economics creates an obstacle to new account acquisition. The unavailability or inadequacy of third-party payer coverage or reimbursement could have a material adverse effect on our business, operating results, and financial condition.

We are subject to extensive regulation by the FDA which could restrict the sales and marketing of ADVANCE and NC-stat DPNCheck, 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.

In the second quarter of 2010, we were notified by the FDA that certain reporting functions of the onCall Information System, or onCall, that operates with our cleared NC-stat device and for which we submitted a 510(k) premarket notification in 2006 were deemed by the FDA to be not substantially equivalent, or NSE, to the cleared NC-stat System or other existing predicate devices. In its letter, the FDA indicated that we could submit another 510(k) with specific additional information identified in the letter. onCall has been in use since 1999, and continued in use with FDA's agreement after we voluntarily submitted a 510(k) in 2006 for these reporting functions, in order to resolve our differences of opinion with FDA as to whether such reporting functions had been covered by previous 510(k) premarket notifications. We submitted an administrative appeal of FDA's NSE determination in July 2010. The appeal was made to the FDA's next level supervisor under Title 21 of the Code of Federal Regulations Part 10.75, Internal Agency Review of Decisions. In December 2010, FDA's next level supervisor upheld the NSE decision and stated that onCall should not be marketed nor should users of NC-stat devices continue to have access to certain components of onCall. The FDA response suggested that we submit a new 510 (k) for certain components of onCall. In our February 2011 reply to the FDA, we reported that we have implemented a year-long program to transition users of NC-stat devices to our 510(k) cleared ADVANCE System which does not use those components of onCall which are addressed in the NSE letter. This transition program is underway and we expect to complete it in the first quarter of 2012. Additionally, we have notified our customers that we will no longer support the NC-stat System.

Our NC-stat DPNCheck device for detection and evaluation of peripheral neuropathy at the point of care is a technical modification to the NC-stat device, has the same intended use, and does not use those portions of the onCall System referenced in the NSE decision. Under the FDA's published guidance on 510(k) requirements for modified devices, we do not believe that a new 510(k) submission is required for NC-stat DPNCheck.

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

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

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

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

We depend on several single source manufacturers to produce 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 all of the components of our NC-stat DPNCheck and ADVANCE systems. In the event that our manufacturers cease to manufacture sufficient quantities of our products 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, particularly our electrodes and biosensors, 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 electrodes and biosensors for the domestic market. Sunburst EMS, Inc. manufactures electronic boards and other components of our NC-stat DPNCheck components which we assemble in-house to produce completed devices. Sunburst EMS, Inc. also manufactures our ADVANCE 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.

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

Currently, our revenues entirely depend upon sales of our ADVANCE and NC-stat systems, the sales of which have been declining in recent years. We are presently focused on commercializing NC-stat DPNCheck, advancing our pipeline of other diabetes products, and supporting the general purpose ADVANCE platform. 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 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;

- 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.

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.

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 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.

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. Failure to comply with the terms of the Deferred Prosecution Agreement and 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.

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 and NC-stat DPNCheck 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. Our products, particularly our electrodes, require a significant degree of technical expertise to produce. If these manufacturers fail to produce our products to specification, or if the manufacturers use defective materials or workmanship in the manufacturing process, the reliability and performance of our products will be compromised.

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

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

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

- legal action.

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

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

Our success largely depends on the skills, experience, and efforts of our 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, Neurodiagnostics; 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 only 58 employees as of December 31, 2011, 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 new products, such as NC-stat DPNCheck, and upgrade existing products, such as ADVANCE. 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 the current systems or any of our other current or future 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 CareFusion Corporation, Cadwell Laboratories, Inc., and Natus Medical Incorporated. These companies enjoy significant competitive advantages, including:

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

As we develop the market for point-of-care nerve testing, particularly 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 point-of-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.

We are dependent upon the computer and communications infrastructure employed and utilized by our customer information system and any failures or disruptions in this infrastructure could impact our revenues and profit margins or harm our reputation.

We are dependent upon the computer and communications infrastructure employed and utilized by our customer information system. Our computer and communications infrastructure consists of standard hardware, off-the-shelf system software components, database servers, proprietary application servers, a modem bank and desktop applications. Our future success will depend, in part, upon the maintenance and growth of this infrastructure. Any failures or outages of this infrastructure as a result of a regulatory action by the FDA, computer virus, intentional disruption of our systems by a third-party, manufacturing failure, telephone system failure, fire, storm, flood, power loss or other similar events, could prevent or delay the operation of our onCall Information System, which could result in increased costs to eliminate these problems and address related security concerns and harm our reputation with our customers. In addition, if our infrastructure fails to accommodate growth in customer transactions, customer satisfaction could be impaired, we could lose customers, our ability to add customers could be impaired or our costs could be increased, any of which would harm our business.

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 continue to 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 6% of our revenues in 2011. We are working to expand market penetration, particularly in Europe. As we continue to expand into foreign markets, we will be subject to new business risks, including:

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

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

Our loan and security agreement with Comerica Bank, which we refer to as our Comerica credit facility, contains financial and operating restrictions that may limit our access to credit. If we fail to comply with covenants in the Comerica 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 Comerica credit facility, provisions in the Comerica 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 Comerica credit facility also contains other customary covenants. We may not be able to comply with these covenants 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 Comerica credit facility. In addition to preventing additional borrowings under the Comerica credit facility, an event of default, if not cured or waived, may result in the acceleration of the maturity of indebtedness outstanding under the Comerica credit facility at the time of the default, which would require us to pay all amounts outstanding. If an event of default occurs, we may not be able to cure it within any applicable cure period, if at all. If the maturity of our indebtedness is accelerated, we may not have sufficient funds available for repayment or we may not have the ability to borrow or obtain sufficient funds to replace the accelerated indebtedness on terms acceptable to us, or at all.

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

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

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

- unanticipated costs.

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

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

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

We may 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 $10.3 million as of December 31, 2011. On February 13, 2012 we closed a public securities offering that generated $8.5 million in gross proceeds and, after transaction costs and fees, yielded approximately $7.5 million in net proceeds. We believe that these resources and the cash to be generated from expected product sales will be sufficient to meet our projected operating requirements for at least the next twelve months. 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 may need to raise additional funds to support our operating and capital needs. 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 and 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.

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

Until we are profitable, we will need significant additional funds to develop our business and sustain our operations. 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 February 1, 2012 our stock price has fluctuated from a low of $1.15 to a high of $247.14. 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 milestones and to do so in accordance with our timing estimates;
- changes in policies affecting third-party coverage and reimbursement in the United States and other countries;
- changes in government regulations and standards affecting the medical device industry and our products;
- ability of our products to achieve market success;

- the performance of third-party contract manufacturers and component suppliers;
- actual or anticipated variations in our results of operations or those of our competitors;
- announcements of new products, technological innovations or product advancements by us or our competitors;
- developments with respect to patents and other intellectual property rights;
- sales of common stock or other securities by us or our stockholders in the future;
- additions or departures of key scientific or management personnel;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- trading volume of our common stock;
- changes in earnings estimates or recommendations by securities analysts, failure to obtain or maintain analyst coverage of our common stock or our failure to achieve analyst earnings estimates;
- public statements by analysts or clinicians regarding their perceptions of our clinical results or the effectiveness of our products;
- decreases in market valuations of medical device companies; and
- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors.

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

Our stock has previously been subject to delisting proceedings on NASDAQ and could be subject to such proceedings in the future which could affect its market price 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, including failure to satisfy the minimum bid price and the minimum stockholders' equity. 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 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 the common stock and your ability to sell our securities in the secondary market.

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

Although our common stock is listed on the NASDAQ Capital Market, our common stock has experienced low trading volume. The 50 day average trading volume through February 1, 2012 as reported by NASDAQ was approximately 19,000 shares. Limited trading volume may subject our common stock to greater price volatility and may make it difficult for investors to sell shares at a price that is attractive to them.

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

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

- authorize the issuance of preferred stock which can be created and issued by the Board of Directors without prior stockholder approval, with rights senior to those of our common stock;
- provide for a classified Board of Directors, with each director serving a staggered three-year term;
- prohibit our stockholders from filling board vacancies, calling special stockholder meetings, or taking action by written consent;
- provide for the removal of a director only with cause and by the affirmative vote of the holders of 75% or more of the shares then entitled to vote at an election of our directors; and
- require advance written notice of stockholder proposals and director nominations.

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

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

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 Comerica credit facility precludes us from paying any dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of potential gain for the foreseeable future.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our headquarters is located in an approximately 30,000 square foot facility in Waltham, Massachusetts, which we occupy under an office lease expiring in March 2013. We believe that our existing facilities are adequate for our current needs.

ITEM 3. 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.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock was traded on the NASDAQ Global Market from its initial listing in July 2004 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 under the symbol "NURO". The price range per share reflected in the table below is the high and low sales prices of our common stock as reported by NASDAQ (rounded to the nearest penny) for the periods indicated.

	Years ended December 31,			
	2011		2010	
	High	Low	High	Low
First quarter	$4.14	$2.58	$16.50	$10.50
Second quarter	3.78	2.46	11.40	6.06
Third quarter	3.30	1.60	7.98	3.12
Fourth quarter	2.05	1.15	4.50	2.82

Stockholders

On February 15, 2012, there were approximately 101 stockholders of record of our common stock. This number does not include stockholders for whom shares were held in a "nominee" or "street" name. On February 15, 2012, the last reported sale price per share of our common stock on the NASDAQ Capital Market was $0.88.

Dividends

We have never declared or paid any cash dividends on our common stock. We currently intend to retain future earnings, if any, to finance the expansion and growth of our business and do not expect to pay any cash dividends in the foreseeable future. Payment of future cash dividends, if any, will be at the discretion of our board of directors after

taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, and plans for expansion. Additionally, the Comerica credit facility restricts our ability to pay dividends.

Issuer Purchases of Equity Securities

We reacquired 883 shares of our common stock, at an average price of $2.86 per share, during the year ended December 31, 2011, in connection with the vesting of certain restricted shares issued pursuant to our Third Amended and Restated 2004 Stock Option and Incentive Plan. We reacquired these shares as part of the settlement of tax withholding obligations by participants under our Third Amended and Restated 2004 Stock Option and Incentive Plan. The following table sets forth these reacquisitions that we made during the year ended December 31, 2011 and reflects a 1-for-6 reverse split of our common stock completed on September 1, 2011:

Period	**Total Number of Shares Purchased**	**Average Price Paid per Share**	**Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs**	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs
January 1, 2011 – January 31, 2011	—	—	N/A	N/A
February 1, 2011 – February 28, 2011	—	—	N/A	N/A
March 1, 2011 – March 31, 2011	—	—	N/A	N/A
April 1, 2011 – April 30, 2011	676	$3.00	N/A	N/A
May 1, 2011 – May 31, 2011	—	—	N/A	N/A
June 1, 2011 – June 30, 2011	—	—	N/A	N/A
July 1, 2011 – July 31, 2011	160	$2.64	N/A	N/A
August 1, 2011 – August 31, 2011	—	—	N/A	N/A
September 1, 2011 – September 30, 2011	—	—	N/A	N/A
October 1, 2011 – October 31, 2011	20	$1.75	N/A	N/A
November 1, 2011 – November 30, 2011	—	—	N/A	N/A

December 1, 2011 – December 31, 2011	27	$1.33	N/A	N/A
Total	883	$2.86	N/A	N/A

30

ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data are derived from our audited financial statements, which have been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm. The selected financial data below should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," Item 7A, "Quantitative and Qualitative Disclosures About Market Risk" and our financial statements and related notes for the years ended 2011, 2010, and 2009 appearing elsewhere in this Annual Report on Form 10-K:

	Years Ended December 31,				
	2011	2010	2009	2008	2007
	(In thousands, except share and per share data)				
Statement of Operations Data:					
Revenues	$10,397	$13,900	$26,137	$31,121	$43,667
Cost of revenues	4,722	7,050	7,536	9,012	11,338
Gross margin	5,675	6,850	18,601	22,109	32,329
Operating expenses:					
Research and development	3,877	5,856	5,611	5,589	4,892
Sales and marketing	6,689	11,072	10,841	14,647	22,837
General and administrative	5,112	7,232	9,119	12,016	14,834
Goodwill impairment	—	—	—	5,833	—
Charge for legal settlement	—	—	—	3,706	—
Intangible asset impairment	—	—	—	1,768	—
Gain from deconsolidation of joint venture	—	—	—	(2,100)	—
Total operating expenses	15,678	24,160	25,571	41,459	42,563
Loss from operations	(10,003)	(17,310)	(6,970)	(19,350)	(10,233)
Loss on available-for-sale investment	—	—	—	(2,500)	—
Interest and other income	22	298	227	721	1,751
Warrants fair value adjustment	—	—	(5,175)	—	—
Loss from continuing operations	(9,981)	(17,012)	(11,918)	(21,129)	(8,482)
(Loss) income from discontinued operations	—	—	—	(6,601)	104
Net loss before taxes	(9,981)	(17,012)	(11,918)	(27,730)	(8,378)
Income tax benefit	—	121	—	—	—
Net loss	$(9,981)	$(16,891)	$(11,918)	$(27,730)	$(8,378)
Loss per common share from continuing operations, basic and diluted	$(2.59)	$(4.40)	$(4.26)	$(9.23)	$(4.03)
	$—	$—	$—	$(2.88)	$0.05

(Loss) income per common share from discontinued operations, basic and diluted					
Net loss per common share, basic and diluted	$(2.59)	$(4.40)	$(4.26)	$(12.11)	$(3.98)

	As of December 31,				
	2011	2010	2009	2008	2007
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents, and short-term investments	$10,290	$16,987	$30,432	$19,797	$29,719
Working capital	10,482	19,020	34,374	21,632	33,304
Total assets	14,221	23,066	40,567	31,147	56,209
Total liabilities	3,132	2,867	4,857	8,314	9,479
Total stockholders' equity	11,089	20,199	35,710	22,833	46,730

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

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

Overview

We are a medical device company focused on the diagnosis and 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.

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 the nerve-related complications of diabetes 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 vertical market and our goal is to be the dominant player in this field.

Our initial product for diabetic neuropathy, NC-stat DPNCheck, was launched in September 2011. 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. Our target market is United States endocrinologists and podiatrists. We believe that this market represents approximately 15,000 physicians who are viewed as leaders in the detection and management of DPN. We have initiated sales into this market through a direct, specialty sales force that we hired, trained and deployed during the third quarter of 2011. As of December 31, 2011, we have placed devices with

customer accounts representing over 200 physicians.

We also market a medical device, which has been cleared by the FDA and which is used for the assessment of neuropathies such as carpal tunnel syndrome, diabetes, and sciatica. Our ADVANCE™ NCS/EMG System, or the ADVANCE System, which is a part of our legacy neurodiagnostics business, is a comprehensive platform for the performance of traditional nerve conduction studies and invasive electromyography procedures. We focus our sales efforts for the ADVANCE System on physician offices and clinics. Our ADVANCE System is comprised of: (1) various types of electrodes and needles, (2) our ADVANCE device and related modules, and (3) a communication hub that enables the physician's office to network their device to our servers for data archiving, report generation and other network services. We do not intend to support the original NC-stat System beyond the first quarter of 2012 and are transitioning our NC-stat customers to the ADVANCE System.

Our neurodiagnostic equipment is used in approximately 3,000 physicians' offices, clinics, and hospitals. Nearly 1.7 million patient studies have been performed with our neurodiagnostic devices since 1999. We manage our neurodiagnostic business to optimize its future cash contribution while maintaining a high standard of customer support.

Results of Operations

Comparison of Years Ended December 31, 2011 and December 31, 2010

Revenues

The following table presents a historical view of our active customers and studies performed:

	Years Ended December 31,			
	2011	2010	Change	% Change
Installed base (active testing accounts)	2,997	3,875	(878)	(22.7)%
Patient studies	104,442	131,272	(26,830)	(20.4)

The following table summarizes our revenues:

	Years Ended December 31,			
	2011	2010	Change	% Change
	(in thousands)			
Revenues	$10,396.8	$13,899.7	$(3,502.9)	(25.2)%

Revenues include sales of medical equipment consisting of sales of the ADVANCE device and, in 2010, the NC-stat device, accessories, extended service agreements, and sales of consumables consisting of various electrodes, which are used with our ADVANCE and NC-stat Systems, and EMG needles which are used with our ADVANCE System. In 2011, revenues also included $85,000 from sales of our initial diabetes product, NC-stat DPNCheck, which was launched in September 2011. Revenues for the year ended December 31, 2011 declined $3.5 million to $10.4 million, compared with $13.9 million for the year ended December 31, 2010, reflecting a 22.7% contraction of our neurodiagnostic installed base that has contributed to lower electrodes sales.

Cost of Revenues and Gross Margin

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

	Years Ended December 31,			
	2011	2010	Change	% Change
	(in thousands)			
Cost of revenues	$4,722.1	$7,050.2	$(2,328.1)	(33.0)%
Gross margin	$5,674.7	$6,849.5	$(1,174.8)	(17.2)

Our cost of revenues decreased $2.3 million to $4.7 million, or 45.4% of revenues for the year ended December 31, 2011, compared with $7.1 million, or 50.7% of revenues, for the year ended December 31, 2010. This decrease is due primarily to lower neurodiagnostic shipment volume, partially offset by the impact of higher electrode costs, which have increased due to lower production volumes, compared with the year ended December 31, 2010. In addition, gross margin for 2010 included inventory charges of $1.8 million related to a strategic change in direction of our business that was announced on January 4, 2011. Our gross margin of 54.6% of revenues for the year ended December 31, 2011 increased from 49.3% of revenues for the same period in 2010. The lower gross margin percentage for 2010 resulted primarily from the inventory charges noted above.

Operating Expenses

The following table presents a breakdown of our operating expenses:

	Years Ended December 31,			
	2011	2010	Change	% Change
	(in thousands)			
Operating expenses:				
Research and development	$3,877.5	$5,855.3	$(1,977.8)	(33.8)%
Sales and marketing	6,688.6	11,072.2	(4,383.6)	(39.6)
General and administrative	5,111.6	7,231.9	(2,120.3)	(29.3)
Total operating expenses	$15,677.7	$24,159.4	$(8,481.7)	(35.1)

Research and Development

Research and development expenses for the years ended December 31, 2011 and 2010 were $3.9 million and $5.9 million, respectively. The comparative results included decreases of $1.1 million in personnel related costs, $411,000 in clinical studies and product development costs, $315,000 in costs of consulting and outside services, $125,000 for licenses and fees, $124,000 for stock-based compensation, $53,000 for amortization of intangible assets, $50,000 for facilities costs, and $39,000 for supplies and equipment costs. These decreases were partially offset by an impairment charge of $192,500 in the second quarter of 2011 to write off the remaining value of intangible assets following our decision to terminate development efforts relating to certain technological and intellectual property assets acquired in 2009, and a $101,000 increase in recruiting costs.

Sales and Marketing

Sales and marketing expenses decreased to $6.7 million for the year ended December 31, 2011 from $11.1 million for the year ended December 31, 2010. Personnel costs decreased $3.4 million and travel and entertainment costs decreased $764,000 reflecting the January 2011 termination of our direct neurodiagnostics sales force in conjunction with a strategic initiative to more efficiently focus on our installed base of active accounts, partially offset by the implementation of a lower cost sales force focused on the endocrinology and podiatry markets beginning in the third quarter of 2011. In addition, recruiting costs decreased $276,000, internal meeting costs decreased $135,000, and stock-based compensation decreased $93,000. These decreases were partially offset by increases of $170,000 in advertising and promotions costs and consulting costs of $76,000 largely related to our diabetes initiative.

General and Administrative

General and administrative expenses decreased to $5.1 million for the year ended December 31, 2011 from $7.2 million for the year ended December 31, 2010. This decrease included $625,000 from personnel costs, reflecting reduced headcount, $500,000 from professional fees, $242,000 from insurance costs, $143,000 from supplies and equipment costs, $131,000 from stock-based compensation, $121,000 from taxes, licenses and fees, $105,000 from bad debt expense, $95,000 from facilities costs, $57,000 from consulting and temporary labor costs, and $45,000 from recruiting costs.

Interest and other income

The following table presents a breakdown of our other income and expenses:

	Years Ended December 31,			
	2011	2010	Change	% Change
	(in thousands)			
Other income and expenses:				
Interest income	$21.9	$53.8	$(31.9)	(59.3)%
Federal grant income	—	244.5	(244.5)	(100.0)
Total other income and expenses	$21.9	$298.3	$(276.4)	(92.7)

Interest income was $22,000 for the year ended December 31, 2011 and $54,000 for the year ended December 31, 2010. In addition, in 2010 we received a $244,000 U.S. Qualifying Therapeutic Discovery Project grant under section 48D of the Internal Revenue Code.

Comparison of Years Ended December 31, 2010 and December 31, 2009

Revenues

The following table presents a historical view of our active customers and studies performed:

	Years Ended December 31,			
	2010	2009	Change	% Change
Installed base (active testing accounts)	3,875	4,493	(618)	(13.8)%
Patient studies	131,272	161,291	(30,019)	(18.6)

The following table summarizes our revenues:

	Years Ended December 31,			
	2010	2009	Change	% Change
	(in thousands)			
Revenues	$13,899.7	$26,137.0	$(12,237.3)	(46.8)%

Revenues for the year ended December 31, 2010, which were related to our neurodiagnostic business, declined $12.2 million to $13.9 million, compared with $26.1 million for the year ended December 31, 2009. This decline was largely due to three primary factors: our installed base of customers contracted by 13.8%; patient studies contracted by 18.6%; and our electrode average sales price, or ASP, declined by 20.1% from $34.61 for 2009 to $27.66 for 2010. Revenues for 2010 reflected the introduction of Medicare CPT code 95905, which was published by the CMS in the fourth quarter of 2009, as well as continued reimbursement uncertainty with commercial insurers relating to our products. Medicare CPT code 95905 addresses nerve conduction studies performed with pre-configured electrode arrays such as those used with the NC-stat System. The code both defines nerve test procedures and assigns values on a different basis than pre-existing codes. The net result was lower physician reimbursement per nerve study which has had a negative impact on our revenues.

Cost of Revenues and Gross Margin

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

	Years Ended December 31,			
	2010	2009	Change	% Change
	(in thousands)			
Cost of revenues	$7,050.2	$7,535.6	$(485.4)	(6.4)%
Gross margin	$6,849.5	$18,601.4	$(11,751.9)	(63.2)

Our cost of revenues was $7.1 million, or 50.7% of revenues, for the year ended December 31, 2010, compared to $7.5 million, or 28.8% of revenues for the year ended December 31, 2009. The decrease of $485,400 in cost of revenues was due to lower shipment volume, partially offset by inventory charges of $1.8 million related to a strategic change in direction of our business that was announced on January 4, 2011. Our gross margin percentage of 49.3% of revenues for the year ended December 31, 2010 decreased from 71.2% of revenues for the same period in 2009. The lower gross margin percentage for 2010 resulted primarily from the inventory charges, as well as lower electrode ASP compared with 2009.

Operating Expenses

The following table presents a breakdown of our operating expenses:

	Years Ended December 31,				
	2010	2009	Change	% Change	
	(in thousands)				
Operating expenses:					
Research and development	$5,855.3	$5,611.3	$244.1	4.3	%
Sales and marketing	11,072.2	10,840.3	231.9	2.1	
General and administrative	7,231.9	9,119.0	(1,887.1)	(20.7	)
Total operating expenses	$24,159.4	$25,570.6	$(1,411.2)	(5.5	)

Research and Development

Research and development expenses increased to $5.9 million for the year ended December 31, 2010 from $5.6 million for the year ended December 31, 2009. The comparative results for 2010 included increases of $504,000 in expensed materials relating to the development of new products and $351,000 for license maintenance fees, partially offset by a $368,000 decrease in stock-based compensation, a $105,000 decrease in professional fees, a $73,000 decrease in the cost of design work, and a $55,000 decrease in the cost of consulting and outside services.

Sales and Marketing

Sales and marketing expenses increased to $11.1 million for the year ended December 31, 2010 from $10.8 million for the year ended December 31, 2009. This increase mainly resulted from a $421,000 increase in compensation and related costs reflecting the addition of international sales staff, which increased costs by $687,000, and the addition of a team of field clinical educators which increased costs by $1.4 million. These increases were largely offset by reduced costs resulting from a reduction in the size of our direct sales force.

General and Administrative

General and administrative expenses decreased to $7.2 million for the year ended December 31, 2010 from $9.1 million for the year ended December 31, 2009. This decrease included reductions of $415,000 for personnel costs, $356,000 for consulting and outside services costs, $292,000 for stock-based compensation, $273,000 for insurance costs, $179,000 for professional fees, and $154,000 for credit card fees.

Interest and other income

The following table presents a breakdown of our other income and expenses:

	Years Ended December 31,			
	2010	2009	Change	% Change
	(in thousands)			
Other income and expenses:				

Interest income	$53.8	$226.9	$(173.1)	(76.3	)%
Federal grant income	244.5	—	244.5	N/A	
Warrants fair value adjustment	—	(5,175.1)	5,175.1	(100.0	)
Total other income and expenses	$298.3	$(4,948.2)	$5,246.5	(106.0	)

Interest and other income was $298,000 and $227,000 for the years ended December 31, 2010 and 2009, respectively. The increase in 2010 resulted from the receipt of a $244,000 U.S. Qualifying Therapeutic Discovery Project grant under section 48D of the Internal Revenue Code. Interest income of $54,000 in 2010 was earned from investments in cash equivalents and short-term investments. The decrease in interest income for the year ended December 31, 2010, as compared to the same period a year ago, reflects lower average invested balances and lower rates of return.

Warrants fair value adjustment

Warrants fair value adjustment represents net charges recorded during 2009 to adjust the liability for outstanding warrants issued in an equity financing in September 2009. During October 2009, we executed addenda to these warrants such that upon a change in control, as defined, the warrant holders will receive the Black-Scholes value of the warrants in the same currency and same proportions as will be received by our common stockholders. Following the addenda, the warrant liability in the amount of $19.7 million was reclassified to additional paid-in capital.

Liquidity and Capital Resources

Our principal source of liquidity is our cash and cash equivalents. As of December 31, 2011, cash and cash equivalents totaled $10.3 million. On February 13, 2012, we completed a public offering of equity securities. We issued 8,530,410 shares of common stock and warrants to purchase 4,265,205 shares of common stock and received offering proceeds, net of discounts, commissions and expenses, of approximately $7.5 million. In addition, the placement agent for the offering was issued warrants to purchase 426,520 shares of common stock. See Note 16, Subsequent Events, of our Notes to Financial Statements contained elsewhere in this Annual Report on Form 10-K for further information regarding this transaction. Our ability to generate revenue will largely depend on the success of our diabetes business initiative and our ability to manage our neurodiagnostic business to optimize cash flow. A low level of market interest in NC-stat DPNCheck, an accelerating decline in our neurodiagnostics consumables sales, or unanticipated increases in our operating costs would have an adverse effect on our liquidity and cash generated from operations. The following table sets forth information relating to our liquidity:

	December 31, 2011	December 31, 2010	Change	% Change
	($ in thousands)			
Cash and cash equivalents	$10,290.4	$ 16,986.8	$(6,696.4)	(39.4)%

Our Comerica credit facility permits us to borrow up to $7.5 million on a revolving basis. The Comerica credit facility expires on May 2, 2012. Amounts borrowed under the Comerica credit facility will bear interest equal to the prime rate plus 0.5%. Any borrowings under the Comerica credit facility will be secured by our cash, accounts receivable, inventory, and equipment. The Comerica credit facility includes traditional lending and reporting covenants, including that certain financial covenants applicable to liquidity are to be maintained by us. As of December 31, 2011, we were in compliance with these covenants and had not borrowed any funds under the Comerica credit facility. See Note 14, Credit Facility, of our Notes to Financial Statements contained elsewhere in this Annual Report on Form 10-K.

During the year ended December 31, 2011, our cash and cash equivalents decreased by $6.7 million, primarily due to net cash used in operating activities.

In managing our working capital, two of the financial measurements we monitor are days sales outstanding, or DSO, and inventory turnover rate, which are presented in the table below for the years ended December 31, 2011 and 2010:

	Years Ended December 31,

	2011	2010
Days sales outstanding (days)	40	68
Inventory turnover rate (times per year)	2.3	2.0

Our payment terms extended to our customers generally require payment within 30 days from invoice date. DSO's have improved over the past year due to improved collection efforts and lower sales on extended payment terms.

Our inventory turnover rate for the year ended December 31, 2011 was 2.3 times per year, compared with 2.0 times per year for the year ended December 31, 2010. The increase in the inventory turnover rate reflects our efforts to improve inventory management.

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

	Years Ended December 31,		
	2011	2010	2009
	(in thousands)		
Net cash used in operating activities	$(6,778.4)	$(13,307.1)	$(6,137.1)
Net cash provided by (used in) investing activities	67.5	7,188.5	(692.1)
Net cash provided by financing activities	14.5	168.0	17,464.3

We expect to continue to incur net losses and negative cash flows for the foreseeable future. Our operating activities used $6.8 million in the year ended December 31, 2011. The primary drivers for the use of cash in our operating activities during 2011 were our net loss of $9.9 million, which included non-cash expenses of $837,000 for stock-based compensation, $376,900 for depreciation and amortization, $192,500 for an intangible asset impairment charge, and $98,600 for inventory charges. Cash outflows were partially offset by reduced working capital balances, particularly a $682,800 decrease in accounts receivable reflecting lower sales and improved collection efforts and a $550,500 decrease in inventories due to improved management of inventories. For the year ended December 31, 2010, our operating activities used $13.3 million in cash. This use of cash resulted largely from the net loss for the year of $16.9 million.

During the year ended December 31, 2011, our investing activities included a $178,500 increase in cash resulting from a release of restricted cash related to our lease, partially offset by $111,000 used for the acquisition of fixed assets. For the year ended December 31, 2010, our investing activities provided $7.2 million in cash. This source of cash resulted primarily from $7.5 million provided by the maturities of investments.

During the year ended December 31, 2011, our financing activities generated $33,600 from the issuance of common stock and used $19,100 for capital lease payments. For the year ended December 31, 2010, our financing activities generated $195,700 from the issuance of common stock and used $27,700 for capital lease payments.

We held cash and cash equivalents of $10.3 million as of December 31, 2011. On February 13, 2012 we closed a public securities offering that generated $8.5 million in gross proceeds and, after transaction costs and fees, yielded approximately $7.5 million in net proceeds. We believe that these resources and the cash to be generated from expected product sales will be sufficient to meet our projected operating requirements for at least the next twelve months. We continue to face significant challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected due to (a) decreases in sales of our products and the uncertainty of future revenues from new products; (b) changes we may make to the business that affect ongoing operating expenses; (c) changes we may make in our business strategy; (d) regulatory developments affecting our existing products and delays in the FDA approval process for products under development; (e) changes we may make in our research and development spending plans; and (f) other items affecting our forecasted level of expenditures and use of cash resources. Accordingly, we will need to raise additional funds to support our operating and capital needs. 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 and 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.

As of December 31, 2011, we have federal and state net operating loss, or NOL, carryforwards available to offset future taxable income of $80.5 million and $32.7 million, respectively, and federal and state tax credits of $956,000 and $816,000, respectively, which may be available to reduce future taxable income and the related taxes thereon. The net operating loss and research and development credit carryforwards will expire at various dates beginning in 2019 for federal taxes and begin to expire in 2012 for state taxes. A full valuation allowance has been provided against our NOL carryforwards and research and development credit carryforwards and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the balance sheet or statement of operations if an adjustment were required.

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

As of December 31, 2011, we did not have any off-balance sheet financing arrangements.

The following table summarizes our principal contractual obligations as of December 31, 2011 and the effects such obligations are expected to have on our liquidity and cash flows in future periods.

		Payments due in		
Contractual Obligations	Total	2012	1-3 years	3-5 years
Operating lease obligations	$948,750	$757,500	$191,250	$ —
Capital lease obligations	40,582	22,136	18,446	—
Purchase order obligations	711,227	711,227	—	—
Total contractual obligations	$1,700,559	$1,490,863	$209,696	$ —

As of December 31, 2011, we have no contractual obligations that extend beyond three years.

Critical Accounting Policies and Estimates

Our financial statements are based on the selection and application of generally accepted accounting principles, which require us to make estimates and assumptions about future events that affect the amounts reported in our financial statements and the accompanying notes. Future events and their effects cannot be determined with certainty. Therefore, the determination of estimates requires the exercise of judgment. Actual results could differ significantly from those estimates, and any such differences may be material to our financial statements. We believe that the policies set forth below may involve a higher degree of judgment and complexity in their application than our other accounting policies and represent the critical accounting policies used in the preparation of our financial statements. If different assumptions or conditions were to prevail, the results could be materially different from our reported results. Our significant accounting policies are presented within Note 2 to our Financial Statements.

Revenue Recognition and Accounts Receivable

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

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

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

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

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

Revenue recognition involves judgments, including assessments of expected returns, allowance for doubtful accounts, and expected customer relationship periods. We analyze various factors, including a review of specific transactions, our historical returns, average customer relationship periods, customer usage, customer balances, and market and economic conditions. Changes in judgments or estimates on these factors could materially impact the timing and amount of revenues and costs recognized. Should market or economic conditions deteriorate, our actual return or bad debt experience could exceed our estimate.

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

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

Inventories

The realizable value of inventories is based upon the types and levels of inventories held, forecasted demand, pricing, competition, and changes in technology. Our consumables have an eighteen-month shelf life. Should current market and economic conditions deteriorate, our actual recoveries could be less than our estimates.

Recently Issued or Adopted Accounting Pronouncements

In September 2009, the Emerging Issues Task Force, or EITF, issued new rules pertaining to the accounting for revenue arrangements with multiple deliverables. The new rules provide an alternative method for establishing fair value of a deliverable when vendor specific objective evidence cannot be determined. The guidance provides for the determination of the best estimate of selling price to separate deliverables and allows the allocation of arrangement consideration using this relative selling price model. The guidance supersedes the prior multiple element revenue arrangement accounting rules. The new guidance was adopted prospectively by us beginning January 1, 2011. Adoption has not had a material effect on our financial statements.

In September 2009, the EITF issued new rules to exclude (a) non-software components of tangible products and (b) software components of tangible products that are sold, licensed, or leased with tangible products when the software components and non-software components of the tangible product function together to deliver the tangible product's essential functionality . The new guidance was adopted prospectively by us beginning January 1, 2011. Adoption has not had a material effect on our financial statements.

In January 2010, the Financial Accounting Standards Board issued Accounting Standards Update No. 2010-06*, "Fair Value Measurements and Disclosures (Topic 820)—Improving Disclosures about Fair Value Measurements"*, or ASU 2010-06. ASU 2010-06 requires new disclosures regarding significant transfers in and out of Levels 1 and 2, as well as information about activity in Level 3 fair value measurements, including presenting information about purchases, sales, issuances, and settlements on a gross versus a net basis in the Level 3 activity roll forward. In addition, ASU 2010-06 also clarifies existing disclosures regarding input and valuation techniques, as well as the level of

disaggregation for each class of assets and liabilities. ASU No. 2010-06 is effective for interim and annual periods beginning after December 15, 2009, except for the disclosures pertaining to purchases, sales, issuances, and settlements in the rollforward of Level 3 activity, which were effective for interim and annual periods beginning after December 15, 2010. The new guidance was adopted prospectively by us beginning January 1, 2011. Adoption has not had a material effect on our financial statements.

In May 2011, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2011-04*, "Fair Value Measurement (Topic 820)—Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs"*, or ASU 2011-04. The amendments in ASU 2011-04 result in common fair value measurement and disclosure requirements in GAAP and International Financial Reporting Standards, or IFRS. Consequently, the amendments change the wording used to describe many of the requirements in GAAP for measuring fair value and for disclosing information about fair value measurements. The new guidance is to be adopted prospectively, effective for interim and annual periods beginning after December 15, 2011. We do not believe adoption of ASU 2011-04 will have a material effect on our financial statements.

In June 2011, the FASB issued ASU No. 2011-05, *"Comprehensive Income (Topic 220) —Presentation of Comprehensive Income"*, or ASU No. 2011-05. ASU No. 2011-05 requires that all nonowner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements, eliminating the option to present other comprehensive income in the statement of changes in equity. Under either choice, items that are reclassified from other comprehensive income to net income are required to be presented on the face of the financial statements where the components of net income and the components of other comprehensive income are presented. In December 2011, the FASB issued ASU No. 2011-12, "*Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05"*, which defers the requirement within ASU No. 2011-05 to present on the face of the financial statements the effects of reclassifications out of accumulated other comprehensive income on the components of net income and other comprehensive income for all periods presented. During the deferral, entities should continue to report reclassifications out of accumulated other comprehensive income consistent with the presentation requirements in effect prior to the issuance of ASU No. 2011-05. These ASUs are to be adopted retrospectively, effective for interim and annual periods beginning after December 15, 2011. We do not believe adoption of these ASUs will have a material effect on our financial statements.

ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk

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

ITEM 8. Financial Statements and Supplementary Data

The information required by this item may be found on pages F-1 through F-22 of this Annual Report on Form 10-K with the exception of the unaudited summarized quarterly financial data which is presented below. Net income per common share is calculated independently for each of the periods presented. Therefore, the sum of the quarterly net loss per common share amounts will not necessarily equal the total for the full fiscal year. Per common share data and share amounts have been adjusted for all periods presented to reflect a 1-for-6 reverse split of our common stock completed on September 1, 2011.

	Year Ended December 31, 2011				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	**Total**
Revenues	$2,904,846	$2,571,840	$2,560,226	$2,359,863	$10,396,775
Cost of revenues	1,255,575	1,110,073	1,156,119	1,200,302	4,722,069
Gross margin	1,649,271	1,461,767	1,404,107	1,159,561	5,674,706
Net loss	(2,697,257)	(2,436,718)	(2,430,842)	(2,416,288)	(9,981,105)
Per common share data, basic and diluted	$(0.70)	$(0.63)	$(0.63)	$(0.63)	$(2.59)

	Year Ended December 31, 2010				
	First Quarter (1)	Second Quarter	Third Quarter	Fourth Quarter	**Total**
Revenues	$3,566,393	$3,852,476	$3,414,335	$3,066,466	$13,899,670
Cost of revenues	1,296,014	1,405,348	1,347,816	3,001,031 (2)	7,050,209
Gross margin	2,270,379	2,447,128	2,066,519	65,435	6,849,461
Net loss	(4,764,029)	(4,519,071)	(3,400,181)	(4,207,867)	(16,891,148)

Per common share data, basic and diluted	$(1.24)	$(1.18)	$(0.89)	$(1.09)	$(4.40)

(1) As reported in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2010, filed with the SEC on August 10, 2010, during the second quarter of 2010, we identified fraudulent sales transactions involving two sales representatives, resulting in a $146,333 overstatement of revenues for the quarter ended March 31, 2010. We believe that these sales transactions, individually and in the aggregate, are not material to the financial results as reported in previously issued interim financial statements for the quarter ended March 31, 2010. As of and for the quarter ended March 31, 2010, these sales transactions affected the financial statements as follows: an overstatement of revenues of $146,333; an overstatement of the associated cost of revenue and sales commissions of $38,078 and $30,937, respectively; an overstatement of accounts receivable of $158,239, which includes an overstatement of sales tax payable of $11,905; an understatement of inventory of $31,673, net of inventory losses of $6,405; an understatement of other current assets of $32,343 related to an insurance receivable for the associated loss claim less a $5,000 deductible; and an understatement of accumulated deficit of $82,318. There was no impact to total net cash used in operating activities within the statement of cash flows for the quarter ended March 31, 2010. The summarized quarterly financial data for the quarter ended March 31, 2010 presented above has been revised to reflect these adjustments.

(2) We recorded inventory charges of $1.8 million related to a strategic change in direction that was announced on January 4, 2011.

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

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

ITEM 9A. Controls and Procedures

(a) Evaluation of disclosure controls and procedures.

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Form 10-K, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2011 based on the criteria in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on our evaluation under the framework in *Internal Control—Integrated Framework* issued by the COSO, our management concluded that our internal control over financial reporting was effective as of December 31, 2011.

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

(c) Changes in internal control over financial reporting.

There have been no changes to our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. Other Information

None.

PART III

ITEM 10. Directors, Executive Officers and Corporate Governance

DIRECTORS AND EXECUTIVE OFFICERS

The following table and biographical descriptions set forth information regarding our executive officers and directors, based on information furnished to us by each executive officer and director, as of February 15, 2012:

Name	Age	Position
Shai N. Gozani, M.D., Ph.D	47	Chairman of the Board, Chief Executive Officer, President and Secretary
Thomas T. Higgins	60	Senior Vice President, Chief Financial Officer and Treasurer
Guy Daniello	67	Senior Vice President of Information Technology
Krishnamurthy Balachandran	53	Senior Vice President, Chief Operating Officer, Neurodiagnostics
Michael Williams, Ph.D	55	Senior Vice President Engineering, Chief Technology Officer
David E. Goodman, M.D.(1)(2)	55	Director
Allen J. Hinkle, M.D.(2)	61	Director
Nancy E. Katz	52	Director
Charles R. LaMantia(1)(3)	72	Director
Timothy R. Surgenor(1)(3)	52	Director

(1) Member of Audit Committee

(2) Member of Compensation Committee

(3) Member of Nominating and Corporate Governance Committee

Shai N. Gozani, M.D., Ph.D. founded our company in 1996 and currently serves as Chairman of our Board of Directors and as our President, Chief Executive Officer and Secretary. Since founding our company in 1996, Dr. Gozani has served in a number of positions at our company including Chairman since 1996, President from 1996 to 1998 and from 2002 to the present, Chief Executive Officer since 1997 and Secretary since July 2008. Dr. Gozani holds a B.A. in computer science, an M.S. in Biomedical Engineering and a Ph.D. in Neurobiology, from the

University of California, Berkeley. He also received an M.D. from Harvard Medical School and the Harvard-M.I.T. Division of Health Sciences at M.I.T. Prior to forming our company, Dr. Gozani completed a neurophysiology research fellowship in the laboratory of Dr. Gerald Fischbach at Harvard Medical School. Dr. Gozani has published articles in the areas of basic and clinical neurophysiology, biomedical engineering and computational chemistry. The Board has concluded that Dr. Gozani should serve as a director because Dr. Gozani's extensive knowledge of engineering and neurophysiology, combined with the unique understanding of our technology and business he has gained as our founder and as a key executive, provides invaluable insight to our Board and to the entire organization.

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

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 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 Chief Operating Officer, Neurodiagnostics. 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 currently serves as an independent consultant and practicing physician. During 2010, Dr. Goodman has served as President and Chief Executive Officer of SEDline, Inc., a research-focused company with the mission to expand the scope and applications for neuromonitoring. From 2008 to 2009, Dr. Goodman served as Executive Vice President of Business Development for Masimo Corporation, a manufacturer of non-invasive patient monitors. From 2006 to 2008, Dr. Goodman served as an independent consultant providing product design, regulatory and analytical consulting services to medical device and biopharmaceutical companies and also served in this capacity from 2003 to 2004 and from 2001 to 2002. From 2005 to 2006, Dr. Goodman served as President and Chief Executive Officer of BaroSense, Inc., a medical device company focused on developing minimally invasive devices for the long-term treatment of obesity. From 2004 to 2005, Dr. Goodman served as President and Chief Executive Officer of Interventional Therapeutic Solutions, Inc., an implantable drug delivery systems company. From 2002 to 2003, Dr. Goodman served as Chairman, President and Chief Executive Officer of Pherin Pharmaceuticals, a pharmaceutical discovery and development company. From 1994 to 2001, Dr. Goodman held various positions, including Chief Executive Officer,

Chief Medical Officer and director, for LifeMasters Supported SelfCare, Inc., a disease management services company that Dr. Goodman founded. Dr. Goodman also 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 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 and Market Development 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.

Charles R. LaMantia has served as a member of our Board of Directors since November 2004. In July 1999, Mr. LaMantia retired from the position of Chief Executive Officer, Chairman and President of Arthur D. Little, Inc, a worldwide professional service company with activities in management consulting, technology and product development, and environmental, health and safety. Mr. LaMantia served as Chief Executive Officer, and President of Arthur D. Little from July 1988 to July 1999. From October 1986 to July 1988, Mr. LaMantia held the position of President and Chief Operating Officer at Arthur D. Little. From 1981 to 1986, Mr. LaMantia served as President and Chief Executive Officer of Koch Process Systems, Inc., an integrated engineering and manufacturing company, owned by Koch Industries. From 1977 to 1981, Mr. LaMantia served as Vice President in charge of Arthur D. Little's Chemical and Metallurgical Engineering business. Mr. LaMantia currently serves on the Board of Directors of State Street Corporation (NYSE: STT). Mr. LaMantia received a B.A., B.S., M.S., and Sc.D. in chemical engineering from Columbia University and completed the Advanced Management Program of Harvard Business School. He was a Sloan Foundation Fellow, a National Science Foundation Fellow, and is a member of Phi Beta Kappa and Tau Beta Pi. He served as an officer in the United States Navy. The Board has concluded that Mr. LaMantia should serve as a director because Mr. LaMantia's extensive corporate leadership experience and public company board experience provides the Board with valuable finance, accounting and executive management experience.

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. 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 MATTERS AND CORPORATE GOVERNANCE

Board of Directors

Our amended and restated certificate of incorporation, as amended, provides for a classified board of directors consisting of three staggered classes of directors (Class I, Class II and Class III). The members of each class of our Board of Directors serve for staggered three-year terms, with the terms of our Class I, Class II and Class III directors expiring upon the election and qualification of directors at the annual meetings of stockholders to be held in 2014, 2012, and 2013, respectively. Currently:

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

Our Board of Directors has determined that Dr. Goodman, Dr. Hinkle, Mr. LaMantia, 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 us as a consultant described below under Item 13, "Certain Relationships and Related Transactions, and Director Independence - Transactions with Related Persons".

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

The Audit Committee currently consists of Mr. Surgenor, Chairman, and Dr. Goodman and Mr. LaMantia. The Audit Committee operates pursuant to a charter that was approved by our Board of Directors, a copy of which is available on our website at *http://www.neurometrix.com* under the heading "Investor Relations" and subheading "Corporate Governance". The purposes of the Audit Committee are to, among other functions, assist the Board of Directors in overseeing the operation of a comprehensive system of internal controls covering the integrity of our financial statements and reports, compliance with laws, regulations and corporate policies, and the qualifications, performance and independence of our registered public accounting firm. Dr. Goodman and Messrs. LaMantia and Surgenor are all "independent" as that term is defined in the rules of the SEC and the applicable NASDAQ rules relating to audit committee members. Our Board of Directors has determined that Messrs. LaMantia and Surgenor each qualify as "audit committee financial experts" as such term is defined in the rules of the SEC. The Audit Committee held five meetings during 2011.

Procedures by which Stockholders may Nominate Directors

There have been no changes to the procedures disclosed in our proxy statement for the 2011 annual meeting of stockholders by which stockholders may nominate directors.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller and persons performing similar functions. A current copy of the Code of Business Conduct and Ethics is available on our website at *http://www.neurometrix.com* under the heading "Investor Relations" and subheading "Corporate Governance," and we intend to disclose on this website any amendment to, or waiver of, any provision of the Code of Business Conduct and Ethics applicable to our directors or executive officers that would otherwise be required to be disclosed under the SEC rules, to the extent permitted, by the NASDAQ rules. A current copy of the Code of Business Conduct and Ethics may also be obtained, without charge, upon written request directed to us at: NeuroMetrix, Inc., 62 Fourth Avenue, Waltham, Massachusetts 02451, Attention: Compliance Officer.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and executive officers and holders of more than 10% of our common stock (collectively, "Reporting Persons") to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock. Such Reporting Persons are required by regulations of the SEC to furnish us with copies of all such filings. Our records reflect that all reports which were required to be filed pursuant to Section 16(a) of the Exchange Act were filed on a timely basis, except that 12 Forms 4 were not filed on a timely basis as a result of administrative error for three transactions for each of Dr. Shai N. Gozani, Thomas T. Higgins, Guy Daniello, and Dr. Michael Williams in connection with the surrender of restricted shares upon vesting of such restricted shares to pay taxes.

ITEM 11. Executive Compensation

The information required by this Item will be contained in our definitive proxy statement for our 2012 Annual Meeting of Stockholders under the captions "Compensation of Executive Officers" and "Director Compensation Table - 2011" and is incorporated by reference herein.

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

PRINCIPAL AND MANAGEMENT STOCKHOLDERS

The following table sets forth certain information concerning beneficial ownership as of February 15, 2012, except as noted below, of our common stock by:

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

The number of common shares "beneficially owned" by each stockholder is determined under rules issued by the SEC regarding the beneficial ownership of securities. This information is not necessarily indicative of beneficial ownership for any other purpose. Under these rules, beneficial ownership of common stock includes (1) any shares as to which the person or entity has sole or shared voting power or investment power and (2) any shares as to which the person or entity has the right to acquire beneficial ownership within 60 days after February 15, 2012, including any shares that could be purchased by the exercise of options or warrants on or within 60 days after February 15, 2012. Each stockholder's percentage ownership is based on 12,430,905 shares of our common stock outstanding as of February 15, 2012 plus the number of shares of common stock that may be acquired by such stockholder upon exercise of options or warrants that are exercisable on or within 60 days after February 15, 2012.

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

	Amount and Nature of Beneficial Ownership				
Name and Address(1) of Beneficial Owner	Common Stock	Options(2)	Total	Percent of Class of Total	
Directors and Executive Officers					
Shai N. Gozani, M.D., Ph.D	154,427	57,351	211,778	1.7	%
David E. Goodman, M.D.	—	9,124	9,124	*	
Allen Hinkle, M.D.	—	9,958	9,958	*	
Nancy E. Katz	—	1,770	1,770	*	
Charles R. LaMantia	—	9,125	9,125	*	
Timothy R. Surgenor	—	3,958	3,958	*	
Krishnamurthy Balachandran	3,949	8,206	12,155	*	
Guy Daniello	4,659	29,920	34,579	*	
Thomas T. Higgins	4,806	8,207	13,013	*	
Michael Williams, Ph.D	4,429	31,426	35,855	*	
All Current Directors and Executive Officers as a group (10 persons)	172,270	169,045	341,315	2.7	%

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

(1) Unless otherwise indicated, the address of each stockholder is c/o NeuroMetrix, Inc., 62 Fourth Avenue, Waltham, Massachusetts 02451.

(2) Includes all options that are exercisable on or within 60 days from February15, 2012 by the beneficial owner, except as otherwise noted.

EQUITY COMPENSATION PLAN INFORMATION

The following table sets forth information as of December 31, 2011 regarding the number of securities to be issued upon exercise, and the weighted average exercise price of outstanding options, warrants, and rights under our equity compensation plans and the number of securities available for future issuance under our equity compensation plans.

Equity Compensation Plan Information as of December 31, 2011

	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights	**Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column a)**	
	(a)	**(b)**	**(c)**	
Equity compensation plans approved by security holders(1)	326,097	$ 13.93	261,584	(2)
Equity compensation plans not approved by security holders(3)	12,500	1.60	70,833	
Totals	338,597	$ 13.47	332,417	

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

(2) As of December 31, 2011, there were 255,330 shares available for future grant under the Third Amended and Restated 2004 Stock Option and Incentive Plan and 6,254 shares available under the 2010 Employee Stock Purchase Plan. No new stock grants or awards will be made under the Amended and Restated 1996 Stock Option/Restricted Stock Plan or the Amended and Restated 1998 Equity Incentive Plan.

(3) Includes information related to our 2009 Non-Qualified Inducement Stock Plan, which is designed to provide equity grants to new employees.

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

TRANSACTIONS WITH RELATED PERSONS

Mr. Surgenor joined our Board of Directors in April 2009. During 2009 we paid Red Sky Partners, LLC, or Red Sky, a total of $49,000 for various consulting services related to the technology we had acquired from Cyberkinetics. Mr. Surgenor was a partner of Red Sky when we made such payments. Red Sky has provided no services to us since 2009 and we have made no payments to Red Sky since 2009.

Pursuant to our audit committee charter currently in effect, the audit committee is responsible for reviewing and approving, prior to our entry into any such transaction, all transactions in which we are a participant and in which any parties related to us has or will have a direct or indirect material interest.

DIRECTOR INDEPENDENCE

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

ITEM 14. Principal Accounting Fees and Services

ACCOUNTING FEES

Aggregate fees for professional services rendered by PricewaterhouseCoopers LLP for the years ended December 31, 2011 and 2010 are as follows:

Audit Fees

The audit fees for PricewaterhouseCoopers LLP for professional services rendered for the 2011 audit of our annual financial statements and the review of the financial statements included in our quarterly reports on Form 10-Q totaled $408,000, of which $265,000 was billed in 2011 and $143,000 was billed in 2012.

The audit fees for PricewaterhouseCoopers LLP for professional services rendered for the 2010 audit of our annual financial statements and the review of the financial statements included in our quarterly reports on Form 10-Q totaled $470,000, of which $310,000 was billed in 2010 and $160,000 was billed in 2011.

Audit-Related Fees

There were no audit related fees for PricewaterhouseCoopers LLP in 2011 and 2010.

All Other Fees

Fees for PricewaterhouseCoopers LLP for services other than audit-related services were $21,800 for 2011, and included fees of $20,000 in connection with our Corporate Integrity Agreement with the Office of Inspector General of the United States Department of Health and Human Services regarding the previously-disclosed investigation into certain of our past sales and marketing practices relating to our NC-stat System and $1,800 for a software subscription used to review accounting literature.

Fees for PricewaterhouseCoopers LLP for services other than audit-related services were $21,800 for 2010, and included fees of $20,000 in connection with our Corporate Integrity Agreement with the Office of Inspector General of the United States Department of Health and Human Services regarding the previously-disclosed investigation into certain of our past sales and marketing practices relating to our NC-stat System and $1,800 for a software subscription used to review accounting literature.

Pre-Approval Policies and Procedures

The Audit Committee approved all audit and non-audit services provided to us by PricewaterhouseCoopers LLP during the 2011 and 2010 fiscal years.

PART IV

ITEM 15. Exhibits and Financial Statement Schedule

(a)1. *Financial Statements*

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

2. *Financial Statement Schedule*

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

3. *Exhibit Index*

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

Exhibit Number	Description
2.1	Asset Purchase Agreement dated November 7, 2008 by and between NeuroMetrix, Inc. and Advanced Diagnostics, LLC(7)
3.1.1	Third Amended and Restated Certificate of Incorporation of NeuroMetrix, Inc.(6)
3.1.2	Certificate of Designations for Series A Junior Cumulative Preferred Stock, par value $0.001 per share(4)
3.1.3	Certificate of Amendment to Restated Certificate of Incorporation of NeuroMetrix, Inc. dated September 1, 2011(18)
3.2.1	Second Amended and Restated Bylaws of NeuroMetrix, Inc.(6)
3.2.2	Amendment No. 1 to Second Amended and Restated Bylaws of NeuroMetrix, Inc.(3)

4.1	Specimen Certificate for Shares of Common Stock(1)
4.2.1	Shareholder Rights Agreement, dated as of March 7, 2007, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent(4)
4.2.2	Amendment to Shareholder Rights Agreement, dated September 8, 2009, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent(11)
4.3	Form of Common Stock Purchase Warrant (11)
4.4	Form of First Addendum to Common Stock Purchase Warrant issued to investors pursuant to Securities Purchase Agreements dated September 8, 2009(13)
4.5	Form of Unit Warrant to purchase Common Stock(21)
4.6	Form of Placement Agent Warrant(21)
10.1.1	Lease Agreement, dated October 18, 2000, between Fourth Avenue LLC and NeuroMetrix, Inc.(1)
10.1.2	Amendment Number One to Lease, dated February 22, 2008, between Fourth Avenue LLC and NeuroMetrix, Inc.(15)
10.2.1	Loan and Security Agreement between NeuroMetrix, Inc. and Comerica Bank, dated March 5, 2010(16)
10.2.2	First Modification to Loan and Security Agreement between NeuroMetrix, Inc. and Comerica Bank, dated March 1, 2011(16)

Exhibit Number	Description
10.3+	Amended and Restated 1996 Stock Option/Restricted Stock Plan(1)
10.4.1+	Amended and Restated 1998 Equity Incentive Plan(1)
10.4.3+	Second Amendment to Amended and Restated 1998 Equity Incentive Plan(1)
10.5+	Second Amended and Restated 2004 Stock Option and Incentive Plan(8)
10.6.1+	Third Amended and Restated 2004 Stock Option and Incentive Plan(10)
10.6.2+	Form of Restricted Stock Agreement pursuant to the Third Amended and Restated 2004 Stock Option and Incentive Plan(16)
10.7+	2010 Employee Stock Purchase Plan(17)
10.8+	2009 Non-Qualified Inducement Stock Plan(20)
10.9+	Form of Indemnification Agreement between NeuroMetrix, Inc. and each of its directors(1)
10.10.1+	Employment Agreement, dated June 21, 2004, by and between NeuroMetrix, Inc. and Shai N. Gozani, M.D., Ph.D.(1)
10.10.2+	First Amendment to Employment Agreement dated December 31, 2008, by and between NeuroMetrix, Inc. and Shai N. Gozani, M.D., Ph.D.(9)
10.10.3+	Indemnification Agreement dated June 21, 2004, by and between Shai N. Gozani, M.D., Ph.D., and NeuroMetrix, Inc.(1)
10.10.4+	NeuroMetrix, Inc. Non-Statutory Stock Option Agreement (pursuant to the Amended and Restated 1998 Equity Incentive Plan), dated as of June 21, 2004, by and between Shai N. Gozani M.D., Ph.D., and NeuroMetrix, Inc.(1)
10.11.1+	Letter Agreement, dated February 5, 2008 between NeuroMetrix, Inc. and Michael Williams, Ph.D.(14)
10.11.2+	