NeuroMetrix, Inc.
Form 10-K
March 12, 2010

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2009

OR

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

For the transition period from to
Commission File Number 001-33351

NEUROMETRIX, INC.

(Exact name of registrant as specified in its charter)

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

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 ý

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 ý 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 o 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. ý

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 ý

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

As of June 30, 2009, 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 $20,604,709 based on the closing sale price of the common stock as reported on the NASDAQ Global Market on June 30, 2009. For this computation, the registrant has excluded the market value of all outstanding shares beneficially owned by any director, executive officer or person known to the registrant to beneficially own 10% or more of the registrant's common stock; such exclusion shall not be deemed to constitute an admission that any such person is an affiliate of the registrant.

As of March 1, 2010, there were 23,027,070 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the registrant's 2010 annual meeting of stockholders, which is expected to be filed pursuant to Regulation 14A within 120 days of the registrant's year ended December 31, 2009, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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NEUROMETRIX, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2009

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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. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "plan" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. The forward-looking statements contained in this annual report are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in the section titled "Risk Factors." Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. *Unless the context otherwise requires, all references to "we", "us", the "Company", or "NeuroMetrix" in this Annual Report on Form 10-K refers to NeuroMetrix, Inc.*

ITEM 1. BUSINESS

Our Business-An Overview

We are a science-based health care company transforming patient care through neurotechnology. To date, our focus has been primarily on the assessment of neuropathies. We are also developing innovative products for preservation and restoration of nerve and spinal cord function, and pain control. Neuropathies affect the peripheral nerves and parts of the spine and are frequently caused by or associated with carpal tunnel syndrome, diabetes, sciatica, and other clinical disorders. We market systems for the performance of nerve conduction studies and needle electromyography procedures. Our product pipeline includes a system designed to deliver pharmacologic agents such as anesthetics and corticosteroids in close proximity to nerves for regional anesthesia, pain control, and the treatment of focal neuropathies. We are also developing devices and pharmaceutical agents to treat peripheral nerve and spinal cord injuries.

We have two medical devices cleared by the United States Food and Drug Administration, or FDA, which are used for the assessment of neuropathies. Our NC-stat System is a point-of-care device for the performance of nerve conduction studies. It has been sold historically to a broad group of physicians, including primary care physicians and specialists since its initial market launch in May 1999. Our NC-stat System is comprised of: (1) single use nerve-specific electrodes, (2) the NC-stat device and related components, and (3) the NC-stat docking station, an optional device that enables the physician's office to transmit data to our onCall Information System. Our ADVANCE NCS/EMG System, or the ADVANCE System, is a comprehensive platform for the performance of traditional nerve conduction studies and invasive electromyography procedures. This system is used primarily by neurologists, physical medicine and rehabilitation, or PM&R, physicians, neurosurgeons, orthopedic and hand surgeons, and pain medicine physicians. Our ADVANCE System is comprised of: (1) various types of electrodes and needles, (2) our ADVANCE device and related modules, and (3) a communication hub that enables the physician's office to network their device to our servers for data archiving, report generation, and other network services. Our neurodiagnostic equipment is used in approximately 4,500

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physicians' offices, clinics, and hospitals. Approximately 1.5 million patient studies have been performed with our neurodiagnostic devices since 1999.

We are presently focusing our sales efforts on our NC-Stat System for primary care physicians and clinics and our ADVANCE System for specialist physicians with peripheral nerve expertise, including neurologists, PM&R physicians, neurosurgeons, orthopedic and hand surgeons, and pain medicine physicians.

Business Developments

We believe that consistent and adequate physician reimbursement for nerve conduction studies performed using our neurodiagnostic devices is essential to our efforts to build our U.S. business and thereby deliver the significant clinical benefits that may be achieved through the use of this technology to patients. A significant, positive step was taken on reimbursement in the fourth quarter of 2009 when the U.S. Centers for Medicare and Medicaid Services, or CMS, published a new Category I CPT code, or CPT code 95905, in the 2010 Physician's Fee Schedule for nerve conduction studies performed with preconfigured electrode arrays, such as those utilized with our NC-stat System. Therefore, we believe that this CPT code may streamline Medicare reimbursement for medically appropriate nerve conduction studies performed using our NC-stat System. This is an important development because the assignment of this code reaffirms the clinical utility of our NC-stat System and supports its use by primary care physicians and internal medicine specialists when medically appropriate. As for any new CPT code, broad adoption by physicians will take time and may have some challenges. However, we believe that physicians using our NC-stat System will find this new code useful and supportive of their efforts to deliver optimal and efficient patient care.

Unlike pre-existing Medicare nerve conduction study codes, but similar to many other diagnostic procedures, CPT code 95905 is billed per limb tested as opposed to per nerve. Although practice patterns will vary, we believe that fewer units of CPT code 95905 will generally be billed per patient than under the pre-existing nerve conduction study codes. Lower physician reimbursement under CPT code 95905 could affect testing patterns and, in the near term, will put downward pressure on our revenues and margins. It is difficult to predict adoption and utilization of this new CPT code in the near term as there are many factors in play. Over time, however, we anticipate the new CPT code may have a positive influence on reimbursement by commercial insurers. We believe that ultimately the effect of the CPT code on revenues will be positive and will allow us to increase revenues over time. In the meantime, we anticipate a period of readjustment that could span several quarters or perhaps longer.

During 2009, we took several significant steps, described below, to position ourselves for this period of readjustment.

We rebuilt our senior management team with new leadership in both sales and finance. Walter Christenson joined us as Senior Vice President, Global Sales and Thomas Higgins joined us as Senior Vice President and Chief Financial Officer.

We strengthened our balance sheet through an equity financing through which we sold common stock and warrants resulting in net proceeds of approximately $17.2 million.

We reorganized our sales organization and customer interface, including:

- reorganizing North America sales in two groups dedicated to the Physician's Office and the Neurointerventional markets;
- initiating a Clinical Educator program to support Physician Office sales and provide direct clinical support to customers;
- refocusing Physician Office sales representatives on new account acquisition;

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merging corporate customer service and account management into a single customer support organization; and

sharpening our European focus with an on-site employee in the UK and extended customer service hours.

We broadened our R&D pipeline with multiple product launches planned for 2010 in both the neurodiagnostic and nerve localization device markets.

In the product pipeline, "Vantage", the anticipated successor to our current NC-stat System, is targeted for commercial launch in 2010 following the achievement of certain development and regulatory milestones. Vantage is designed to facilitate nerve conduction studies by primary care physicians and other non-specialists. It will be compatible with our current pre-configured electrodes and will include additional productivity enhancing features.

"ASCEND", another device under development is designed to precisely deliver pharmacologic agents such as anesthetics and corticosteroids in close proximity to nerves for regional anesthesia, pain control, and the treatment of focal neuropathies such as Carpal Tunnel Syndrome, or CTS. Commercial launch of ASCEND is also targeted for 2010 pending certain regulatory milestones.

Within our pipeline of pharmacologic compounds for neural conduction enhancement, we are developing our lead compound, NM101, for use in chronic spinal cord injury. We plan to advance the compound through a Phase 1 clinical trial and then evaluate strategic options. We are presently performing the pre-clinical work required to file an investigational new drug application with the FDA.

"Andara" is our implantable stimulator for spinal nerve repair. The FDA recently provided greater clarity on the clinical requirements for approval. Our next step would be to design and conduct a clinical trial targeting the same safety and efficacy endpoints as the original study but with a larger sample size. This project is currently on hold as we focus our resources on our other pipeline products.

Neuropathies

Disorders of the nerves are broadly described by the term neuropathies. There are two basic types of neuropathies, those that are focal or localized in nature, and those that are systemic. Focal neuropathies are typically caused by a compression of one or more specific nerves. Systemic neuropathies are typically caused by a metabolic disturbance that results in widespread damage to nerves throughout the body. The most common clinical conditions associated with neuropathies include:

Diabetes. Diabetes is a disease in which the body either does not produce sufficient quantities of insulin or does not properly use insulin. Insulin is a hormone that is needed to convert sugar, starches, and other food into energy needed for daily body function. Diabetes often results in a high level of glucose in the blood, called hyperglycemia. Chronic hyperglycemia is associated with complications of diabetes including nerve, eye, and kidney disease. The most common form of diabetes-related nerve disease is a systemic neuropathy called diabetic peripheral neuropathy, or DPN. The symptoms of DPN include impaired sensation or pain in the feet and hands. The American Diabetes Association, or ADA, estimates that 60% to 70% of people with diabetes are affected by DPN, although a majority of these individuals are unaware of their nerve disease because they have no symptoms. DPN, if left undiagnosed and unmanaged, can result in the development of lower extremity ulcers and, in severe cases, amputation. It is estimated by the ADA that over 75% of all foot amputations are in patients with DPN. Other neuropathies may be present in as many as 30% of patients with diabetes, including CTS, radiculopathy, and chronic inflammatory demyelinating polyneuropathy, or CIDP.

Low back pain. Low back pain can have many causes. When low back pain has a neurological source, it is often focal in nature and associated with pain that radiates from the lower back

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region into the leg, called sciatica. In some cases, the patient may also experience loss of sensation and weakness in the lower leg. In advanced cases, these symptoms can become disabling. The symptoms result from pressure on the nerve roots, the precursors of the nerve, as they exit the spine. The source of the pressure is usually part of an intervertebral disc that is displaced from its normal location between the vertebral bodies. These disorders are often called herniated or ruptured discs.

Carpal Tunnel Syndrome. CTS, is caused by swelling of the tendons that traverse the wrist alongside the median nerve. The swollen tendons compress the median nerve, resulting in damage to the nerve that leads to numbness in the first three fingers of the hand, weakness in the thumb, and occasionally wrist and hand pain. CTS is the most common focal neuropathy.

Other medical conditions associated with neuropathies. Common chronic disorders such as obesity, rheumatoid arthritis, and spinal stenosis, or narrowing of the spinal canal, are commonly associated with neuropathies. In these complicated cases, it is particularly important for the physician to confirm or exclude neuropathies in order to develop effective treatment programs.

Nerve damage caused by chemotherapy. A number of widely used chemotherapeutic agents are toxic to nerves. Unfortunately, by the time patients report symptoms, significant nerve damage has often already occurred.

NeuroMetrix Marketed Products for the Assessment of Neuropathies

NC-stat System

Our point-of-service neurodiagnostic solution is known as the NC-stat System. The NC-stat System is comprised of: (1) single use electrodes that are placed non-invasively on the patient's body, (2) the NC-stat device and related components, and (3) the NC-stat docking station, an optional device that enables the physician to transmit data to our onCall Information System. The NC-stat System assists the physician in rapidly and accurately examining the patient in a manner that may be cost-effective for the patient and third-party payer. The onCall Information System also provides our NC-stat customers with report creation, device management, data archiving, and other services that are accessible via the web, e-mail, and facsimile. Use of the onCall Information System is optional; however, we believe that substantially all of our NC-stat customers use this system in all neurodiagnostic studies they conduct.

ADVANCE System

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.

Consumables

We market a variety of consumables and accessories for use with our neurodiagnostic equipment. These include our nerve specific electrodes which are single use, self-adhesive, electrode arrays that are placed on the body and connected to the neurodiagnostic device. Currently, we sell nerve specific electrodes for six nerves. The electrodes are designed to be positioned according to common anatomical landmarks with a configuration that facilitates correct placement. We also market electrodes, which are individually placed and may be used to test any nerve at distal and proximal locations, and EMG needles and various cables and other accessories for performing nerve conduction studies and needle electromyography procedures.

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Customers

We market our products directly to physicians, clinics, and hospitals. The NC-stat System is marketed primarily to primary care and internal medicine physicians. The ADVANCE System is marketed primarily to neurologists, PM&R physicians, neurosurgeons, orthopedic and hand surgeons, and pain medicine physicians. As of December 31, 2009, we had approximately 4,500 active NC-stat and ADVANCE customers. No single customer accounted for more than 10% of our revenues in 2009, 2008, or 2007.

Geographic Information

Substantially all of our assets, revenues, and expenses for the years ended December 31, 2009, 2008, and 2007 were located at or derived from operations in the United States. In addition, we have had limited sales in the United Kingdom, the Netherlands, and various other countries. For the year ended December 31, 2009, international revenues accounted for approximately 2% of our total revenues. For the years ended December 31, 2008 and 2007, international revenues accounted for less than 1% of our total revenues.

Sales, Marketing, and Distribution

Our products are directly marketed and distributed within the United States. We have limited but growing sales through distributors in the United Kingdom, the Netherlands, and various other countries. Our success is highly dependent on our ability to maintain our direct sales force and to effectively manage the efforts of our international distributors.

Our U.S. sales operations are organized into a Physician's Office sales group supporting primary care, internal medicine, endocrinology, and rheumatology, and a Neurointerventional sales group supporting neurology, physical medicine and rehabilitation and orthopedics. We recently initiated a Clinical Educator program to support the Physician's Office sales group and provide direct clinical support to our customers. The Clinical Educators program allows our Physician's Office sales representatives to focus primarily on new account acquisition. We have a Customer Service organization at our corporate offices to provide support to customers regarding the operation of our NC-stat and ADVANCE Systems and for reordering our consumable products. International sales are made through a network of distributors. We recently employed a European sales manager who is based in the United Kingdom and manages European distributors. Our sales organization currently has 51 field positions, including 34 sales representatives, 10 clinical educators, six sales directors and a Senior Vice President, Global Sales.

We invest significant efforts in technical, clinical, and business practices training for our regional sales managers. We also require each sales representative to attend periodic sales and product training programs. The efforts of our regional sales managers are enhanced by proprietary software tools that are accessed via a secure website, which we refer to as the sales portal. This portal gives our sales personnel access to real time customer sales and product usage information, various applications to help identify and close new business, and marketing materials. The portal also provides customer relationship management functions.

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 or

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ADVANCE devices, docking station/communication hubs, 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, 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.

We seek to obtain products from our manufacturers in order to maintain sufficient inventory to satisfy our customer obligations and we did not experience any inventory shortages on any established products in 2009. Additionally, during 2009, we experienced a significantly lower rate of defects in electrodes manufactured by Parlex, as we rejected less than 1% of electrodes shipped to us by Parlex, compared to 3-5% in 2008. This was a result of our efforts to focus Parlex on reducing the defect rate. We are continuing to work closely with Parlex to maintain and further reduce this low rate of rejection. If our third-party manufacturers are unable to manufacture sufficient quantities of our products that meet our specifications, we will not meet expectations for our business.

Parlex has been manufacturing our nerve specific electrodes since early 1999. 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 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.

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

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 NC-stat and ADVANCE Systems are 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 focus our research and development efforts on our new product platforms, including Vantage and ASCEND, as well as further enhancements to the ADVANCE System, including new electrodes and other accessories. Vantage, the anticipated successor to our current NC-stat System, is designed to facilitate nerve conduction studies by primary care physicians and other non-specialists. It will be compatible with our current pre-configured electrodes and will include additional productivity enhancing features. ASCEND is designed to precisely deliver pharmacologic agents such as anesthetics

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and corticosteroids in close proximity to nerves for regional anesthesia, pain control, and the treatment of focal neuropathies such as CTS.

Our research and development group consists of 25 people, including seven who hold Ph.D. or M.D. degrees. This group has extensive experience in neurophysiology, biomedical instrumentation, signal processing, biomedical sensors, and information systems. Our research and development group works closely with our marketing group, our clinical support group (led by a board-certified neurologist), and our customers to design products that are focused on improving clinical outcomes.

Research and development expenses were $5.6 million, $5.6 million, and $4.9 million, for the years ended December 31, 2009, 2008, and 2007, respectively.

Neurodiagnostic Devices

Most of our research and development efforts are currently directed towards the completion of development and regulatory approval of the Vantage System and towards additional functionality for the ADVANCE System. We are also developing new electrodes used to perform nerve conduction studies and needle electromyography procedures. Vantage is targeted for commercial launch in 2010.

Regional Anesthesia, Pain Control, and the Treatment of Neuropathies

We are developing the ASCEND platform, a proprietary neuro-electrical guidance system, to help physicians position drug delivery devices, such as hypodermic needles and catheters, safely and quickly in very close proximity to specific nerves to optimize therapeutic benefits without damaging the nerves in the process. The use of nerve localization instrumentation and needles is a standard of care for nerve block procedures, which represents the increasingly preferred form of anesthesia for many surgical procedures, particularly within orthopedics. The instrumentation can provide physicians with confirmation that the needle is in the proper location to optimize the efficacy of the anesthesia. We believe that our ASCEND products may reduce the risk of not properly placing needles involved in providing these treatments.

Current approaches to regional anesthesia and nerve block include ultrasound and some alternative approaches to nerve localization. Clinical studies have been performed by third parties that demonstrate that the two approaches, ultrasound and nerve stimulation, are comparable. The limitations of ultrasound include the fact that a high level of expertise and training is required, there is no objective evidence that a nerve has been successfully blocked, and there may be difficulty in visualizing the tip of the injection needle. While the current generation of nerve localization technology is generally effective, it is limited with respect to both accuracy and usability. Confirmation of the effectiveness of the treatment is subjective. Based on discussions with anesthesiologists, we believe that there is a need for improvements in nerve localization products that may be provided by our ASCEND platform.

Our ASCEND platform will resemble our neurodiagnostic products and will be comprised of (1) consumables, including proprietary nerve localization and drug delivery needles, and electrodes, and (2) an electronic instrument linked to local and/or remote information systems. We are targeting ASCEND for commercial launch into anesthesia markets in the second half of 2010 after receiving clearance of an additional 510(k) application. After establishing the technology in anesthesia, we plan to proceed into the broader market for select clinical conditions, such as the treatment and management of CTS and common pain syndromes.

NM101

Within our pipeline of pharmacologic compounds for neural conduction enhancement, we are developing our lead compound, NM101, for use in chronic spinal cord injury. We plan to advance the compound through a Phase 1 clinical trial and then evaluate strategic options. We are presently performing the pre-clinical work required to file an investigational new drug application with the FDA.

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Andara OFS Device

Our Andara Oscillating Frequency Stimulation, or OFS, device for spinal cord injury is an investigational device designed as a single use implant to enhance neurological recovery in patients with devastating loss of movement and sensation from acute spinal cord injuries. We believe, based on the results of pre-clinical development and clinical trials to date, that targeted electrical stimulation promotes the growth of nerve fibers across the damaged portion of the spinal cord. We believe that the Andara OFS device could enhance the natural process of neuroplasticity to make new connections in the spinal cord that lead to partial restoration of neurological functions such as sensation below the injury. The FDA recently provided greater clarity on the clinical requirements for approval of the Andara OFS device under a Humanitarian Device Exemption, or HDE. Our next step would be to design and conduct a clinical trial targeting the same safety and efficacy endpoints as the original study but with a larger sample size. This project is currently on hold as we focus our resources on our other pipeline products.

Competition

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.

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 and ADVANCE Systems. 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, 2009, we had 26 issued U.S. patents, 26 issued foreign patents, and 45 pending patent applications, including 32 U.S. applications, 2 international PCT applications, and 11 foreign national applications.

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 important 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.

In connection with the acquisition of certain technological and intellectual property assets of Cyberkinetics Neurotechnology Systems, Inc., or Cyberkinetics, in January 2009, we also license technology relating to the Andara (OFS) technology from the Purdue Research Foundation.

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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.

As the number of entrants into our market increases, the possibility of third-parties alleging patent infringement claims against us grows. Although we have not received notice of any claims, and are not aware that our products infringe other parties' patents and proprietary rights, our products and methods may be covered by U.S. patents held by our competitors. In addition, our competitors may assert that future products we may market infringe their patents.

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, ASCEND, UNIVERSAL, ANDARA, and OFS. We hold certain foreign trademark registrations for the marks NEUROMETRIX and NC-STAT.

Third-Party Reimbursement

We expect that the procedures that are performed with our medical devices will generally be paid for by third-party payers such as government health programs such as Medicare, private insurance, and managed care organizations. Reimbursement by third-party payers is an important element of success for medical device companies. Over the last several years, physicians using our NC-stat System have experienced and may continue to experience challenges from third-party payers and governmental health programs regarding the reimbursement of nerve conduction studies performed using this device. A number of third-party payers, including commercial payers, have decided to not reimburse physicians for procedures performed using our NC-stat System. We believe that the 2010 Physicians Fee Schedule published by CMS on October 30, 2009, which included a new Category I code for nerve conduction studies performed with pre-configured electrode arrays could improve reimbursement clarity for physicians using our NC-stat Systems. However, it will likely take time to achieve broad physician awareness of the code, and for the reimbursement effects, if any, of the new code to be realized by third-party payers. While we are unable to predict either the timing of these events or the ultimate effects on third-party payers, we believe that the new code is a benefit to our business and that

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physicians using our NC-stat System will find the code useful and supportive of their efforts to deliver optimal and efficient patient care.

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. 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. 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.

Our success in selling the ADVANCE System will be dependent upon, among other things, our customers' receiving, and our potential customers' belief that they will receive, sufficient reimbursement from third-party payers for performing procedures using the ADVANCE System. Similarly, our success in selling the Vantage System which we are targeting for commercial launch during 2010 also will be dependent upon, among other things, our customers' receiving, and our potential customers' belief that they will receive, sufficient reimbursement from third-party payers for performing procedures using the Vantage System.

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.

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

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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 downclassification 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 downclassify 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,

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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.

Humanitarian Device Exemption Process

The Humanitarian Device Exemption, or HDE, provisions of the FDCA were enacted by Congress to provide an incentive for development of devices to be used in the treatment of rare diseases or conditions affecting small numbers of patients. Under the FDCA and FDA's Humanitarian Use Device, or HUD, regulations, medical devices that are intended to treat and diagnose rare diseases or conditions that affect fewer than 4,000 individuals in the United States per year may be approved without the demonstration of a reasonable assurance of effectiveness required for a PMA; however, a reasonable assurance of safety must still be demonstrated. A company must first obtain HUD designation by, among other things, identifying the rare disease or condition targeted and the proposed indications for use and demonstrating occurrence in fewer than 4,000 individuals per year. If HUD designation is obtained, marketing approval for an HUD may be sought by submission of an HDE application, and demonstration of the following: that there is no comparable device, other than another

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HUD approved under the HDE regulation, or a device being studied under an approved Investigational Device Exemption, available to treat or diagnose the disease or condition; that the device does not expose patients to an unreasonable or significant risk of illness or injury; and that the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternate forms of treatment. The FDA must issue an order approving or disapproving an HDE within 75 days of receipt of an application that is accepted for filing; however, the agency may also ask for additional information that would constitute a major amendment to the application and restart the review clock for another 75 days. After approval or clearance of an HDE, certain regulatory requirements apply to HUD marketing and use, including a requirement for use in facilities with Institutional Review Board, or IRB, oversight and IRB approval prior to use, and that, with the exception of certain pediatric devices, the HUD not be sold for an amount that exceeds the costs of research and development, fabrication, and distribution of the device. In addition, HUDs are subject to other FDA requirements for devices including establishment registration and device listing, requirements relating to labeling, and corrections and removals and adverse event reporting.

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 has been the subject of several 510(k) clearances, the most recent in July 2006. 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.

During the fourth quarter of 2006, at the request of the FDA, we submitted a 510(k) relating to portions of the onCall Information System that are currently in use. In April 2009, we responded to the third additional information request that we have received from the FDA relating to this filing.

We plan to launch two new products in 2010 (subject to receipt of regulatory approval). We expect to release a new neurodiagnostic system called Vantage through our Physician Office channel in 2010. This product candidate will have expanded functionality relative to the NC-stat System. Our launch of the ASCEND System is also expected to take place in 2010. The ASCEND System has received two 510(k) clearances for its core functionality. However, we believe that expanded indications are important for market adoption and we are planning to perform a clinical trial in order to justify an expanded indication. In the fourth quarter of 2009 we received questions from the FDA pertaining to a pre-IDE clinical protocol we submitted to expand the indications for use of ASCEND. In the first quarter of 2010 we plan to respond to the FDA regarding these questions.

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 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 FDA finds significant violations, we could be subject to fines, recalls, requirements to halt manufacturing, or other administrative or judicial sanctions.

U.S. Anti-Kickback and False Claims Laws

In the United States, the federal Anti-Kickback Statute, as well as numerous state anti-kickback laws, prohibit the offer, payment, solicitation or receipt of kickbacks, bribes or other remuneration,

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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, provide 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.

Employees

As of December 31, 2009, we had a total of 102 employees. Of the total employees, 25 were in research and development, 50 in sales and marketing, and 27 in general and administrative services. One employee holds both M.D. and Ph.D. degrees, six additional employees hold Ph.D. degrees, and one additional employee holds 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 & Chief Executive Officer, Shai N. Gozani, M.D., Ph.D. We originally were incorporated in Massachusetts in 1996, and we reincorporated in Delaware in 2001. Our principal offices are located at 62 Fourth Avenue, Waltham, Massachusetts 02451.

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ITEM 1A. RISK FACTORS

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

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

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, 2009, 2008, and 2007, were approximately $11.9 million, $27.7 million, and $8.4 million, respectively, reflecting a decline in revenues. At December 31, 2009, we had an accumulated deficit of approximately $101.7 million. We cannot assure you that we will be able to reach or sustain profitability.

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 be severely harmed.

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 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. If we are pressured to lower our prices, our revenues may decline and our profitability could be harmed. CMS guidelines 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.

On October 30, 2009, the Physician Fee Schedule for 2010 was published by CMS and included a new category I CPT code for nerve conduction studies performed with preconfigured electrode arrays, such as those utilized with our NC-stat System. It will likely take time to achieve broad physician

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awareness of this CPT code, for implementation of this code within the Medicare system, and for the reimbursement effects, if any, of the Medicare code to be realized among other third-party payers. We are unable to predict when these events will occur, if ever.

In addition, this new CPT code is billed per limb tested as opposed to per nerve. We anticipate that this change could result in decreased revenues and margins, at least in the near term.

Prior to the assignment of the new CPT code, a significant number of commercial payers, including the majority of regional Blue Cross Blue Shield carriers, and other major private payers, had adopted policies indicating that they would not provide reimbursement for the use of our NC-stat System. These commercial payers had cited various reasons for their reimbursement policies, including, among others, that the NC-stat System is experimental and investigational. Third-party payers may also impose requirements on physicians to submit additional paperwork supporting the medical necessity of nerve conduction studies performed using the NC-stat System. We believe these requirements are negatively impacting the use of the NC-stat System by existing customers and our sales to new customers, both of which are having an adverse impact on our revenues. The recently published Medicare CPT code for nerve conduction studies performed with preconfigured electrode arrays such as those utilized with the NC-stat System may have a positive influence on future policy decisions by commercial payers regarding reimbursement for use of the NC-stat System, but at this time we cannot assure you of any positive impact such decisions may have on our revenues. These issues may also affect rates of reimbursement for our Vantage System, which we expect to be released in 2010.

We face uncertainty relating to health care reform, which may make it difficult or impossible to sell our products on commercially reasonable terms.

The efforts of governments and third-party payers to contain or reduce the cost of health care will continue to affect the business and financial condition of medical device companies including ours. A number of legislative and regulatory proposals to change the health care system are currently being discussed and could reduce or cap the reimbursement amounts for procedures performed using our products. Lower-than-expected, or decreases in reimbursement amounts for procedures performed using our products, may decrease the amounts physicians and other practitioners are able to charge patients, which in turn may adversely affect the willingness of physicians and other practitioners to purchase our products at the prices we target, or at all. If we are not able to sell our products at target prices, then we will suffer a decrease in expected profitability that would likely adversely affect our business, financial condition and results of operations.

We may be unable to expand the market for the NC-stat and ADVANCE Systems, which would limit our ability to increase our revenues.

For our future growth, we are relying, in part, on increased use of nerve conduction studies by physicians. A number of factors could limit the increased use of nerve conduction studies and consequently, the need for the NC-stat and ADVANCE Systems to perform the studies, including:

- third-party payers challenging, or the threat of third-party payers challenging, the necessity of increased levels of nerve conduction studies;
- third-party payers reducing or eliminating reimbursement for procedures performed by physicians using the NC-stat System;
- decreased rates of patient visits to physicians;
- unfavorable experiences by physicians using the NC-stat or ADVANCE System;
- physicians' lack of awareness of, or reluctance to rely on, the new CPT code for reimbursement of nerve conduction studies performed with preconfigured electrode arrays;

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physicians' reluctance to alter their existing practices; and

the failure of other companies' existing drug development programs to produce an effective treatment for DPN, which may limit the perceived need and the actual use of the NC-stat System in connection with this disease, and thereby limit or delay our growth in the DPN market, which we have estimated to be our largest potential market for our NC-stat System.

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

If we are unable to successfully sell our products to primary care, specialist physicians and other health care providers, our ability to increase our revenues will be limited.