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

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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

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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

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PART I

The statements contained in this Annual Report on Form 10-K, including under the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other sections of this Annual Report, include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including, without limitation, statements regarding our or our management's expectations, hopes, beliefs, intentions or strategies regarding the future, such as our estimates regarding anticipated operating losses, future revenues and projected expenses; our 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 repu