# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# **FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2010

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

Common Stock \$0 0001 par value pe

Name of exchange on which registered

Common Stock, \$0.0001 par value per share

The NASDAQ Stock Market LLC The NASDAQ Stock Market LLC

**Preferred Stock Purchase Rights** 

Securities registered pursuant to Section 12(g) of the Act

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 🗵

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

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

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):

 $\text{Large accelerated filer o} \qquad \qquad \text{Accelerated filer o} \qquad \qquad \text{Non-accelerated filer o} \qquad \qquad \text{Smaller reporting company} \ \boxtimes$ 

(Do not check if a smaller reporting company)

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

As of June 30, 2010, 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 \$25,506,449 based on the closing sale price of the common stock as reported on the NASDAQ Global Market on June 30, 2010.

As of March 1, 2011, there were 23,197,537 shares of Common Stock outstanding.

# DOCUMENTS INCORPORATED BY REFERENCE

None

# NEUROMETRIX, INC. ANNUAL REPORT ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2010

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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 for 2011 and beyond; our expectations that a rapid low cost point-of-care test for peripheral nerve disease, also called diabetic peripheral neuropathy, or DPN represents a U.S. and international market opportunity, and our expectations surrounding the timeline by which this product could be developed and commercially launched; our beliefs regarding the outcome of discussions with the United States Food and Drug Administration, or FDA, concerning its notice to us that certain reporting functions of the onCall Information System are not substantially equivalent to the cleared NC-stat System; our liquidity and our expectations regarding our needs for and ability to raise additional capital; and other factors discussed elsewhere in this Annual Report on Form 10-K or any document incorporated by reference herein or therein. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "plan" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. The forward-looking statements contained in this annual report are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in the section titled "Risk Factors." Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. Unless the context otherwise requires, all references to "we", "us", the "Company", or "NeuroMetrix" in this Annual Report on Form 10-K refers to NeuroMetrix, Inc.

# ITEM 1. BUSINESS

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

We are a science-based health care company transforming patient care through neurotechnology. We develop and market innovative products for the detection, diagnosis, and monitoring of peripheral nerve and spinal cord disorders, such as those associated with diabetes, carpal tunnel syndrome, lumbosacral disc disease and spinal stenosis. Historically, our general focus has been primarily on the assessment of neuropathies. 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.

We recently shifted our primary focus to diabetes, specifically the detection and monitoring of diabetic neuropathy, which is a common complication of the disease. We view diabetes as representing the largest and fastest growing opportunity for our proprietary technology as countries around the world struggle to cope with an epidemic of Type II diabetes. Neuropathy is a common and serious complication of the disease that may lead to foot ulcers and limb amputation. We have over a decade of experience in neuropathy detection and believe we are uniquely positioned to address the unmet

need for a rapid, cost-effective, objective test for diabetic neuropathy. We anticipate a mid-2011 launch of NC-stat SL, which is a modified version of our NC-stat device designed specifically for assessment of diabetic neuropathy at the point-of-care. In support of our efforts, we have assembled a scientific advisory board of international experts.

We currently market a medical device cleared by the FDA which is used for the assessment of neuropathies. Our ADVANCE<sup>TM</sup> NCS/EMG System, or the ADVANCE System, is a comprehensive platform for the performance of traditional nerve conduction studies and invasive electromyography procedures. We focus our sales efforts for the ADVANCE System on physician offices and clinics. Our ADVANCE System is comprised of: (1) various types of electrodes and needles, (2) our ADVANCE device and related modules, and (3) a communication hub that enables the physician's office to network their device to our servers for data archiving, report generation, and other network services. We sold a predecessor device, the NC-stat System, to a broad group of physicians from its initial market launch in May 1999 through September 2010. Our NC-stat System is a point-of-care device for the performance of nerve conduction studies. We do not intend to support the NC-stat System beyond 2011 and are transitioning our NC-stat customers to the ADVANCE System. Our neurodiagnostic equipment is used in over 3,800 physicians' offices, clinics, and hospitals. Over 1.5 million patient studies have been performed with our neurodiagnostic devices since 1999.

# **Business Developments**

In January 2011, we announced a shift to diabetes care as our primary business focus but we will also continue to support our neurodiagnostic products. Within neurodiagnostics, a key objective is maintaining our high standard of product support for the accounts in our active installed base. Our general purpose NC-stat device, which has been on the market since 1999, will not be supported beyond 2011. We intend to transition all of these accounts to the ADVANCE System, which currently represents over 40% of tests performed using our technology. We believe that a variable cost sales channel is preferable during this transition period. As a result, we restructured our organization in January 2011 by eliminating our direct sales force and intend to manage new account acquisition through third party distribution. Our international business, which employs the ADVANCE System and corresponding technology and is transacted through a network of independent distributors, was unaffected by this restructuring.

Although Medicare now provides coverage for nerve testing using our proprietary pre-configured electrodes under CPT Code 95905, most commercial insurance companies have not yet revised their coverage policies to include this procedure. We believe there are many evidence-based studies documenting the accuracy and clinical utility of the procedure, particularly for carpal tunnel syndrome. While we are working towards broader insurance coverage, uncertain physician economics have made new account acquisition challenging, and therefore the cost of a direct sales force cannot be justified. For this reason, we have 1) prioritized our large installed base of active accounts, 2) restructured our organization to support active accounts, and 3) shifted to third-party distribution for new account acquisition.

In 2011, our goal is to manage neurodiagnostics to achieve a positive net cash contribution to the Company. The restructuring instituted in January 2011 involved a 27% reduction in employee positions, realignment of responsibilities, and a charge of approximately \$2.3 million related to severance and inventory. In accordance with generally accepted accounting principles, \$2.0 million of the charge was recorded in the fourth quarter of 2010, and the remaining \$0.3 million will be recorded in the first quarter of 2011.

# **Overall Outlook**

We believe that today's health care environment is characterized by uncertainty. Health care providers face a range of challenges including changes in reimbursement, declining patient visits, and uncertainty arising from national health care reform. These factors have resulted in downward pressure on our revenues and margins for our neurodiagnostic products.

In spite of this environment, we have been encouraged by the potential application of our technology in the field of diabetes care. The diabetes epidemic, particularly related to Type II diabetes, is a worldwide concern, as highlighted by the following 2007 statistics (from the Centers for Disease Control and Prevention):

- In the United States, 24 million people have diabetes, 57 million are pre-diabetic, and there are 1.6 million new cases of diabetes each year.
- Worldwide, there are at least 200 million diabetics, and that number is projected to reach 300 million by 2025.
- DPN is a common complication of diabetes affecting 60% to 70% of diabetics. Nerve disease can lead to foot ulcers and amputations, increased risk of falling, reduction in mobility, and substantial pain.

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 diabetic neuropathy. 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 assert 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. We believe we are uniquely positioned to address this unmet need.

Specifically, we are developing "NC-stat SL". This device measures nerve conduction in the sural nerve, which is a nerve located in the lower leg. Nerve conduction studies are now widely considered the gold standard test for diabetic neuropathy and have even become primary endpoints in Phase III clinical trials for neuropathy therapeutics. Nerve conduction abnormalities in the sural nerve, in particular, are considered the earliest and most informative indication of diabetic neuropathy.

Our NC-stat SL device is easy to learn and operate. A test only takes about 30 seconds to perform. We have also focused a great deal of effort on making the test uniquely cost effective and have made considerable progress. We do not expect third-party reimbursement initially, but given the low costs and tremendous potential benefits of this test to people with diabetes and to physicians caring for them, we believe that an out-of-pocket payment model will develop. Concurrently, 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 for several years and cannot be sure of our success in obtaining such coverage.

Our development efforts are being aided by an advisory board of international experts in diabetic neuropathy who agree that this device has the potential to profoundly improve the management of diabetic neuropathy. Several of these thought leaders are authors of widely followed clinical guidelines, such as those from the American Diabetes Association (ADA).

Our development pathway has been relatively straightforward because NC-stat SL is a modification of our well established general purpose NC-stat device and has the same clinical indications with respect to diabetic neuropathy. The NC-stat System has been on the market since 1999. Over 1.5 million patient studies have been performed with this technology, including over 600,000 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 diabetic neuropathy.

Our NC-stat SL product development has been moving rapidly. From product concept in the second quarter of 2010, we have taken the device through product feasibility and now have working prototypes. As product development continues, we are shifting our focus to market strategy and distribution to U.S. endocrinologists followed by primary care physicians. We believe these markets represent our largest and best opportunities. They are also markets in which we have relevant experience from our neurodiagnostic business.

In December 2010, we strengthened our Board of Directors with the appointment of Nancy Katz, a recognized marketing innovator in diabetes. We also expect to add diabetes related sales and marketing expertise to our management team over the next several quarters. Our goal is to launch NC-stat SL at the June 2011 American Diabetes Association meeting followed by direct customer rollout in the third quarter of 2011.

#### 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 DPN. The symptoms of DPN include impaired sensation or pain in the feet and hands. The 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 carpal tunnel syndrome, or 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 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

# ADVANCE NCS/EMG 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. The ADVANCE System currently represents over 40% of the nerve tests performed using our technology.

# NC-stat System

The NC-stat System is no longer marketed and is in the process of being replaced by the ADVANCE System. We do not intend to support the NC-stat System beyond 2011 and are actively working to transition our NC-stat customers to the ADVANCE System. The NC-stat System currently represents less than 60% of the nerve tests performed using our technology. 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 physicians 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.

# Consumables

We market a variety of consumables and accessories for use with our neurodiagnostic devices. 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.

#### **Customers**

Through December 2010, we primarily marketed our products through a direct sales force. In conjunction with the shift in our business focus, we intend to market our products primarily through third party distributors to physicians, clinics, and hospitals comprised of primary care, internal medicine, orthopedic and hand surgeons, pain medicine physicians, neurologists, physical medicine and rehabilitation, or PM&R, physicians, and neurosurgeons. As of December 31, 2010, we had over 3,800 active ADVANCE and NC-stat customers. No single customer accounted for more than 10% of our revenues in 2010, 2009, or 2008.

#### **Geographic Information**

Substantially all of our assets, revenues, and expenses for the years ended December 31, 2010, 2009, and 2008 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, and various other countries. For each of the years ended December 31, 2010 and 2009, international revenues accounted for approximately 2% of our total revenues and for the year ended December 31, 2008, accounted for less than 1% of our total revenues.

# Sales, Marketing, and Distribution

As discussed above, through December 2010, we primarily marketed our products through a direct sales force. We intend to market our neurodiagnostic products within the United States through a combination of independent sales representatives and the telemarketing efforts of our customer service representatives. Distribution is handled directly by us. We have limited but growing sales through distributors in the United Kingdom, the Netherlands, and various other countries. Our success is dependent on our ability to effectively manage the efforts of our sales organization, independent sales representatives, and international distributors, as well as our customer service representatives.

As of January 2011, we sell to new customers in the U.S. physician office and specialty markets through 16 distributors that utilize over 40 sales representatives. After sale support for all new and existing customers is provided by our team of field-based clinical educators. We believe that this team is positively impacting customer testing by providing high quality technical and clinical support. The customer service organization at our corporate offices provides support to customers regarding the operation of our ADVANCE and NC-stat systems and for reordering our consumable products. International sales are made through a network of distributors. Our sales organization currently has 19 field positions, including 15 clinical educators, 2 directors, a Senior Vice President and Chief Operating Officer, Neurodiagnostics, and a Vice President, Marketing.

We invest significant effort in technical, clinical, and business practices training for our sales organization 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 ADVANCE and NC-stat 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 2010. Additionally, during 2010, we experienced a continued low rate of defects in electrodes manufactured by Parlex, as we rejected less than 1% of electrodes shipped to us by Parlex in each of 2010 and 2009, compared to 3% to 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 ADVANCE device 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 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 are currently focusing our research and development efforts on our new diabetes product NC-stat SL, as well as further enhancements to the ADVANCE System, including new electrodes and other accessories.

Our research and development group consists of 17 people, including six who hold Ph.D. or M.D. degrees. In addition, our Chief Executive Officer, who holds both M.D. and Ph.D. degrees, spends significant efforts related to research and development. The research and development 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 approximately \$5.9 million, \$5.6 million, and \$5.6 million for the years ended December 31, 2010, 2009, and 2008.

*NC-stat SL for monitoring diabetic peripheral neuropathy* 

Our NC-stat SL development efforts are being aided by an advisory board of international experts in diabetic neuropathy. The development pathway has been relatively straightforward because NC-stat

SL is a modification of our established general purpose NC-stat device and has the same clinical indications with respect to diabetic neuropathy. The NC-stat has been on the market since 1999. Over 1.5 million patient studies have been performed with this technology, including over 600,000 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 diabetic neuropathy.

Our NC-stat SL product development has been moving rapidly. From product concept in the second quarter of 2010, we have taken this through product feasibility and now have working prototypes.

# 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 preclinical work required to file an investigational new drug application with the FDA.

#### 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 has recently provided us with 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 NC-stat SL for monitoring diabetic peripheral neuropathy.

# Competition

We believe that there is currently no objective and standardized test for diabetic neuropathy widely available at the point-of-care. The ADA and other organizations recommend at least annual evaluation of all people with diabetes for diabetic neuropathy. 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. Monofilament (5.07/10g) is 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.

# **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, 2010, we had 31 issued U.S. patents, 26 issued foreign patents, and 40 pending patent applications, including 25 U.S. applications, 2 international PCT applications, and 13 foreign national applications. We have filed two provisional patent applications related to NC-stat SL.

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.

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 plan to launch NC-stat SL in mid-2011. Initially, we do not expect third-party reimbursement for health care providers using the system to detect and monitor diabetic neuropathy. 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 may develop. Concurrently, 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 for several years and cannot be sure of our eventual success in obtaining such coverage.

Procedures performed with our neurodiagnostic medical devices will often be paid for by third-party payers, including government health programs, such as Medicare, and private insurance and managed care organizations. The 2011 Physicians Fee Schedule published by CMS includes a Category I CPT code or CPT 95905 for nerve conduction studies performed with pre-configured electrode arrays such as are used with our ADVANCE and NC-stat systems. We believe that physicians are generally receiving reimbursement under CPT 95905 from Medicare for medically necessary nerve conduction studies performed using pre-configured electrode arrays. We also believe that physicians are receiving reimbursement for CPT 95905 from a small number of commercial insurers. We continue to work 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 from commercial insurers for procedures performed with our neurodiagnostic devices.

In the United States, some insured individuals are receiving their medical care through managed care programs, which monitor and often require preapproval 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' expectation that they will receive sufficient

reimbursement from third-party payers or directly from patients for performing procedures using the ADVANCE 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 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, 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 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 the NC-stat System. In June 2010 we received a not substantially equivalent (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 the onCall System referenced in the NSE decision. This transition program is expected to be accomplished during 2011. Further, we indicated that we plan to take advantage of the next appeal level under FDA regulations and intend to submit a formal appeal request. We continue to maintain a dialogue with the FDA's Center for Devices and Radiological Health regarding the FDA's concerns.

We believe our NC-stat SL device is a technical modification to the 510(k) cleared NC-stat device (K041320), 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 SL at this time.

#### 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.

#### **Employees**

As of December 31, 2010, we had a total of 69 employees. Of these employees, 17 were in research and development, 35 in sales and marketing, 3 in distribution and 14 in general and administrative services. One employee holds both M.D. and Ph.D. degrees, five additional employees hold a Ph.D. degree, 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 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, 2010, 2009, and 2008, were approximately \$16.9 million, \$11.9 million, and \$27.7 million, respectively, reflecting a decline in revenues. At

December 31, 2010, we had an accumulated deficit of approximately \$118.6 million. We cannot assure you that we will be able to reach or sustain profitability.

We have shifted our business focus to diabetes care, specifically detection and monitoring of diabetic neuropathy. We cannot assure you that we will be successful in developing and commercializing NC-stat SL for screening and monitoring diabetic neuropathy.

We are developing a rapid, cost-effective, objective test for diabetic neuropathy. We are working toward a mid-2011 launch of NC-stat SL, which is a modified version of our existing NC-stat device designed specifically for assessment of diabetic neuropathy at the point of care. Our future prospects are closely tied to our success with NC-stat SL which, in turn, depends upon successful and timely completion of the development process, market acceptance, and growth in future revenues. We cannot assure you that our strategy for NC-stat SL will be successful or that we will achieve this success, which could materially affect our revenues and results of operations.

We have launched the ADVANCE System into the physician office market where we previously sold the NC-stat System. If our physician office customers do not adopt the ADVANCE System in sufficient numbers, it could have a material adverse effect on our business and results of operations.

With the evolution of our product line and launch of the ADVANCE System into the physician office market in October 2010, we are no longer promoting the NC-stat System in that market. The NC-stat System has been sold into the physician office market since its initial launch in May 1999. The ADVANCE System has been sold into specialty markets such as neurology, orthopedic surgery, and pain management since 2008.

We may be unable to convince physicians that the ADVANCE System provides an effective diagnostic solution. In addition, physicians may be reluctant to make the investment required to acquire and transition to the ADVANCE System. If we are unable to encourage sufficient adoption and utilization of the ADVANCE System in the physician office market, our revenues will decline and our business will suffer.

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.

On October 30, 2009, the Physician Fee Schedule for 2010 was published by CMS and included a new category I CPT code, CPT code 95905, for nerve conduction studies performed with preconfigured electrode arrays, such as those utilized with our ADVANCE System. During the course of 2010, the new code was adopted throughout the Medicare system. Although Medicare now provides coverage for nerve testing using our proprietary pre-configured electrodes under CPT 95905, most commercial insurance companies have not yet revised their coverage policies despite the abundance of evidence based studies documenting the accuracy and clinical utility of the procedure, particularly for carpal tunnel syndrome and diabetic neuropathy. While we are working towards broader coverage, uncertain physician economics have made new account acquisition challenging.

We are subject to extensive regulation by the FDA, which could restrict the sales and marketing of the ADVANCE System 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 and shipping. 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 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 ("onCall") that operates with the company's 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 (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 21of 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 FDA we reported that we have implemented a 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 expected to be accomplished within 2011. Further, we indicated that we plan to take advantage of the next appeal level under FDA regulations and intend to submit a formal appeal request. We continue to maintain a dialogue with the FDA's Center for Devices and Radiological Health regarding their concerns. We cannot currently predict the outcome of further administrative appeal or FDA's evaluation of our transition plan.

With the evolution of our product line and launch of the ADVANCE System into the physician office market in October 2010, the NC-stat device with onCall is no longer being sold to new customers. Our installed base of NC-stat accounts built up over the past decade continues to perform nerve conduction testing using the NC-stat System including onCall. If the FDA does not ultimately clear these reporting functions or find our ADVANCE transition plan acceptable and we are unable to offer onCall in its present configuration, we may be required to modify or remove these reporting functions. We believe that we could manage the modifications in an orderly manner and in a way that the NC-stat System might retain its current utility for physicians. However, we are not able to predict the impact such modifications might have on our ability to generate revenues from the NC-stat System, particularly during a transition period, or the costs involved in transitioning these customers to the ADVANCE System. Either resolution, even if successful, could have a material adverse impact on our business.

Our NC-stat SL device, for monitoring diabetic 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 SL at this time.

We also are subject to numerous post-marketing regulatory requirements, including 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. In addition, 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 may be required to raise additional funds to finance our operations and remain a going concern; we may not be able to do so when necessary, and/or the terms of any financings may not be advantageous to us.

Although we believe that our current cash and cash equivalents and the cash to be generated from expected product sales will be sufficient to meet our projected operating requirements into 2012, our capital requirements are uncertain and will depend on many factors, including:

- the revenues generated by sales of our products;
- the costs associated with our sales and marketing efforts;
- the expenses we incur in manufacturing and selling our products;
- the costs of developing new products or technologies and enhancements to existing products;
- the cost of obtaining and maintaining FDA approval or clearance of our products and products in development;
- the costs associated with any expansion; and
- the number and timing of any acquisitions or other strategic transactions.

As a result of these factors, we may need to raise additional funds, and these funds may not be available on favorable terms, or at all. Furthermore, if we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. If we cannot raise funds on acceptable terms, we may not be able to develop or enhance our products, execute our business plan, take advantage of future opportunities, or respond to competitive pressures or unanticipated customer requirements. If any of these events occurs, our ability to achieve our development and commercialization goals would be adversely affected.

If we fail to continue to meet all applicable NASDAQ Global Market requirements and The NASDAQ Stock Market determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock, impair the value of your investment, and harm our business.

Our common stock is currently listed on the NASDAQ Global Market. In order to maintain that listing, we must satisfy minimum financial and other requirements. On September 24, 2010, we received notice from the Listing Qualifications Department of the NASDAQ Stock Market, or NASDAQ, that our common stock had not met the \$1.00 per share minimum bid price requirement for the last 30 consecutive business days pursuant to NASDAQ Listing Rule 5450(a)(1) and that, if we were unable to

demonstrate compliance with this requirement during the applicable grace periods, our common stock would be delisted after that time. The notification letter stated that pursuant to NASDAQ Listing Rule 5810(c)(3)(A) we would be afforded 180 calendar days, or until March 23, 2011, to regain compliance with the minimum bid price requirement. In order to regain compliance, shares of our common stock must maintain a minimum closing bid price of at least \$1.00 per share for a minimum of ten consecutive business days. If we do not regain compliance by March 23, 2011, NASDAQ will provide written notification to us that our common stock will be delisted. At that time, we may appeal NASDAQ's delisting determination to a NASDAQ Listing Qualifications Panel. Alternatively, we may be eligible for an additional 180 day grace period if we satisfy all of the requirements, other than the minimum bid price requirement, for listing on the NASDAQ Capital Market set forth in NASDAQ Listing Rule 5505. The closing bid price of our common stock on the NASDAQ Global Market was \$0.51 on March 1, 2011.

While we intend to engage in efforts to regain compliance, and thus maintain our listing, there can be no assurance that we will be able to regain compliance during the applicable time periods set forth above. If we fail to continue to meet all applicable NASDAQ Global Market requirements in the future and NASDAQ determines to delist our common stock, the delisting could substantially decrease trading in our common stock and adversely affect the market liquidity of our common stock; adversely affect our ability to obtain financing on acceptable terms, if at all, for the continuation of our operations; and harm our business. Additionally, the market price of our common stock may decline further and stockholders may lose some or all of their investment.

# We may be unable to expand the market for the ADVANCE System, 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 ADVANCE System 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 ADVANCE System;
- decreased rates of patient visits to physicians;
- unfavorable experiences by physicians using the 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;
- · 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, or DPN, which may limit the perceived need and the actual use of the ADVANCE 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 ADVANCE System.

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

We depend on several single source manufacturers to produce the ADVANCE System, and any materially 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 manufactures to manufacture all of the components of the ADVANCE System. 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, 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 for the manufacture of the electrodes, and Sunburst for the manufacture of 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.

We currently rely entirely on sales of the products that comprise the ADVANCE System to generate substantially all of our revenues, and any factors that negatively impact our sales of these products could significantly reduce our ability to generate revenues.

We introduced the ADVANCE System to the market in June 2008. We sold the NC-stat System from its initial market launch in May 1999 through September 2010. We have derived, and continue to derive, substantially all of our revenues from sales of the products that comprise these two systems, and we expect that sales of the ADVANCE System will continue to constitute the majority of our sales for the foreseeable future. Accordingly, our ability to generate revenues is reliant on our ability to market and sell the products that comprise the ADVANCE System, particularly electrodes, sales of which (including the predecessor NC-stat system) accounted for approximately 85-91% of our total revenues in each of the past three years. Our sales of these products may be negatively impacted by many factors, including:

changes in reimbursement rates or policies relating to our products by third-party payers;

- rate of adoption of the new Medicare Category I CPT code for nerve conduction studies performed with pre-configured electrode arrays, such as are utilized with the ADVANCE System;
- the failure of the market to accept our products;
- 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;
- · competitive pricing and related factors; and
- results of clinical trials relating to our products or our competitors' products.

If any of these events occurs, our ability to generate revenues could be significantly reduced.

# 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 neurodiagnostic systems and those sales have been declining in recent quarters. At the present time, we are focused on supporting the ADVANCE NCS/EMG platform and we are modifying the NC-stat device into a rapid, low cost, point-of-care test for DPN. If we are not successful advancing our pipeline products through development, the regulatory process and commercial launch, our business, financial condition, and results of operations will be adversely affected. We expect that advancing our pipeline products to commercialization, if possible, will require significant time and resources. We may not be successful in our commercialization efforts of 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.

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. 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. In particular, we have sought no patent protection for the technology and algorithms we use in our onCall Information System. We rely on trade secrets to protect this information. 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;
- 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.

Because our lead therapeutic product candidate is in a very early stage of development, there is a high risk of failure, and we may never succeed in developing marketable pharmacologic compounds or generating product revenue from them.

We do not have any therapeutic products that have received regulatory approval for commercial sale and do not expect to have any commercial therapeutic products on the market for at least the next several years, if at all. We are currently performing the pre-clinical work required to file an investigational new drug application with the FDA for our lead compound, NM101, for use in chronic spinal cord injury. Trial and error is inherent in science, and we may fail at numerous stages along the way. Success in preclinical studies of a therapeutic product may not be predictive of similar results in humans during clinical trials, and successful results from early clinical trials of a therapeutic product may not be replicated in later clinical trials. We will only receive regulatory approval to commercialize a product candidate if we can demonstrate to the satisfaction of the FDA or the applicable foreign regulatory authority, in well-designed and conducted clinical trials, that the therapeutic product is safe and effective and otherwise meets the appropriate standards required for approval for a particular indication. Clinical trials are lengthy, complex, and extremely expensive processes with uncertain results. A failure of one or more of our clinical trials may occur at any stage of testing. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. Additionally, if our clinical trials are unsuccessful or if we decide to discontinue our clinical trials, it could cause adverse publicity, and thus could harm our business, financial condition, and results of operations.

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

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

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

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

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

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

In February 2009, we announced that we had reached a resolution with the United States Department of Justice, or DOJ, and the Office of Inspector General, or OIG, of the United States Department of Health and Human Services regarding the previously-disclosed investigation into certain of our past sales and marketing practices relating to our NC-stat System. As part of the resolution with the DOJ and OIG, we entered into a three-year Deferred Prosecution Agreement with the DOJ and a five-year Corporate Integrity Agreement with the OIG. Failure to comply with the terms of the Deferred Prosecution Agreement and the Corporate Integrity Agreement could result in substantial civil or criminal penalties and being excluded from government health care programs, which could materially reduce our sales and adversely affect our financial condition and results of operations.

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

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

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

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

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

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

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

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

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

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

Our success largely depends on the skills, experience, and efforts of our officers, including Shai N. Gozani, M.D., Ph.D., our founder, Chairman, President and Chief Executive Officer; Thomas T. Higgins, our Senior Vice President and Chief Financial Officer; Krishnamurthy Balachandran, our Senior Vice President and Chief Operating Officer, Neurodiagnostics; Guy Daniello, our Senior Vice President of Information Technology; Michael Williams, Ph.D., our Senior Vice President of Engineering; and our other key employees. We do not maintain key person life insurance policies covering any of our employees. The loss of any of our officers or key employees could weaken our management and technical expertise significantly and harm our business.

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

We are a small company with only 69 employees as of December 31, 2010, and our ability to retain our skilled labor force and our success in attracting and hiring new skilled employees will be a critical factor in determining our future performance. We may not be able to meet our future hiring needs or retain existing personnel, particularly given the challenges our business has recently faced. We will face challenges and risks in hiring, training, managing and retaining engineering and sales and marketing employees. Failure to attract and retain personnel, particularly technical and sales and marketing personnel would materially harm our ability to compete effectively and grow our business.

If we are unable to successfully expand, develop, and retain our independent sales representatives and distributors, our revenues may decline, our future revenue growth may be limited and our expenses may increase.

We are dependent on independent sales representatives and distributors to generate revenues from new accounts. Our ability to develop and maintain a strong force of independent sales representatives and distributors will be affected by a number of factors, including:

- our ability to attract, integrate, and motivate sales personnel;
- our ability to effectively train sales personnel;
- the ability of sales personnel to sell an increased number of products;
- the length of time it takes new sales personnel to become productive;

- the competition we face from other companies in hiring and retaining sales personnel;
- our ability to effectively manage a multi-location, independent sales distribution channel;
- · our ability to enter into agreements with prospective independent sales representatives and distributors on commercially reasonable terms; and
- our ability to get our independent international sales distributors who may sell products of multiple companies to commit the necessary resources to effectively market and sell our products.

If we are unable to successfully build, develop, and retain a strong group of independent sales representatives and distributors, our revenues may decline.

# Failure to develop or enter into relationships to sell products other than our existing products or enhance our existing products could have an adverse effect on our business prospects.

For the year ended December 31, 2010, the majority of our revenues were derived from selling the ADVANCE System and the NC-stat system. Our future business and financial success will depend, in part, on our ability to continue to introduce or sell new products, including the NC-stat SL, and upgraded products into the marketplace. Developing new products and upgrades to existing and future products imposes burdens on our research and development department and our management. This process is costly, and we cannot assure you that we will be able to successfully develop new products or enhance the current systems or any of our other current or future products. We also may not be able to enter into relationships with other companies to sell additional products. In addition, as we develop the market for our products, future competitors may develop desirable product features earlier than we do which could make our competitors' products less expensive or more effective than our products and could render our products obsolete or unmarketable. If our product development efforts are unsuccessful, we will have incurred significant costs without recognizing the expected benefits and our business prospects may suffer.

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

We currently do, and in the future may need to, compete directly and indirectly with a number of other companies that may have competitive advantages over us. We compete with companies that sell traditional NCS/EMG equipment including CareFusion Corporation, Cadwell Laboratories, Inc., and Natus Medical Incorporated. Of these companies, CareFusion Corporation, in particular, enjoys significant competitive advantages, including:

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

As we develop the market for point-of-service nerve conduction studies, we may be faced with competition from these companies or others that decide and are able to enter this market. Some or all of our future competitors in the point-of-service market may enjoy competitive advantages such as

those described above. If we are unable to compete effectively against existing and future competitors, our sales will decline and our business will be harmed.

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

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

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

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

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

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

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

In addition, we are required to meet certain financial covenants customary with this type of credit facility, including maintaining a minimum specified tangible net worth. The Comerica credit facility also contains other customary covenants. We may not be able to comply with these covenants in the future. Our failure to comply with these covenants may result in the declaration of an event of default and could cause us to be unable to borrow under the Comerica credit facility. In addition to preventing additional borrowings under the Comerica credit facility, an event of default, if not cured or waived, may result in the acceleration of the maturity of indebtedness outstanding under the Comerica credit facility at the time of the default, which would require us to pay all amounts outstanding. If an event of default occurs, we may not be able to cure it within any applicable cure period, if at all. If the maturity of our indebtedness is accelerated, we may not have sufficient funds available for repayment or we may not have the ability to borrow or obtain sufficient funds to replace the accelerated indebtedness on terms acceptable to us, or at all.

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

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

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

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

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

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

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

Foreign markets represented approximately 2% of our revenues in 2010 and we are working to expand market penetration, particularly in Europe. As we continue to expand into foreign markets, we will be subject to new business risks, including:

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

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

# If we are unsuccessful in pending and potential litigation matters, our financial condition may be adversely affected.

We are currently involved in a class action lawsuit against certain of our current and former officers and directors relating to allegedly making false and misleading statements and failing to disclose material information to the investing public and engaging in improper business practices. If we are ultimately unsuccessful in this lawsuit, we could be required to pay substantial amounts of cash to the other parties including any legal fees not covered by our insurance. The amount and timing of any of these payments could adversely affect our financial condition.

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

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

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

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

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

# We do not intend to pay cash dividends.

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

#### ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

#### ITEM 2. PROPERTIES

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

#### ITEM 3. LEGAL PROCEEDINGS

As previously disclosed in our filings with the SEC, on March 17, 2008, a putative securities class action complaint was filed in the United States District Court for the District of Massachusetts against us and certain of our current and former officers. On March 27, 2008, a related putative securities class action complaint was filed in the same court, against the same defendants. These two actions were subsequently consolidated, and the court appointed a lead plaintiff. On November 10, 2008, a consolidated amended class action complaint was filed, which alleged, among other things, that between October 27, 2005 and February 12, 2008, the defendants violated the federal securities laws by allegedly making false and misleading statements and failing to disclose material information to the investing public. The plaintiffs sought unspecified damages. On January 30, 2009, we filed a motion to dismiss the consolidated amended complaint on the grounds, among others, that it failed to state a claim on which relief can be granted. On December 8, 2009, the Court entered an order granting defendants' motion to dismiss and dismissing the consolidated amended complaint in its entirety with prejudice. The plaintiffs filed a notice of appeal with the United States Court of Appeals for the First Circuit on January 6, 2010. Oral arguments on the plaintiffs' appeal were conducted on September 15, 2010. The appeal is currently pending.

The litigation process is inherently uncertain, and we cannot guarantee that the outcome of the above lawsuit will be favorable for us or that it will not be material to our business, results of operations, or financial position. However, we do not believe that a loss related to this litigation is probable. Accordingly, no accrual relating to this matter has been recorded at December 31, 2010.

As previously disclosed in our filings with the SEC, on April 22, 2008, a shareholder derivative action was filed in the United States District Court for the District of Massachusetts against a number of our current and former directors and officers. On December 10, 2008, a verified amended shareholder derivative complaint was filed, alleging, among other things, that, between August 2004 and the date the action was filed, the defendants breached various fiduciary duties to us based on conduct similar to that alleged in the putative securities class actions, including that the defendants caused us to make false and misleading statements, to fail to disclose material information to the public and to engage in improper business practices. The plaintiff sought various forms of monetary and non-monetary relief. The parties reached an agreement to resolve the shareholder derivative action, subject to Court approval, and executed a formal stipulation of settlement on December 21, 2009. On February 23, 2010, the Court entered an order approving the parties' settlement and entered a judgment dismissing the case in its entirety, with prejudice. In conjunction with the settlement, our insurance carrier paid directly to third parties \$350,000 for the plaintiff's counsel's attorneys fees and reimbursement of expenses. No payment was required by us.

As previously disclosed in our filings with the SEC, on February 9, 2009, we announced that we had reached a resolution with the United States Department of Justice, or DOJ, and the Office of Inspector General, or OIG, of the United States Department of Health and Human Services regarding the previously-disclosed investigation into certain of our past sales and marketing practices relating to our NC-stat System.

As part of the resolution, we entered into a Deferred Prosecution Agreement, or the Deferred Prosecution Agreement, dated February 5, 2009, with the DOJ related to our operation of marketing referral programs. Pursuant to the Deferred Prosecution Agreement, we agreed to a \$1.2 million payment, and the DOJ has agreed not to prosecute us in return for compliance with the terms of the three-year Deferred Prosecution Agreement.

In addition, we entered into a civil Settlement Agreement with the DOJ and OIG, or the Settlement Agreement, dated February 9, 2009. The Settlement Agreement involves the referral programs and allegations that, where physicians performed a nerve conduction study using the NC-stat System and did not obtain an F-wave measurement, in limited circumstances, we caused physicians to seek reimbursement using the slightly higher valued 95903 CPT code payable for nerve conduction studies where an F-wave measurement is obtained, rather than the 95900 CPT code. While we did not admit to the allegations with respect to the F-wave coding issue, we agreed to pay \$2.5 million to settle this dispute and enter into a five-year Corporate Integrity Agreement with OIG. We remain fully eligible to participate in all federal health care programs.

The settlement payments discussed above in the total amount of \$3.7 million were paid in the first quarter of 2009.

#### ITEM 4. [Removed and Reserved]

#### **PART II**

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

Our common stock is quoted on the NASDAQ Global Market under the symbol "NURO". The price range per share reflected in the table below is the high and low sales prices of our common stock as reported by NASDAQ for the periods indicated.

	Years ended December 31,								
	20	10	200	9					
	High	Low	High	Low					
First quarter	\$ 2.75	\$ 1.75	\$ 1.93	\$ 0.66					
Second quarter	1.90	1.01	2.67	1.40					
Third quarter	1.33	0.52	3.60	1.70					
Fourth guarter	0.75	0.47	3.39	2.00					

On March 1, 2011, there were approximately 104 stockholders of record of our common stock. This number does not include stockholders for whom shares were held in a "nominee" or "street" name. On March 1, 2011, the last reported sale price per share of our common stock on the NASDAQ Global Market was \$0.51.

We have never declared or paid any cash dividends on our common stock. We currently intend to retain future earnings, if any, to finance the expansion and growth of our business and do not expect to pay any cash dividends in the foreseeable future. Payment of future cash dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, and plans for expansion.

## ITEM 6. SELECTED FINANCIAL DATA

The data set forth below should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," Item 7A, "Quantitative and Qualitative Disclosures About Market Risk" and our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K:

	Years Ended December 31,										
	_	2010	. –.	2009	_	2008		2007	_	2006	
Statement of Operations Data:		(.	In t	housands, ex	cep	share and p	er s	share data)			
Revenues	\$	13,900	\$	26,137	\$	31,121	\$	43 667	\$	55,250	
Cost of revenues	Ψ	7,050	Ψ	7,536	Ψ	9,012	Ψ	11,338	Ψ	13,558	
Gross margin	_	6,850	_	18,601	-	22,109	_	32,329	_	41,692	
Operating expenses:		0,050		10,001		22,100		52,525		11,002	
Research and development		5,856		5,611		5,589		4,892		5,011	
Sales and marketing		11,072		10,840		14,647		22,837		22,014	
General and administrative		7,232		9,119		12,016		14,834		11,805	
Goodwill impairment				_		5,833		_		_	
Charge for legal settlement		_		_		3,706		_		_	
Intangible asset impairment		_		_		1,768		_		_	
Gain from deconsolidation of joint venture		_		_		(2,100)		_		_	
Total operating expenses		24,160	_	25,570		41,459	_	42,563		38,830	
(Loss) income from operations		(17,310)		(6,969)		(19,350)		(10,233)		2,862	
Loss on available-for-sale investment		_		_		(2,500)				_	
Interest and other income		298		227		721		1,751		1,598	
Warrants fair value adjustment		_		(5,175)		_		_		_	
(Loss) income from continuing operations		(17,012)		(11,917)		(21,129)		(8,482)		4,460	
(Loss) income from discontinued operations		_		_		(6,601)		104		_	
(Loss) income before income taxes		(17,012)		(11,917)		(27,730)		(8,378)		4,460	
Income tax (provision) benefit		121		_		_		_		(193)	
Net (loss) income	\$	(16,891)	\$	(11,917)	\$	(27,730)	\$	(8,378)	\$	4,267	
Net (loss) income per common share from continuing	_		_		=		_				
operations:											
Basic	\$	(0.73)	\$	(0.71)	\$	(1.54)	\$	(0.67)	\$	0.34	
Diluted	\$	(0.73)	\$	(0.71)		(1.54)		(0.67)	\$	0.33	
Net (loss) income per common share from discontinued		` ′		Ì		`		, ,			
operations:											
Basic	\$	_	\$	_	\$	(0.48)	\$	0.01	\$	_	
Diluted	\$	_	\$	_	\$	(0.48)	\$	0.01	\$	_	
Net (loss) income per common share:											
Basic	\$	(0.73)		(0.71)		(2.02)		(0.66)		0.34	
Diluted	\$	(0.73)	\$	(0.71)	\$	(2.02)	\$	(0.66)	\$	0.33	

	As of December 31,									
		2010		2009		2008		2007		2006
					(in t	housands)				
Balance Sheet Data:										
Cash, cash equivalents, and short-term investments	\$	16,987	\$	30,432	\$	19,797	\$	29,719	\$	40,321
Working capital		19,020		34,374		21,632		33,304		41,894
Total assets		23,066		40,567		31,147		56,209		55,543
Total liabilities		2,867		4,857		8,314		9,479		12,134
Total stockholders' equity		20,199		35,710		22,833		46,730		43,409

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

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

#### Overview

We are a science-based health care company transforming patient care through neurotechnology. We develop and market innovative products for the detection, diagnosis, and monitoring of peripheral nerve and spinal cord disorders such as those associated with diabetes, carpal tunnel syndrome, lumbosacral disc disease, and spinal stenosis. Historically, our general focus has been primarily on the assessment of neuropathies. 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.

We recently shifted our primary focus to diabetes, specifically the detection and monitoring of diabetic neuropathy, which is a common complication of the disease. We view diabetes as representing the largest and fastest growing opportunity for our proprietary technology as countries around the world struggle to cope with an epidemic of Type II diabetes. Neuropathy is a common and serious complication of the disease that may lead to foot ulcers and limb amputation. We have over a decade of experience in neuropathy detection and believe we are uniquely positioned to address the unmet need for a rapid, cost-effective, objective test for diabetic neuropathy. We anticipate a mid-2011 launch of NC-stat SL, which is a modified version of our NC-stat device designed specifically for assessment of diabetic neuropathy at the point-of-care. In support of our efforts, we have assembled a scientific advisory board of international experts.

We currently market a medical device cleared by the FDA which is used for the assessment of neuropathies. Our ADVANCE<sup>TM</sup> NCS/EMG System, or the ADVANCE System, is a comprehensive platform for the performance of traditional nerve conduction studies and invasive electromyography procedures. We focus our sales efforts for the ADVANCE System on physician offices and clinics. Our ADVANCE System is comprised of: (1) various types of electrodes and needles, (2) our ADVANCE device and related modules, and (3) a communication hub that enables the physician's office to network their device to our servers for data archiving, report generation, and other network services. We sold a predecessor device, the NC-stat System, to a broad group of physicians from its initial market launch in May 1999 through September 2010. Our NC-stat System is a point-of-care device for the performance of nerve conduction studies. We do not intend to support the NC-stat System beyond 2011 and are transitioning our NC-stat customers to the ADVANCE System. Our neurodiagnostic equipment is used in over 3,800 physicians' offices, clinics, and hospitals. Over 1.5 million patient studies have been performed with our neurodiagnostic devices since 1999.

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 are presently performing the pre-clinical work required to file an investigational new drug application with the FDA and we plan to continue to advance the compound at a low level of funding through pre-clinical testing as we evaluate strategic options.

Andara is our implantable stimulator for spinal nerve repair. The FDA provided us with greater clarity on the clinical requirements for approval of this product. Our next step is to design and conduct

a clinical trial targeting the same safety and efficacy endpoints as the original study conducted by us but with a larger sample size. However, this project is currently on hold as we focus our resources on our other pipeline products.

#### **Recent Developments**

In January 2011, we announced a shift to diabetes care as our primary business focus but we will also continue to support our neurodiagnostic products. Within neurodiagnostics, a key objective is maintaining our high standard of product support for the accounts in our active installed base. Our general purpose NC-stat System, which has been on the market since 1999, will not be supported beyond 2011. We intend to transition all of these accounts to the ADVANCE System, which currently represents over 40% of tests performed using our technology. We believe that a variable cost sales channel is preferable during this transition period. As a result, in January 2011 we restructured our organization by eliminating our direct sales force and intend to manage new account acquisition through third party distribution. Our international business, which employs the ADVANCE System and corresponding technology and is transacted through a network of independent distributors, was unaffected by this restructuring.

Although Medicare now provides coverage for nerve testing using our proprietary pre-configured electrodes under CPT Code 95905, most commercial insurance companies have not yet revised their coverage policies to include this procedure. We believe there are many evidence-based studies documenting the accuracy and clinical utility of the procedure, particularly for carpal tunnel syndrome. While we are working towards broader insurance coverage, uncertain physician economics have made new account acquisition challenging, and therefore the cost of a direct sales force cannot be justified. For this reason, we have 1) prioritized our large installed base of active accounts, 2) restructured our organization to support active accounts, and 3) shifted to third-party distribution for new account acquisition.

In 2011, our goal is to manage neurodiagnostics to achieve a positive net cash contribution to the Company. The restructuring instituted in January 2011 involved a 27% reduction in headcount, realignment of responsibilities, and a charge of approximately \$2.3 million related to severance and inventory. In accordance with generally accepted accounting principles, \$2.0 million of the charge was recorded in the fourth quarter of 2010, and the remaining \$0.3 million will be recorded in the first quarter of 2011.

## **Results of Operations**

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

#### Revenues

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

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

The following table summarizes our revenues from medical equipment and consumables:

		Years Ended	Dec	ember 31,			
	_	2010	-6	(in thousands)		Change	% Change
Revenues:			(,	ii tiiousuiius)			
Medical equipment	\$	2,151.3	\$	2,713.4	\$	(562.1)	(20.7)%
Consumables		11,748.4		23,423.6		(11,675.2)	(49.8)
Total revenues	\$	13,899.7	\$	26,137.0	\$	(12,237.3)	(46.8)

Revenues for 2010 reflect the introduction of Medicare CPT code 95905, which was published by the CMS in the fourth quarter of 2009, as well as continued reimbursement uncertainty with commercial insurers relating to our products. Medicare CPT code 95905 addresses nerve conduction studies performed with pre-configured electrode arrays such as those used with the NC-stat System. The new code both defines nerve test procedures and assigns values on a different basis than pre-existing codes. The net result is lower physician reimbursement per nerve study which has had a negative impact on our revenues.

Medical equipment revenues, consisting of sales of the NC-stat and ADVANCE devices, related modules, and revenues from extended service agreements, were \$2.2 million and \$2.7 million for the years ended December 31, 2010 and 2009, respectively, a decrease of \$562,100, or 20.7%. This decrease reflects lower average selling price, or ASP, on system shipments in 2010 compared to 2009. We shipped 282 NC-stat and ADVANCE devices, net, to new customers during 2010 compared with 287 devices, net, shipped to new customers during 2009. In addition, during 2010, we sold 19 ADVANCE devices to international distributors, compared to 32 ADVANCE devices sold to international distributors in 2009. Medical equipment revenue reflects a proportional allocation of invoice amounts between the multiple elements of the arrangement.

Consumables revenues, consisting of single use nerve specific electrodes, which are used with our NC-stat System and our ADVANCE System, and EMG needles, which are used with our ADVANCE System, were \$11.7 million and \$23.4 million for 2010 and 2009, respectively, a decrease of \$11.7 million, or 49.8%. Three primary factors contributed to the decline between 2009 and 2010: our installed base of customers contracted by 13.8%; patient studies contracted by 18.6%; and our electrode ASP declined by 20.1% from \$34.61 for 2009 to \$27.66 for 2010.

## Cost of Revenues and Gross Margin

The following table presents a breakdown of our cost of revenues:

Years Ended	December 31,			
2010	2009	Change	% Change	
	(in thousands)			
\$ 2,850.6	\$ 860.9	\$ 1,989.7	231.1%	
4,199.6	6,674.7	(2,475.1)	(37.1)	
\$ 7,050.2	\$ 7,535.6	\$ (485.4)	(6.4)	
	\$ 2,850.6 4,199.6	(in thousands)  \$ 2,850.6 \$ 860.9 4,199.6 6,674.7	\$ 2,850.6 \$ 860.9 \$ 1,989.7 4,199.6 6,674.7 (2,475.1)	

Our cost of revenues was \$7.1 million, or 50.7% of revenues, for the year ended December 31, 2010, compared to \$7.5 million, or 28.8% of revenues for the year ended December 31, 2009. The decrease of \$485,400 in cost of revenues was due to lower shipment volume, partially offset by inventory charges of \$1.8 million related to a strategic change in direction for the Company that was announced on January 4, 2011. Our gross margin percentage of 49.3% of revenues for the year ended

December 31, 2010 decreased from 71.2% of revenues for the same period in 2009. The lower gross margin percentage for 2010 resulted primarily from the inventory charges, as well as lower electrode ASP compared with 2009.

## Operating Expenses

The following table presents a breakdown of our operating expenses:

		Years Ended	Dec	mber 31,			
	2010			2009	Change		% Change
	(in thousands)						
Operating expenses:							
Research and development	\$	5,855.3	\$	5,611.3	\$	244.1	4.3%
Sales and marketing		11,072.2		10,840.3		231.9	2.1
General and administrative		7,231.9		9,119.0		(1,887.1)	(20.7)
Total operating expenses	\$	24,159.4	\$	25,570.6	\$	(1,411.2)	(5.5)
Sales and marketing General and administrative	\$	11,072.2 7,231.9	_	10,840.3 9,119.0	_	231.9 (1,887.1)	2. (20.)

#### Research and Development

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

#### Sales and Marketing

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

#### General and Administrative

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

#### Other Income and Expenses

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

	Ye	ars Ende	d De	cember 31,					
	_	2010		(in thousands)				Change	% Change
Other income and expenses:			(	,					
Interest income	\$	53.8	\$	226.9	\$	(173.1)	(76.3)%		
Federal grant income		244.5		_		244.5	N/A		
Warrants fair value adjustment				(5,175.1)		5,175.1	(100.0)		
Total other income and expenses	\$	298.3	\$	(4,948.2)	\$	5,246.5	(106.0)		

#### Interest and other income

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

#### Warrants fair value adjustment

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

## Comparison of Years Ended December 31, 2009 and December 31, 2008

#### Revenues

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

	Years Ended I	December 31,			
	2009	2008	Change	% Change	
Installed base (active testing accounts)	4,493	5,189	(696)	(13.4)%	
Studies performed	161,291	207,667	(46,376)	(22.3)	

The following table summarizes our revenues from medical equipment and consumables:

	 Years Ended	Dec	ember 31,			
	 2009		2008		Change	% Change
		(in	thousands)			
Revenues:						
Medical equipment	\$ 2,713.4	\$	2,709.1	\$	4.3	0.2%
Consumables	23,423.6		28,411.7		(4,988.1)	(17.6)
Total revenues	\$ 26,137.0	\$	31,120.8	\$	(4,983.8)	(16.0)

Medical equipment revenues consisting of the NC-stat and ADVANCE Systems, related modules, and revenues from extended service agreement revenues, were \$2.7 million for each of the years ended December 31, 2009 and 2008. Although fewer devices were sold in 2009 as compared with 2008, the average selling price was higher in 2009.

Consumables revenues, consisting of sales of single use nerve specific electrodes, EMG needles, and other accessories, were \$23.4 million and \$28.4 million for the years ended December 31, 2009 and 2008, respectively, a decrease of \$5.0 million. This decrease resulted mainly from decreased volume in 2009, as reflected by a 22.3% decline in patient studies performed in comparison to 2008, and a corresponding decline in electrodes used and sold. Factors contributing to the decline include continued uncertainty surrounding reimbursement, as well as the overall state of the economy causing an overall reduction in health care purchasing. Also contributing to this decline was our decision to reduce our direct sales force by approximately 40% in the second quarter of 2008 and a generally higher turnover rate in the sales force in 2009.

## Cost of Revenues and Gross Margin

The following table presents a breakdown of our cost of revenues:

	Y	ears Ended	Dec	ember 31,			
	2009		2009 2008 (in thousands)			Change	% Change
Cost of revenues:			(111	uiousanus)			
Medical equipment	\$	860.9	\$	1,232.6	\$	(371.7)	(30.2)%
Consumables		6,674.7		7,779.4		(1,104.7)	(14.2)
Total cost of revenues	\$	7,535.6	\$	9,011.9	\$	(1,476.3)	(16.4)

Our overall cost of revenues decreased to \$7.5 million, or 28.8% of revenues, for the year ended December 31, 2009, compared to \$9.0 million, or 29.0% of revenues for the same period in 2008. Medical equipment cost of revenues decreased \$372,000 in 2009 to \$861,000 from \$1.2 million in 2008 reflecting the sale of fewer devices in 2009. Consumables cost of revenues decreased \$1.1 million in 2009 to \$6.7 million from \$7.8 million in 2008, primarily resulting from decreased sales of consumables in 2009.

Our overall gross margin percentage of 71.2% of revenues for the year ended December 31, 2009 increased slightly from 71.0% of revenues for the same period in 2008. Gross margin on medical devices improved to 68.3% in 2009 from 54.5% in 2008 reflecting the effects of higher device average selling prices during 2009. Gross margin on consumables declined slightly to 71.5% in 2009 from 72.6% in 2008.

#### **Operating Expenses**

The following table presents a breakdown of our operating expenses:

	,	Years Ended	Dece	ember 31,			
		2009		2008	Change		% Change
			(iı	n thousands)			
Operating expenses:							
Research and development	\$	5,611.3	\$	5,589.2	\$	22.1	0.4%
Sales and marketing		10,840.3		14,647.0		(3,806.7)	(26.0)
General and administrative		9,119.0		12,016.1		(2,897.1)	(24.1)
Goodwill impairment		_		5,833.5		(5,833.5)	(100.0)
Legal settlement		_		3,705.9		(3,705.9)	(100.0)
Intangible asset impairment		_		1,767.5		(1,767.5)	(100.0)
Gain from deconsolidation of joint venture		_		(2,100.0)		2,100.0	(100.0)
Total operating expenses	\$	25,570.6	\$	41,459.2	\$	(15,888.6)	(38.3)
Total operating expenses	Ψ	20,070.0	Ψ	11, 100.2	Ψ	(10,000.0)	(50.5)

#### Research and Development

Research and development expenses for the years ended December 31, 2009 and 2008 were \$5.6 million. The comparative results included a \$263,000 decrease in the amortization of intangible assets and slightly lower employee compensation cost offset by a \$316,000 increase in costs with respect to our pharmacologic compounds and legal fees related to intellectual property.

#### Sales and Marketing

Sales and marketing expenses decreased \$3.8 million to \$10.8 million for the year ended December 31, 2009 from \$14.6 million for the year ended December 31, 2008. The decrease largely reflected savings of \$2.6 million in employee compensation due to the reduction of the size of our direct sales force in May 2008. Further savings included \$356,000 in travel and entertainment expenses, \$232,000 in consulting costs, \$202,000 in advertising and promotion expenses, \$180,000 in the cost of meetings, \$162,000 in shipping and freight, and \$151,000 in the cost of subscriptions. These decreases were partially offset by an increase of \$249,000 in recruiting costs. Although overall sales and marketing costs have decreased, in the second half of 2009, we expanded our sales force, including the hiring of clinical educators to provide direct clinical support to customers.

## General and Administrative

General and administrative expenses decreased \$2.9 million to \$9.1 million for the year ended December 31, 2009 from \$12.0 million for the year ended December 31, 2008. The decrease included savings of \$1.8 million in reduced legal fees, largely related to the government investigations by the DOJ and the OIG, to which we were subject, which were settled in the first quarter of 2009 and further savings of \$310,000 in employee compensation, \$297,000 in taxes, licenses, and \$205,000 in insurance costs.

## Goodwill Impairment

As of March 31, 2008, our publicly traded market value was significantly below our net book value indicating that an interim goodwill impairment test was required. We performed step two of the impairment test in which we assessed the fair value of all recorded and unrecorded tangible and intangible assets and liabilities, including EyeTel Imaging, Inc., or EyeTel, and PNIR (Peripheral Nerve Injury Repair) LLC, or PNIR, intangibles. We determined that our non-goodwill assets were

unimpaired; however, we also determined that there was no residual value of goodwill. Accordingly, we recorded a charge of \$5.8 million to write off goodwill during the quarter ended March 31, 2008.

## Legal Settlement

As of December 31, 2008, we accrued \$3.7 million for a settlement with the DOJ and OIG which was included in "Accrued expenses" on our Balance Sheet at that date and which was subsequently paid in the first quarter of 2009.

#### Intangible Asset Impairment and Gain from Deconsolidation of Joint Venture

During the fourth quarter of 2008, we dissolved our joint venture with Cyberkinetics Neurotechnology Systems, Inc, or Cyberkinetics, which was focused on development of a product for the treatment of peripheral nerve injury. We recorded a charge of approximately \$1.8 million for the remaining balance of intangible assets representing the value of the technological and intellectual property of the joint venture and booked a gain of \$2.1 million representing our share in the assets of the joint venture on deconsolidation.

## Other Income and Expenses

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

	Years Ended De	ecember 31,		
	2009	2008	Change	% Change
		(in thousands)		
Other income and expenses:				
Loss on available-for-sale investments	\$ —	\$ (2,500.0)	\$ 2,500.0	(100.0)%
Interest income	226.9	720.9	(494.0)	(68.5)
Warrants fair value adjustment	(5,175.1)	_	(5,175.1)	N/A
Total other income and expenses	\$ (4,948.3)	\$ (1,779.1)	\$ (3,169.2)	178.1

#### Loss on Available-for-Sale Investment

In November 2007, we purchased approximately 5.4 million shares of common stock of Cyberkinetics, representing approximately 13% of Cyberkinetics' common stock, for an aggregate purchase price of \$2.5 million. On November 3, 2008, Cyberkinetics disclosed that existing cash and cash equivalents were only sufficient to meet projected operating requirements for approximately 30 days and that it was in the process of winding down its operations. Since the value of our investment in Cyberkinetics was adversely affected, we then marked this investment to market as of December 31, 2008 and recorded year-to-date charges of \$2.5 million to write down this investment to zero.

#### Interest Income

Interest income was \$227,000 and \$721,000 for the years ended December 31, 2009 and 2008, respectively. Interest income was earned from investments in cash equivalents and short-term investments. The decrease in interest income for the year ended December 31, 2009, as compared to the same period in 2008 reflects lower average invested balances and lower rates of return.

## Warrants fair value adjustment

Warrants fair value adjustment represents net charges recorded during 2009 to adjust the liability for outstanding warrants issued in an equity financing in September 2009. During October 2009, we executed addend to these warrants such that upon a change in control, as defined, the warrant holders

will receive the Black-Scholes value of the warrants in the same currency and same proportions as will be received by our common stockholders. Following the addenda, the warrant liability in the amount of \$19.7 million was reclassified to additional paid-in capital.

#### Loss from Discontinued Operations

On September 30, 2008, we approved a plan to discontinue sales and support of DigiScopes and DigiScope related services, effective November 1, 2008. On November 7, 2008, we sold substantially all of the assets related to the DigiScope business to Advanced Diagnostics, LLC in exchange for assuming certain identified commitments of approximately \$400,000 and a cash payment of \$50,000. Loss from discontinued operations in 2008 includes loss on operations and sale of assets relating to the discontinued operations.

#### **Liquidity and Capital Resources**

Our principal source of liquidity is our cash and cash equivalents. As of December 31, 2010, these totaled \$17.0 million. Our ability to generate cash from operations is dependent upon our ability to generate revenue from sales of our products, as well as our ability to manage our operating costs and net assets. Our ability to generate revenue will largely depend on the success of our shift in our business focus to diabetes, specifically detection and monitoring of diabetic neuropathy which is a common complication of the disease. At the same time, we will continue to support our neurodiagnostic business, which we intend to manage to optimize cash flow. A further decrease in demand for our products or unanticipated increases in our operating costs would likely have an adverse effect on our liquidity and cash generated from operations. The following sets forth information relating to our liquidity:

	Decem	ber 31,		
	2010	2009	Change	% Change
		(in thousands)		
Cash and cash equivalents	\$ 16,986.8	\$ 22,937.4	\$ (5,950.6)	(25.9)%
Short-term investments	_	7,495.0	(7,495.0)	(100.0)
Total cash, cash equivalents and short-term investments	\$ 16,986.8	\$ 30,432.4	\$ (13,445.6)	(44.2)

We have a one year Loan and Security Agreement, or the credit facility, with a bank, which permits us to borrow up to \$7.5 million on a revolving basis. The facility expires in March 2012. Amounts borrowed under the facility bear interest equal to the prime rate plus 0.5%. Borrowings are secured by our cash, accounts receivable, inventory, and equipment. We have not borrowed any funds under this credit facility.

During 2010, our cash, cash equivalents, and short-term investments decreased by \$13.4 million, primarily due to net cash used in operating activities of \$13.3 million.

In managing our working capital, two of the financial measurements we monitor are days sales outstanding (DSO), and inventory turnover rate, which are presented in the table below for the years ended December 31, 2010 and December 31, 2009:

	Years E Decemb	
	2010	2009
DSO (annual average receivables)*	51	47
DSO (fourth quarter average receivables)*	38	49
Inventory turnover rate (times per year)	2.0	1.5

 <sup>\*</sup> Accounts with traditional payment terms.

Our payment terms extended to our customers generally require payment within 30 days from invoice date. DSO measured on the basis of annual sales and average receivables balances showed a deterioration to 51 days at December 31, 2010 from 47 days at December 31, 2009. Reflecting improved collection efforts, DSO based on quarterly sales and average receivables balances for the fourth quarter showed an improvement to 38 days at December 31, 2010 from 49 days at December 31, 2009.

Our inventory turnover rate for the year ended December 31, 2010 was 2.0 times, compared with 1.5 times for the year ended December 31, 2009. The increase in the inventory turnover rate for the year ended December 31, 2010 reflected a decreased inventory value due primarily to inventory charges related to the business restructuring.

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

	Years Ended December 31,						
	2010	2009	2008				
		in thousands)					
Net cash used in operating activities	\$ (13,307.1) \$	(6,137.1)	(10,688.5)				
Net cash provided by (used in) investing							
activities	7,188.5	(692.1)	15,750.6				
Net cash provided by financing activities	168.0	17,464.3	142.9				

In 2010, our net cash used in operating activities was \$13.3 million. The primary drivers for the use of cash in our operating activities during 2010 were our net loss of \$16.9 million, which included non-cash expenses of \$2.1 million for inventory charges, \$1.2 million for stock-based compensation, and \$524,000 for depreciation and amortization. In addition, cash was used in operating activities for a \$1.6 million decrease in accounts payable and accrued expenses, a \$251,000 decrease in net deferred revenue, deferred costs, and other, and a \$199,000 increase in prepaid expenses and other current assets, partially offset by a \$1.7 million decrease in accounts receivable and a \$121,000 decrease in inventories.

In 2009, our net cash used in operating activities was \$6.1 million. The primary drivers for the use of cash in our operating activities during 2009 were our net loss of \$11.9 million, which included certain non-cash expenses. In addition, cash was used in operating activities for a \$3.7 million settlement with the DOJ and OIG and a \$225,000 decrease in net deferred revenue, deferred costs, and other, partially offset by a \$1.0 million reduction in inventories, a \$766,000 increase in accounts payables and accrued expenses, and a \$103,000 decrease in accounts receivable.

In 2008, our net use of cash in operating activities was \$10.7 million, including a \$6.6 million loss from discontinued operations and an investment in net operating assets of \$3.0 million. The primary drivers for the uses of cash in our investment in net operating assets during 2008 were a decrease in accounts payable and accrued expense of \$3.9 million, a \$837,000 decrease in net deferred revenue, deferred costs, and other, an increase in our inventories of approximately \$252,000 primarily related to an increase in consumables inventories, partially offset by a \$2.1 million decrease in accounts receivable, mainly due to a decline in revenues and a \$171,000 decrease in prepaid and other assets. Our net loss excluding the \$6.6 million loss attributed to discontinued operations and excluding non-cash items was approximately \$1.1 million.

Our investing activities provided \$7.2 million of cash in 2010, used \$692,000 in 2009, and provided \$15.8 million in 2008. In 2010, cash was provided by the maturity of \$7.5 million of investments, partially offset by the purchase of fixed assets totaling \$306,000. In 2009, cash was used in investing activities to purchase technological and intellectual property for \$350,000 and to purchase fixed assets totaling \$342,000. In 2008, the primary sources of cash from investment activities were \$23.7 million in investment maturities and a release of \$1.1 million of restricted cash. Primary uses of cash in investment activities in 2008 were \$8.5 million for the purchase of investments and \$510,000 for purchases of fixed assets, primarily related to computer equipment and tooling equipment for new products.

Our financing activities provided approximately \$168,000, \$17.5 million, and \$143,000 of cash in 2010, 2009, and 2008, respectively. Cash provided by financing activities in 2010 primarily represented the proceeds from the issuance of shares under our employee stock purchase plan. Cash provided by financing activities in 2009 primarily resulted from net proceeds of \$17.2 million from our equity offering in September 2009. Cash provided by financing activities in 2008 primarily represented the proceeds from the issuance of shares under our employee stock purchase plan and the exercise of stock options.

We expect to incur net losses and negative cash flows from operations for the foreseeable future. Based upon our current plans, we believe that our cash and cash equivalents, and the cash to be generated from expected product sales will be sufficient to meet our projected operating requirements into 2012. We are currently facing significant challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected due to (a) changes in future revenues; (b) changes we make to our ongoing operating expenses; (c) changes in our business strategy; (d) regulatory developments affecting us and our products; (e) changes we make to research and development spending plans; (f) the outcome of the class action lawsuit against us; and (g) other items affecting our forecasted level of expenditures and use of cash resources. Accordingly, we may need to raise additional funds to support operating and capital needs.

As of December 31, 2010, we have federal and state net operating loss carryforwards available to offset future taxable income of \$70.7 million and \$44.1 million, respectively, and federal and state research and development credits of \$905,000 and \$763,000, respectively, which may be available to reduce future taxable income and the related taxes thereon. The net operating loss and research and development credit carryforwards will expire at various dates beginning in 2019 for federal taxes and have begun to expire in 2010 for state taxes. Ownership changes in our company, as defined in the Internal Revenue Code, are expected to have a modest limitation on the amount of net operating loss and research and development credit carryforwards that can be utilized annually to offset future taxable income and taxes, based on an analysis of the provisions of Section 382 of the Internal Revenue Code. Subsequent changes in our ownership could further affect the limitation in future years.

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

As of December 31, 2010, we did not have any off-balance sheet financing arrangements.

The following table summarizes our principal contractual obligations as of December 31, 2010 and the effects such obligations are expected to have on our liquidity and cash flows in future periods.

		Payments due in				
Contractual Obligations	Total	2011	1-3 years	3-5 years		
Operating lease obligations	\$ 1,676,250	\$ 727,500	\$ 948,750	\$ —		
Capital lease obligations	60,873	22,136	38,737			
Purchase order obligations	1,293,287	1,263,942	29,345	_		
Total contractual obligations	\$ 3,030,410	\$ 2,013,578	\$ 1,016,832	\$ —		

As of December 31, 2010, we have no contractual obligations that extend beyond three years.

## **Critical Accounting Policies and Estimates**

Our financial statements are based on the selection and application of generally accepted accounting principles, which require us to make estimates and assumptions about future events that affect the amounts reported in our financial statements and the accompanying notes. Future events and their effects cannot be determined with certainty. Therefore, the determination of estimates requires the exercise of judgment. Actual results could differ significantly from those estimates, and any such

differences may be material to our financial statements. We believe that the policies set forth below may involve a higher degree of judgment and complexity in their application than our other accounting policies and represent the critical accounting policies used in the preparation of our financial statements. If different assumptions or conditions were to prevail, the results could be materially different from our reported results. Our significant accounting policies are presented within Note 2 to our Financial Statements.

# Revenue Recognition and Accounts Receivable

Our revenue recognition policy is to recognize revenues from our ADVANCE System and NC-stat System devices and consumables upon shipment if the fee is fixed or determinable, persuasive evidence of an arrangement exists, delivery has occurred and risk of loss has passed, collection of the resulting receivables is reasonably assured and product returns are reasonably estimable. Revenues from our docking station and access to the onCall Information System are considered one unit of accounting and are deferred and recognized over the estimated useful life of the product, currently three years.

When multiple elements are contained in a single arrangement, we allocate revenue between the elements based on their relative fair value, provided that each element meets the criteria for treatment as a separate unit of accounting. An element is considered a separate unit of accounting if it has value to the customer on a stand-alone basis, there is objective, reliable evidence of the fair value of the undelivered elements and delivery or performance of the undelivered elements is considered probable and substantially in our control. Fair value is determined based upon the price charged when the element is sold separately.

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

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

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

## Inventories

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

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

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

In September 2009, the EITF issued new rules to exclude (a) non-software components of tangible products and (b) software components of tangible products that are sold, licensed, or leased with tangible products when the software components and non-software components of the tangible product function together to deliver the tangible product's essential functionally. The new guidance can be prospectively applied by us beginning January 1, 2011 or can be early or retrospectively adopted. We do not believe adoption will have a material effect on our financial statements.

In January 2010, the Financial Accounting Standards Board issued Accounting Standards Update No. 2010-06, "Fair Value Measurements and Disclosures (Topic 820)—Improving Disclosures about Fair Value Measurements" ("ASU 2010-06"). ASU 2010-06 requires new disclosures regarding significant transfers in and out of Levels 1 and 2, as well as information about activity in Level 3 fair value measurements, including presenting information about purchases, sales, issuances, and settlements on a gross versus a net basis in the Level 3 activity roll forward. In addition, ASU 2010-06 also clarifies existing disclosures regarding input and valuation techniques, as well as the level of disaggregation for each class of assets and liabilities. ASU No. 2010-06 is effective for interim and annual periods beginning after December 15, 2009, except for the disclosures pertaining to purchases, sales, issuances, and settlements in the roll forward of Level 3 activity, which are effective for interim and annual periods beginning after December 15, 2010. The adoption of ASU 2010-06 had no current impact and is expected to have no subsequent impact on our financial statements.

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

#### ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item may be found on pages F-1 through F-31 of this Annual Report on Form 10-K with the exception of the unaudited summarized quarterly financial data which is presented below:

		Year Ended December 31, 2010							
	Firs	t Quarter(1)	Second Quar	ter	Third Quarter	For	urth Quarter		Total
Revenues	\$	3,566,393	\$ 3,852,4	176	\$ 3,414,335	\$	3,066,466	\$	13,899,670
Cost of revenues		1,296,014	1,405,3	348	1,347,816		3,001,031(2)	)	7,050,209
Gross margin		2,270,379	2,447,1	28	2,066,519		65,435		6,849,461
Net loss	(	4,764,029)	(4,519,0	)71)	(3,400,181)		(4,207,867)		(16,891,148)
Per common share, basic:									
Net loss	\$	(0.21)	\$ (0	.20) \$	\$ (0.15)	\$	(0.18)	\$	(0.73)
Per common share, diluted:									
Net loss		(0.21)	(0	.20)	(0.15)		(0.18)		(0.73)

	Year Ended December 31, 2009									
		First Quarter		Second Quarter		Third Quarter		Fourth Quarter		Total
Revenues	\$	6,825,578	\$	6,760,419	\$	6,325,951	\$	6,225,078	\$	26,137,026
Cost of revenues		1,940,388		1,934,920		1,826,599		1,833,709		7,535,616
Gross margin		4,885,190		4,825,499		4,499,352		4,391,369		18,601,410
Net (loss) income		(1,216,505)		(1,800,766)		(9,263,460)		363,231		(11,917,500)
Per common share, basic:										
Net (loss) income	\$	(0.09)	\$	(0.13)	\$	(0.57)	\$	0.02	\$	(0.71)
Per common share, diluted:										
Net (loss) income		(0.09)		(0.13)		(0.57)		0.01		(0.71)

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

Net (loss) income per common share is calculated independently for each of the periods presented. Therefore, the sum of the quarterly net loss per common share amounts will not necessarily equal the total for the full fiscal year.

<sup>(2)</sup> The Company recorded inventory charges of \$1.8 million related to a strategic change in direction for the Company that was announced on January 4, 2011

#### ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

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

#### ITEM 9A. CONTROLS AND PROCEDURES

#### (a) Evaluation of disclosure controls and procedures.

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

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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2010 based on the criteria in *Internal Control—Integrated Framework* issued by the Coson, our management concluded that our internal control over financial reporting was effective as of December 31, 2010.

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

## (c) Changes in internal control over financial reporting.

There have been no changes to our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the quarter ended December 31, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### ITEM 9B. OTHER INFORMATION

None.

#### **PART III**

## ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

#### DIRECTORS AND EXECUTIVE OFFICERS

The following table and biographical descriptions set forth certain information with respect to our directors and executive officers who are not directors, based on information furnished to us by each director and executive officer as of February 28, 2011.

Name	Age	Position
Shai N. Gozani, M.D., Ph.D.	46	Chairman of the Board, Chief Executive Officer, President and Secretary
Thomas T. Higgins	59	Senior Vice President, Chief Financial Officer and Treasurer
Guy Daniello	66	Senior Vice President of Information Technology
Krishnamurthy Balachandran	52	Senior Vice President, Chief Operating Officer, Neurodiagnostics
Michael Williams, Ph.D.	54	Senior Vice President of Engineering
David E. Goodman, M.D.(1)(2)	54	Director
Allen J. Hinkle, M.D.(2)	60	Director
Nancy E. Katz	51	Director
Charles R. LaMantia(1)(3)	71	Director
Timothy R. Surgenor(1)(3)	51	Director

- (1) Member of Audit Committee
- (2) Member of Compensation Committee
- (3) Member of Nominating and Corporate Governance Committee

Allen J. Hinkle, M.D. has served as a member of our Board of Directors since January 2006. From December 2010 through the present, Dr. Hinkle has served as the Chief Medical Officer of MVP Health Care, a not-for-profit health insurer. Dr. Hinkle was the Chief Medical Officer and Senior Vice President for Tufts Health Plan in Massachusetts, a health insurance provider, where he was responsible for medical management programs and initiatives from 2004 to 2009. Prior to becoming the Chief Medical Officer of Tufts Health Plan, Dr. Hinkle was Senior Medical Director and Vice President of Health Care Quality, Policy and Innovations at Blue Cross Blue Shield of Massachusetts, a health insurance provider, from 2001 through September 2004. From 1995 to 2001, Dr. Hinkle was the Chief Medical Officer and Senior Vice President of Quality—Healthcare Management for Anthem Blue Cross Blue Shield of New Hampshire and Matthew Thornton Plan, health insurance provider organizations. Dr. Hinkle has over 30 years of experience in the healthcare field. Dr. Hinkle received a B.S. from the University of Massachusetts at Amherst and an M.D. from Albert Einstein College of Medicine in New York. He is board certified in pediatrics and anesthesiology and is an Associate Professor of Anesthesiology and Pediatrics at Dartmouth Medical School and Associate Professor of Medicine at Tufts University School of Medicine. He also owns several U.S. patents on medical devices. The Board has concluded that Dr. Hinkle should serve as a director because Dr. Hinkle's years of experience as a physician and in executive positions in the health insurance industry provide the Board with valuable insights in the areas of product development and reimbursement.

**Timothy R. Surgenor** has served as a member of our Board of Directors since April 2009. Since April 2009, Mr. Surgenor has been a partner at Red Sky Partners, LLC., a provider of general

management consulting services to the biotechnology and medical device industries. From 2003 to 2009, Mr. Surgenor served as President, Chief Executive Officer and director of Cyberkinetics Neurotechnology Systems, a medical device company. From January 1999 to January 2003, Mr. Surgenor was Executive Vice President at Haemonetics Corporation, which is a medical device company. From 1994 to 1999, Mr. Surgenor was President of Genzyme Tissue Repair, the cell therapy division of Genzyme Corporation. Previously, Mr. Surgenor was Executive Vice President and Chief Financial Officer of BioSurface Technology, Inc. and also held various positions in operations at Integrated Genetics. Mr. Surgenor received a B.A. in Biochemistry from Williams College and an M.B.A. from Harvard Business School. The Board has concluded that Mr. Surgenor should serve as a director because Mr. Surgenor's long career in the medical device and biotechnology business as both an entrepreneur and in senior executive positions in public companies provides the Board with important industry experience as well as valuable finance, accounting and executive management expertise.

David E. Goodman, M.D. has served as a member of our Board of Directors since June 2004. Dr. Goodman currently serves as an independent consultant and practicing physician. During 2010, Dr. Goodman has served as President and Chief Executive Officer of SEDline, Inc., a research-focused company with the mission to expand the scope and applications for neuromonitoring. From 2008 to 2009, Dr. Goodman served as Executive Vice President of Business Development for Masimo Corporation, a manufacturer of non-invasive patient monitors. From 2006 to 2008, Dr. Goodman served as an independent consultant providing product design, regulatory and analytical consulting services to medical device and biopharmaceutical companies and also served in this capacity from 2003 to 2004 and from 2001 to 2002. From 2005 to 2006, Dr. Goodman served as President and Chief Executive Officer of BaroSense, Inc., a medical device company focused on developing minimally invasive devices for the long-term treatment of obesity. From 2004 to 2005, Dr. Goodman served as President and Chief Executive Officer of Interventional Therapeutic Solutions, Inc., an implantable drug delivery systems company. From 2002 to 2003, Dr. Goodman served as Chairman, President and Chief Executive Officer of Pherin Pharmaceuticals, a pharmaceutical discovery and development company. From 1994 to 2001, Dr. Goodman held various positions, including Chief Executive Officer, Chief Medical Officer and director, for LifeMasters Supported SelfCare, Inc., a disease management services company that Dr. Goodman founded. Dr. Goodman also serves as a director of Sound Surgical Technologies LLC, a private manufacturer of aesthetic surgical tools. Dr. Goodman holds a B.A.S. in applied science and bioengineering and a M.S.E. in bioengineering from the University of Pennsylvania. He also received an M.D. from Harvard Medical School and the Harvard-M.I.T. Division of Health Sciences and Technology. The Board has concluded that Dr. Goodman should serve as a director because Dr. Goodma

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

Nancy E. Katz has served as a member of our Board of Directors since December 2010. Most recently, Ms. Katz was Senior Vice President, Bayer Diabetes Care—North America. Previously, she was President and Chief Executive Officer of Calypte Biomedical Corporation, a manufacturer of HIV diagnostics, President of Zila Pharmaceutical, Inc, a manufacturer of oral care products, and held senior marketing positions with the Lifescan division of Johnson & Johnson (blood glucose diabetes products), Schering-Plough Healthcare Products, and with American Home Products. She has served on the Boards of Directors of Neoprobe Corporation, Calypte Biomedical Corporation, LXN Corporation and Pepgen Corporation. The Board has concluded that Ms. Katz should serve as a director because her experience in diabetes care and marketing into the diabetes sector provides valuable insight to the Board and management in our diabetes strategy.

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

Executive Officers Who Are Not Directors

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

Krishnamurthy Balachandran has served as our Senior Vice President and General Manager, International since April 2010. In January 2011 he assumed additional responsibilities as Chief Operating Officer, Neurodiagnostics. Prior to joining NeuroMetrix, Mr. Balachandran was Vice President and General Manager of Cardinal Health's NeuroCare Division, a provider of technology and services to the neurophysiology industry. Before joining Cardinal Health in 2007, Mr. Balachandran was with Hewlett Packard as Senior Director, Global Alliances. Prior to joining Hewlett Packard, Mr. Balachandran was Vice President, International Sales and Marketing for Nicolet Biomedical, the leading business in EMG and nerve conduction testing which was subsequently acquired by Cardinal Health and became its NeuroCare division. Mr. Balachandran started his career in sales with Blue

Star, Ltd of India. Mr. Balachandran, an electrical engineer from the National Institute of Technology in India, holds an MBA in Marketing from the Indian Institute of Management in Ahmedabad, India.

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

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

## **BOARD MATTERS AND CORPORATE GOVERNANCE**

#### **Board of Directors**

Our amended and restated certificate of incorporation provides for a classified board of directors consisting of three staggered classes of directors (Class I, Class II and Class III). The members of each class of our Board of Directors serve for staggered three-year terms, with the terms of our Class I, Class II and Class III directors expiring upon the election and qualification of directors at the annual meetings of stockholders to be held in 2011, 2012, and 2013, respectively. Currently:

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

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

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

The Audit Committee currently consists of Mr. Surgenor, Chairman, and Dr. Goodman and Mr. LaMantia. The Audit Committee operates pursuant to a charter that was approved by our Board of Directors, a copy of which is available on our website at <a href="http://www.neurometrix.com">http://www.neurometrix.com</a> under the heading "Investor Relations" and subheading "Corporate Governance". The purposes of the Audit Committee are to, among other functions, assist the Board of Directors in overseeing the operation of a comprehensive system of internal controls covering the integrity of the Company's financial statements and reports, compliance with laws, regulations and corporate policies, and the qualifications, performance and independence of the Company's registered public accounting firm. Dr. Goodman and Messrs. LaMantia and Surgenor are all "independent" as that term is defined in the rules of the SEC

and the applicable NASDAQ rules relating to audit committee members. Our Board of Directors has determined that Messrs. LaMantia and Surgenor each qualify as "audit committee financial experts" as such term is defined in the rules of the SEC. The Audit Committee held six meetings during 2010.

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

There have been no changes to the procedures disclosed in our proxy statement for the 2010 annual meeting of stockholders by which stockholders may nominate directors.

#### **Code of Business Conduct and Ethics**

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

## Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our directors and executive officers and holders of more than 10% of our common stock (collectively, "Reporting Persons") to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock. Such Reporting Persons are required by regulations of the SEC to furnish us with copies of all such filings. Our records reflect that all reports which were required to be filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, as amended, were filed on a timely basis except that one Form 3 and two Forms 4 were filed late for our Senior Vice President and General Manager, Krishnamurthy Balachandran, reporting two transactions. We received a written statement from our directors, officers, and 10% stockholders or know from other means that any required Forms 5 were filed or that no Forms 5 were required to be filed

#### ITEM 11. EXECUTIVE COMPENSATION

#### **DIRECTORS' COMPENSATION**

The non-employee members of our Board of Directors receive annual cash compensation in the amount of \$10,000 for service as a member of our Board of Directors, which is paid following each annual meeting of our stockholders. In addition, these non-employee directors receive the sum of \$1,500 for each board or committee meeting that they attend, provided that they are not entitled to additional compensation for attending committee meetings that occur on the same day as a board meeting at which they attend. This cash compensation will be in addition to any stock options or other equity compensation that we determine to grant to our directors on a case by case basis. Dr. Gozani, the only member of our Board of Directors who is also an employee, is not separately compensated for his service on our Board of Directors.

In addition to the compensation described above, we also reimburse all non-employee directors for their reasonable out-of-pocket expenses incurred in attending meetings of our Board of Directors or any committees thereof.

The following table shows compensation information with respect to services rendered to us in all capacities during the fiscal year ended December 31, 2010 for each non-employee member of the Board of Directors.

#### Director Compensation Table—2010

Name_	Fees Earned or Paid in Cash (\$)	Option Awards (\$)(1)	All Other Compensation (\$)(2)	Total Compensation (\$)
David E. Goodman, M.D.	35,550	—(3)	4,246	39,796
Allen J. Hinkle, M.D.	25,000	(4)		25,000
Nancy E. Katz	_	8,973(5)	_	8,973
Charles R. LaMantia	32,500	—(6)	_	32,500
W. Mark Lortz	7,500	<b>—</b> (7)	_	7,500
Timothy R. Surgenor	33,000	-(8)	_	33,000

- (1) These amounts represent the aggregate grant date fair value for option awards for fiscal year 2010 computed in accordance with FASB ASC Topic 718. A discussion of the assumptions used in determining grant date fair value may be found in Note 3 to our Financial Statements, included in our Annual Report on Form 10-K for the year ended December 31, 2010.
- (2) Consists of reimbursement of travel expenses.
- (3) As of December 31, 2010, Dr. Goodman held options to purchase 66,000 shares of common stock, 46,000 of which were vested.
- (4) As of December 31, 2010, Dr. Hinkle held options to purchase 66,000 shares of common stock, 51,000 of which were vested.
- (5) Ms. Katz became a director of the Company effective December 14, 2010. As of December 31, 2010, Ms. Katz held options to purchase 30,000 shares of common stock, none of which were vested.
- (6) As of December 31, 2010, Mr. LaMantia held options to purchase 66,000 shares of common stock, 46,000 of which were vested.
- (7) Mr. Lortz ceased serving as a director on May 13, 2010 and, as of December 31, 2010, did not hold any options to purchase shares of our common stock.
- (8) As of December 31, 2010, Mr. Surgenor held options to purchase 30,000 shares of common stock, 15,000 of which were vested.

#### COMPENSATION OF EXECUTIVE OFFICERS

#### **Summary of Executive Compensation**

The following table sets forth compensation information with respect to services rendered to us in all capacities during the fiscal years ended December 31, 2010 and 2009 for (i) the individual who served as the Chief Executive Officer during the year ended December 31, 2010, (ii) the individual who served as the Chief Financial Officer during the year ended December 31, 2010, and (iii) each of the four other most highly compensated executive officers who were serving as executive officers at December 31, 2010 (we refer to these individuals, collectively, as the "named executive officers"):

## **Summary Compensation Table**

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards(1) (\$)	Total (\$)
Shai N. Gozani, M.D. Ph.D.	2010	375,000		37,125	84,135	496,260
Chairman of the Board, Chief Executive Officer, President and Secretary	2009	375,000	110,625	_	281,480	767,105
Thomas T. Higgins(2) Senior Vice President, Chief Financial Officer and Treasurer	2010 2009	275,000 87,841	— —(3)	20,790 25,311(3)	47,116 175,010	342,906 288,162
Krishnamurthy Balachandran(2)	2010	180,926	_	_	104,980	285,906
Chief Operating Officer, Neurodiagnostics	2009	N/A	N/A	N/A	N/A	N/A
Walter Christensen(4) Former Senior Vice President of Global Sales	2010 2009	250,000 214,395	— 48,675	20,790 —	47,116 143,450	317,906 406,520
Cuy Daniella	2010	239,532		14,850	33,654	288,036
Guy Daniello Senior Vice President of Information Technology	2010	213,868	31,545	14,050 —	70,370	315,783
AC L LYTH DID	2010	227.040		1.4.050	22.654	056 450
Michael Williams, Ph.D.	2010	227,949		14,850	33,654	276,453
Senior Vice President of Engineering	2009	223,168	32,917	_	70,370	326,455

<sup>(1)</sup> These amounts represent the aggregate grant date fair value for option and stock awards for fiscal years 2010 and 2009, respectively, computed in accordance with FASB ASC Topic 718. A discussion of the assumptions used in determining grant date fair value may be found in Note 3 to our Financial Statements, included in our Annual Report on Form 10-K for the year ended December 31, 2010.

<sup>(2)</sup> Messrs. Higgins and Balachandran joined the Company in September 2009 and April 2010, respectively.

<sup>(3)</sup> The named executive officer received a portion of his 2009 bonus amount in shares of our common stock at a price per share of \$2.07, which represented the closing price of our common stock as reported on The NASDAQ Global Market on March 9, 2010, the date of the compensation committee meeting at which his bonus amount was approved.

<sup>(4)</sup> Mr. Christensen departed from the Company effective January 31, 2011.

#### **Discussion of Summary Compensation Table**

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

#### Cash Compensation

We pay our executive officers a base salary, which we review and determine annually. In 2010, we increased the base salaries of the following named executive officers: Mr. Daniello's base salary increased from \$213,868 to \$239,532 per year, an increase of 12% and Dr. Williams' base salary increased from \$223,168 to \$227,949 per year, an increase of 2%. Base salaries for Dr. Gozani, Mr. Higgins, and Mr. Christensen were not adjusted. Mr. Balachandran joined the Company in 2010 and was not eligible for an increase in his base salary during 2010.

#### **Bonus Payments**

The established targets for annual bonus payments for each of our executive officers for 2010 were as follows: Dr. Gozani—50% of base salary; Mr. Higgins—40% of base salary; Mr. Balachandran—40% of base salary; Mr. Christensen—50% of base salary; Mr. Daniello—30% of base salary; and Dr. Williams—30% of base salary. After performing an overall assessment of our performance in 2010, the Compensation Committee decided that no discretionary bonuses would be paid to the named executive officers.

## Long-Term Incentive Compensation

We grant long-term equity incentive awards in the form of stock options to executives as part of our total compensation package. On April 2, 2010, we made the following equity grants, comprised of stock options and restricted shares, to our then current named executive officers under our Second Amended and Restated 2004 Stock Option and Incentive Plan with an exercise price of \$1.69 per share: Dr. Gozani—83,750 stock options and 20,625 restricted shares; Mr. Higgins—46,900 stock options and 11,550 restricted shares; Mr. Christensen—46,900 stock options and 11,550 restricted shares; Mr. Daniello—33,500 stock options and 8,250 restricted shares; and Dr. Williams 33,500 stock options and 8,250 restricted shares. In addition, upon joining NeuroMetrix, our new named executive officer, Krishnamurthy Balachandran, was granted stock options under the 2009 Non-Qualified Inducement Stock Plan (the "2009 Inducement Plan"). On April 19, 2010, Mr. Balachandran was granted stock options for 100,000 shares exercisable at \$1.77 per share. These stock options have a term of ten years and vest over four years with 25% of the total award vesting after one year and the remainder vesting in equal quarterly installments thereafter. Generally, to the extent vested, each stock option is exercisable during the term of the option while the grantee is employed by us and for a period of three months thereafter, unless such termination is upon death or disability, in which the grantee may continue to exercise the option for a period of 12 months, or for cause, in which case the option terminates immediately. Vesting of stock options is also subject to acceleration in some certain circumstances in connection with a change-in-control as described below in "Employment Agreements and Potential Payments upon Termination or Change-in-Control." The restricted shares are subject to forfeiture provisions which expire with continuing service to the Company at the rate of 25% one year following the date of grant and 6.25% quarterly thereafter.

## **Outstanding Equity Awards at Fiscal Year-End**

The table below sets forth information with respect to our named executive officers concerning the outstanding equity awards as of December 31, 2010.

		Option Award	ls	Stock Awards		
	Unde	of Securities erlying sed Options  Unexercisable (#)	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)
Shai N. Gozani, M.D., Ph.D.	375,000		8.00	6/21/14		( <del>+)</del>
	47,250	3,150(1)	9.52	3/27/17	_	_
	21,875	13,125(2)	1.99	4/01/18	_	_
	170,000	30,000(3)	2.13	6/03/18	_	_
	87,500	112,500(4)	1.70	2/12/19	_	_
	_	83,750(5)	1.69	4/02/20	20,625(21)	14,025
Thomas T. Higgins	31,250 —	68,750(6) 46,900(7)	2.33 1.69	9/10/19 4/02/20	— 11,550(21)	— 7,854
Krishnamurthy Balachandran	_	100,000(8)	1.77	4/19/20	_	_
Walter Christensen	56,250 17,587	43,750(9) 29,313(10)	1.73 1.69	5/01/11 5/01/11	— 11,550(21)	— 7,854
Guy Daniello	3,750		2.25	10/13/12		
Guy Danieno	1,358	_	2.25	1/01/13	_	_
	1,250	_	4.48	6/05/13	_	
	25,000	_	30.10	1/04/16	_	_
	36,000	2,400(11)	9.52	3/27/17	_	_
	21,875	13,125(12)	1.99	4/01/18	_	_
	42,500	7,500(13)		6/03/18	_	_
	21,875	28,125(14)		2/12/19	_	_
		33,500(15)	1.69	4/02/20	8,250(21)	5,610
Michael Williams, Ph.D.	2,276		2.25	1/01/13	_	_
	187	_	2.25	1/15/12	_	_
	11,250	_	2.25	9/18/13	_	_
	625	_	2.25	6/05/13	_	_
	1,875	_	4.48	6/05/13	_	_
	25,000	_	30.10	1/04/16		_
	36,000	2,400(16)		3/27/17		_
	21,875	13,125(17)	1.99	4/1/18		_
	42,500	7,500(18)		6/3/18		_
	21,875	28,125(19)	1.70	2/12/19	_	_
	_	33,500(20)	1.69	4/02/20	8,250(21)	5,610

<sup>(1)</sup> Reflects the unexercised portion of a stock option for 50,400 shares of common stock that was granted on March 27, 2007. The option vests/vested 25% on the first anniversary of the grant date and then 1/16th each quarter thereafter until fully vested.

<sup>(2)</sup> Reflects the unexercised portion of a stock option for 35,000 shares of common stock that was granted on April 1, 2008. The option vests/vested 25% on the first anniversary of the vest start date and then 1/16th each quarter thereafter until fully vested.

- (3) Reflects the unexercised portion of a stock option for 200,000 shares of common stock that was granted on June 3, 2008. The option vests/vested 35% on the first anniversary of the vest start date and then 8.75% each quarter during the second year and 7.5% each quarter during the third year.
- (4) Reflects the unexercised portion of a stock option for 200,000 shares of common stock that was granted on February 12, 2009. The option vests/vested 25% on the first anniversary of the vest start date and then 1/16th each quarter thereafter until fully vested.
- (5) Reflects the unexercised portion of a stock option for 83,750 shares of common stock that was granted on April 2, 2010. The option vests 25% on the first anniversary of the vest start date and then 1/16th each quarter thereafter until fully vested.
- (6) Reflects the unexercised portion of a stock option for 100,000 shares of common stock that was granted on granted on September 10, 2009. The option vests/vested 25% on the first anniversary of the vest start date and then 1/16th each quarter thereafter until fully vested.
- (7) Reflects the unexercised portion of a stock option for 46,900 shares of common stock that was granted on granted on April 2, 2010. The option vests 25% on the first anniversary of the vest start date and then 1/16th each quarter thereafter until fully vested.
- (8) Reflects the unexercised portion of a stock option for 100,000 shares of common stock that was granted on granted on April 19, 2010. The option vests 25% on the first anniversary of the vest start date and then 1/16th each quarter thereafter until fully vested.
- (9) Reflects the unexercised portion of a stock option for 100,000 shares of common stock that was granted on May 4, 2009. The option vests/vested 25% on the first anniversary of the vest start date and then 1/16th each quarter thereafter until fully vested. However, 18,750 shares for Mr. Christensen, who departed from the Company effective January 31, 2010, were vested early due to an acceleration clause in his letter agreement. All of Mr. Christensen's unvested options have been forfeited. Mr. Christensen will have until May 1, 2011 to exercise his vested options, otherwise they will also be forfeited.
- (10) Reflects the unexercised portion of a stock option for 46,900 shares of common stock that was granted on granted on April 2, 2010. The option vests 25% on the first anniversary of the vest start date and then 1/16th each quarter thereafter until fully vested. However, 17,587 shares for Mr. Christensen, who departed from the Company effective January 31, 2010, were vested early due to an acceleration clause in his letter agreement. All of Mr. Christensen's unvested options have been forfeited. Mr. Christensen will have until May 1, 2011 to exercise his vested options, otherwise they will also be forfeited.
- (11) Reflects the unexercised portion of a stock option for 38,400 shares of common stock that was granted on March 27, 2007. The option vests/vested 25% on the first anniversary of the grant date and then 1/16th each quarter thereafter until fully vested.
- (12) Reflects the unexercised portion of a stock option for 35,000 shares of common stock that was granted on April 1, 2008. The option vests/vested 25% on the first anniversary of the vest start date and then 1/16th each quarter thereafter until fully vested.
- (13) Reflects the unexercised portion of a stock option for 50,000 shares of common stock that was granted on June 3, 2008. The option vests/vested 35% on the first anniversary of the vest start date and then 8.75% each quarter during the second year and 7.5% each quarter during the third year.
- (14) Reflects the unexercised portion of a stock option for 50,000 shares of common stock that was granted on February 12, 2009. The option vests/vested 25% on the first, second, third and fourth anniversaries of the grant date.

- (15) Reflects the unexercised portion of a stock option for 33,500 shares of common stock that was granted on granted on April 2, 2010. The option vests 25% on the first anniversary of the vest start date and then 1/16th each quarter thereafter until fully vested.
- (16) Reflects the unexercised portion of a stock option for 38,400 shares of common stock that was granted on March 27, 2007. The option vests/vested 25% on the first anniversary of the grant date and then 1/16th each quarter thereafter until fully vested.
- (17) Reflects the unexercised portion of a stock option for 35,000 shares of common stock that was granted on April 1, 2008. The option vests/vested 25% on the first anniversary of the vest start date and then 1/16th each quarter thereafter until fully vested.
- (18) Reflects the unexercised portion of a stock option for 50,000 shares of common stock that was granted on June 3, 2008. The option vests/vested 35% on the first anniversary of the vest start date and then 8.75% each quarter during the second year and 7.5% each quarter during the third year.
- (19) Reflects the unexercised portion of a stock option for 50,000 shares of common stock that was granted on February 12, 2009. The option vests/vested 25% on the first anniversary of the vest start date and then 1/16th each quarter thereafter until fully vested.
- (20) Reflects the unexercised portion of a stock option for 33,500 shares of common stock that was granted on February 12, 2009. The option vests 25% on the first anniversary of the vest start date and then 1/16th each quarter thereafter until fully vested.
- (21) Reflects the unvested portion of a restricted stock grant for the indicated number of shares of common stock that was granted on April 2, 2010. The restricted shares vest 100% on the first anniversary of the vest start date. However, shares for Mr. Christensen, who departed from the Company effective January 31, 2010, were forfeited as of that date.

## **Employment Agreements and Potential Payments upon Termination or Change-in-Control**

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

We entered into an employment agreement with Dr. Gozani, effective as of June 21, 2004 and amended on December 31, 2008. Under the terms of the employment agreement, Dr. Gozani is to be paid an annual base salary determined by the Compensation Committee but not less than \$250,000. Dr. Gozani's salary for 2010 was \$375,000. Dr. Gozani is also eligible to receive an annual cash performance bonus of up to 50% of his annual salary if certain performance objectives, determined by Dr. Gozani and our Compensation Committee, are met. In addition, pursuant to this employment agreement, on June 21, 2004, we granted Dr. Gozani stock options to purchase 375,000 shares of common stock at an exercise price of \$8.00 per share, equal to the price per share at our initial public offering. This stock option has a term of ten years from the grant date and vested over four years from the grant date with 25% of the total award vesting after one year and the remainder vesting ratably over the following three years on a quarterly basis.

The employment agreement may be terminated by us with or without cause or by Dr. Gozani. Under the terms of the employment agreement, if (1) we terminate Dr. Gozani for any reason other than willful non-performance of his duties under the employment agreement, intentional fraud or dishonesty with respect to our business or conviction of a felony, which we refer to as a termination without cause, or (2) Dr. Gozani resigns as a result of a reduction in his responsibilities with us, reduction in his status with us, reduction of his salary, relocation of our corporate offices more than 35 miles from their current location or breach by us of the employment agreement, which we refer to as a termination for good reason, Dr. Gozani will be entitled to his full base salary at his then-current annual rate of pay, plus benefits and applicable bonus payments, through the date of his termination. In addition, in the event of such a termination, we will continue to pay Dr. Gozani his then-current

annual base salary for one year following the termination. Additionally, Dr. Gozani will be entitled to his full annual cash performance bonus in the year that any of the following transactions occurs:

- a sale of substantially all of our assets;
- a merger or combination with another entity, unless the merger or combination does not result in a change in ownership of our voting securities of more than 50%; or
- the sale or transfer of more than 50% of our voting securities.

#### Thomas T. Higgins

We entered into a letter agreement with Mr. Higgins effective September 2, 2009, which provides for our employment of Mr. Higgins as our Senior Vice President, Chief Financial Officer and Treasurer, on an at-will basis. Under the letter agreement, Mr. Higgins' annual salary was set at \$275,000, subject to periodic review and adjustment at our discretion. Mr. Higgins' annual salary for 2010 was \$275,000. Under the letter agreement, Mr. Higgins will also be eligible to receive an annual cash performance bonus of up to 40% of his annual salary.

Under the terms of the letter agreement, if (1) we terminate Mr. Higgins' employment without cause or (2) Mr. Higgins resigns as a result of our material breach of the terms of the letter agreement, which we refer to as a termination for good reason, then Mr. Higgins will be entitled to receive his base salary and continuation of health benefits for a period of nine months from the date of such termination of Mr. Higgins, subject to Mr. Higgins executing a release agreement with us. Additionally, in the event of a termination of Mr. Higgins without cause or for good reason, Mr. Higgins will be entitled to the acceleration of nine months of vesting under any option grants made subsequent to the date of his letter agreement.

## Krishnamurthy Balachandran

We entered into a letter agreement with Mr. Balachandran effective April 19, 2010, which provides for our employment of Mr. Balachandran as our Senior Vice President and General Manager International, on an at-will basis. Under the letter agreement, Mr. Balachandran's annual salary was set at \$275,000, subject to periodic review and adjustment at our discretion. Under the letter agreement, Mr. Balachandran will also be eligible to receive an annual cash performance bonus of up to 40% of his annual salary.

Under the terms of the letter agreement, if (1) we terminate Mr. Balachandran's employment without cause or (2) Mr. Balachandran resigns as a result of our material breach of the terms of the letter agreement, which we refer to as a termination for good reason, then Mr. Balachandran will be entitled to receive his base salary and continuation of health benefits for a period of nine months from the date of such termination of Mr. Balachandran, subject to Mr. Balachandran executing a release agreement with us. Additionally, in the event of a termination of Mr. Balachandran without cause or for good reason, Mr. Balachandran will be entitled to the acceleration of nine months of vesting under any option grants made subsequent to the date of his letter agreement.

#### Walter Christensen

We entered into a letter agreement with Mr. Christensen effective May 4, 2009, which provided for our employment of Mr. Christensen as our Senior Vice President of Global Sales, on an at-will basis. Under the letter agreement, Mr. Christensen's annual salary was \$250,000, subject to periodic review and adjustment at our discretion. Under the letter agreement, Mr. Christensen was also eligible to receive an annual cash performance bonus of up to 50% of his annual salary.

Mr. Christensen departed from the Company effective January 31, 2011. In accordance with the terms of his letter agreement, he will receive nine months of severance, to be paid out in semi-monthly installments through October 31, 2011. In addition, in accordance with the terms of his letter agreement, the vesting of his option grants was accelerated by nine months of vesting upon his departure.

#### **Guy Daniello**

We entered into a letter agreement with Mr. Daniello effective February 5, 2008 and amended on December 31, 2008, which provides for our employment of Mr. Daniello, as our Senior Vice President of Information Technology, on an at-will basis. Under the letter agreement, Mr. Daniello's annual salary was set at \$199,690, subject to periodic review and adjustment at our discretion. Mr. Daniello's annual salary for 2010 was \$239,532. Under the letter agreement, Mr. Daniello will be also eligible to receive an annual cash performance bonus of up to 25% of his annual salary.

Under the terms of the letter agreement, if (1) we terminate Mr. Daniello's employment without cause or (2) Mr. Daniello resigns as a result of our material breach of the terms of the letter agreement, which we refer to as a termination for good reason, then Mr. Daniello will be entitled to receive his base salary and continuation of health benefits for a period of nine months from the date of such termination of Mr. Daniello, subject to Mr. Daniello executing a release agreement with us. Additionally, in the event of a termination of Mr. Daniello without cause or for good reason, Mr. Daniello will be entitled to the acceleration of nine months of vesting under any option grants made subsequent to the date of his letter agreement.

#### Michael Williams, Ph.D.

We entered into a letter agreement with Dr. Williams effective February 5, 2008 and amended on December 31, 2008, which provides for our employment of Dr. Williams, as our Senior Vice President of Engineering, on an at-will basis. Under the letter agreement, Dr. Williams' annual salary was set at \$208,373, subject to periodic review and adjustment at our discretion. Dr. Williams' annual salary for 2010 was \$227,949. Under the letter agreement, Dr. Williams will be also eligible to receive an annual cash performance bonus of up to 25% of his annual salary.

Under the terms of the letter agreement, if (1) we terminate Dr. Williams' employment without cause or (2) Dr. Williams resigns as a result of our material breach of the terms of the letter agreement, which we refer to as a termination for good reason, then Dr. Williams will be entitled to receive his base salary and continuation of health benefits for a period of nine months from the date of such termination of Dr. Williams, subject to Dr. Williams executing a release agreement with us. Additionally, in the event of a termination of Dr. Williams without cause or for good reason, Dr. Williams will be entitled to the acceleration of nine months of vesting under any option grants made subsequent to the date of his letter agreement.

Dr. Gozani, Mr. Higgins, Mr. Balachandran, Mr. Daniello, and Dr. Williams have each entered into a confidentiality and non-competition agreement with us, which provides for protection of our confidential information, assignment to us of intellectual property developed by the executive officer and non-compete and non-solicitation obligations that are effective during, and for 12 months following termination of, the executive officer's employment.

Under our 1998 Equity Incentive Plan and our Second Amended and Restated 2004 Stock Option and Incentive Plan, vesting of the stock options granted thereunder fully accelerates in connection with certain sale events, as described therein, unless such stock options are continued, assumed or replaced in the transaction constituting such sale event.

# ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

# PRINCIPAL AND MANAGEMENT STOCKHOLDERS

The following table sets forth certain information concerning beneficial ownership as of January 31, 2011, except as noted below, of our common stock by:

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

The number of common shares "beneficially owned" by each stockholder is determined under rules issued by the SEC regarding the beneficial ownership of securities. This information is not necessarily indicative of beneficial ownership for any other purpose. Under these rules, beneficial ownership of common stock includes (1) any shares as to which the person or entity has sole or shared voting power or investment power and (2) any shares as to which the person or entity has the right to acquire beneficial ownership within 60 days after January 31, 2011, including any shares that could be purchased by the exercise of options or warrants on or within 60 days after January 31, 2011. Each stockholder's percentage ownership is based on 23,197,537 shares of our common stock outstanding as of January 31, 2011 plus the number of shares of common stock that may be acquired by such stockholder upon exercise of options or warrants that are exercisable on or within 60 days after January 31, 2011.

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

Amount and Nature of

	Am Be			
Name and Address(1) of Beneficial Owner	Common Stock	Options(2)	Total	Percent of Class of Total
Directors and Executive Officers				
Shai N. Gozani, M.D., Ph.D.	845,286	736,650	1,581,936	6.6%
David E. Goodman, M.D.	_	46,000	46,000	*
Allen Hinkle, M.D.	_	51,000	51,000	*
Nancy E. Katz	_	_	_	_
Charles R. LaMantia	_	46,000	46,000	*
W. Mark Lortz	_	_	_	*
Timothy R. Surgenor	_	15,000	15,000	*
Krishnamurthy Balachandran	10,000	_	10,000	*
Walter Christensen	16,550	37,500	54,050	*
Guy Daniello	18,778	167,258	186,036	*
Thomas T. Higgins	16,129	37,500	53,629	*
Michael Williams, Ph.D.	17,510	177,113	194,623	*
All Current Directors and Executive Officers as a group (12 persons)	924,253	1,314,021	2,238,274	9.1%

Beneficial Ownership			
Common Stock	Options(2)	Total	Percent of Class of Total
3,460,809		3,460,809	13.5%
3,681,417	_	3,681,417	14.7%
3,681,417		3,681,417	14.7%
1,569,321	_	1,569,321	6.3%
3,540,655		3,540,655	15.3%
1,843,928	_	1,843,928	7.9%
	3,460,809 3,681,417 3,681,417 1,569,321 3,540,655	Common Stock         Options(2)           3,460,809         —           3,681,417         —           1,569,321         —           3,540,655         —	Beneficial Ownership           Common Stock         Options(2)         Total           3,460,809         —         3,460,809           3,681,417         —         3,681,417           3,689,321         —         1,569,321           3,540,655         —         3,540,655

- \* Represents less than 1% of the outstanding shares of common stock.
- (1) Unless otherwise indicated, the address of each stockholder is c/o NeuroMetrix, Inc., 62 Fourth Avenue, Waltham, Massachusetts 02451.

Amount and Nature of

- (2) Includes all options that are exercisable on or within 60 days from January 31, 2011 by the beneficial owner, except as otherwise noted.
- (3)This information is based solely on Amendment No. 4 to Schedule 13G filed on February 3, 2011 by Deerfield Capital, L.P. and related persons. Includes 367,472 shares of common stock and warrants, which are exercisable within 60 days of January 31, 2011, to purchase 876,489 shares of common stock held by Deerfield Special Situations Fund, L.P. and 672,098 shares of common stock and warrants, which are exercisable within 60 days of January 31, 2011, to purchase 1,544,750 shares of common stock held by Deerfield Special Situations Fund International Limited. James E. Flynn has shared voting power and shared dispositive power with respect to all of these shares of common stock and warrants. Deerfield Capital, L.P. and Deerfield Special Situations Fund, L.P. have shared voting power and shared dispositive power over the shares of common stock and warrants held by Deerfield Special Situations Fund, L.P. Deerfield Management Company, L.P. and Deerfield Special Situations Fund International Limited have shared voting power and shared dispositive power over the shares of common stock and warrants held by Deerfield Special Situations Fund International Limited. The reporting persons set forth above each disclaim beneficial ownership of the shares reported that are underlying the warrants to the extent beneficial ownership of such shares would cause all reporting persons, in the aggregate, to beneficially own in excess of 9.99% of the total number of shares of the Company then outstanding. The address of James E. Flynn, Deerfield Management Company, L.P., Deerfield Capital, L.P. and Deerfield Special Situations Fund, L.P. is 780 Third Avenue, 37th Floor, New York, NY 10017. The address of Deerfield Special Situations Fund International Limited is c/o Citi Hedge Fund Services (B.V.I.) Ltd., Bison Court, Columbus Centre, P.O. Box 3460, Road Town, Tortola, D8 British Virgin Islands.
- (4) This information is based solely on Schedule 13G filed on September 18, 2009 by Delphi Ventures VIII, L.P. ("DV VIII") and related persons. Includes 1,869,650 shares of common stock and warrants, which are exercisable within 60 days of January 31, 2010, to purchase 1,776,168 shares of common stock held by DV VIII and 18,256 shares of common stock and warrants, which are exercisable within 60 days of January 31, 2010, to purchase 17,343 shares of common stock held by Delphi BioInvestments VII, L.P. ("DBI VIII"). DV VIII, DBI VIII and Delphi Management Partners VIII, L.L.C. ("DMP VIII"), which is the general partner of both DV VIII and DBI VIII, and James J. Bochnowski ("Bochnowski"), David L. Douglass ("Douglass"), John F. Maroney ("Maroney"), Douglas A. Roeder ("Roeder") and Deepika R. Pakianathan, Ph.D. ("Pakianathan"), the managing members of DMP VIII, all may be deemed to shared voting power and dispositive power over the shares of common stock and warrants held by DV VIII and DBI VIII. Additionally,

as the general partner of both DV VIII and DBI VIII, DMP VIII may be deemed to have sole voting power and dispositive power over the shares of common stock and warrants held by DV VIII and DBI VIII. DMP VIII and its managing members, Bochnowski, Douglass, Roeder, and Pakianathan disclaim beneficial ownership of the reported securities held by DV VIII and DBI VIII except to the extent of any pecuniary interest therein. The address for DV VIII and related persons is c/o Delphi Ventures, 3000 Sand Hill Road, #1-135, Menlo Park, CA 94025.

- (5) This information is based solely on Schedule 13G filed on January 15, 2010 by Growth Equity Opportunities Fund, LLC ("GEO") and related persons. Includes 1,887,906 shares of common stock and warrants, which are exercisable within 60 days of January 31, 2010, to purchase 1,793,511 shares of common stock held by GEO. GEO, New Enterprise Associates 12, Limited Partnership ("NEA 12"), which is the sole member of GEO, NEA Partners 12, Limited Partnership ("NEA Partners 12"), which is the general partner of NEA 12, NEA 12 GP, LLC ("NEA 12 GP"), which is the general partner of NEA Partners 12, all share voting power and dispositive power over the shares of common stock and warrants held by GEO. Additionally, the individual managers of NEA 12 GP are Michael James Barrett ("Barrett"), Peter J. Barris ("Barris"), Forest Baskett ("Baskett"), Ryan D. Drant ("Drant"), Patrick J. Kerins ("Kerins"), Krishna S. Kolluri ("Kolluri"), C. Richard Kramlich ("Kramlich"), Charles M. Linehan ("Linehan"), Charles W. Newhall III ("Newhall"), Mark W. Perry ("Perry"), Scott D. Sandell ("Sandell") and Eugene A. Trainor III ("Trainor") (collectively, the "Managers"), and also share voting power and dispositive power over the shares of common stock and warrants held by GEO. Each reporting person set forth above disclaims beneficial ownership of such shares of common stock except for the shares, if any, such reporting person holds of record. The address of GEO, NEA 12, NEA Partners 12, NEA 12 GP, Newhall and Trainor is New Enterprise Associates, 1954 Greenspring Drive, Suite 600, Timonium, MD 21093. The address of Baskett, Kolluri, Kramlich, Linehan, Perry and Sandell is New Enterprise Associates, 2855 Sand Hill Road, Menlo Park, California 94025. The address of the principal business office of Barrett, Barris, Drant and Kerins is New Enterprise Associates, 5425 Wisconsin Avenue, Suite 800, Chevy Chase, MD 20815.
- (6) This information is based solely on Amendment No. 1 to Schedule 13G filed on February 14, 2011 by Great Point Partners, LLC ("Great Point") and related persons. Consists of warrants, which are exercisable within 60 days of January 31, 2011, to purchase 820,690 shares of common stock held by Biomedical Value Fund, L.P. ("BVF") and 533,569 shares of common stock held by Biomedical Offshore Value Fund, Ltd. ("BOVF") and 215,062 shares of common stock held by Biomedical Institutional Value Fund, L.P. ("BIVF") Great Point is the investment manager of BVF, BOVF and BIVF and may be deemed to share voting power and dispositive power with respect to the shares of common stock and warrants held by BVF, BOVF and BIVF. Additionally, each of Dr. Jeffrey R. Jay, M.D. ("Dr. Jay"), as senior managing member of Great Point, and Mr. David Kroin ("Mr. Kroin"), as special managing member of Great Point, may be deemed to share voting power and dispositive power with respect to the shares of common stock and warrants held by BVF, BOVF, BIVF. Great Point, Dr. Jay and Mr. Kroin disclaim beneficial ownership of the shares of common stock and warrants held by BVF, BOVF and BIVF, except to the extent of their respective pecuniary interests. The address for Great Point and related persons is 165 Mason Street, 3rd Floor, Greenwich, CT 06830.
- (7) This information is based solely on Schedule 13G filed on February 9, 2011 by GRT Capital Partners, LLC and related persons. Includes 1,357,425 shares of common stock held by GRT Capital Partners LLC ("GRTCP"), 1,091,615 shares of common stock held by GRT Health Care GP, LLC ("GRTHCGP"), 1,091,615 shares of common stock held by GRT Health Care, L.P. ("GRTHC") which are exercisable within 60 days of January 31,2011. GRTCP, GRTHCGP and GRTHC disclaim beneficial ownership over the securities reported herein except to the extent of their respective pecuniary interest therein. The address of GRTCP, GRTHCGP, GRTHC is 50 Milk Street, Floor 21, Boston, MA 02109.

(8) This information is based solely on Amendment No. 5 to Schedule 13D filed on May 3, 2010 by Andre Danesh and related persons. Includes 150,000 shares of common stock held directly by the Andre Danesh 1997 IRRV (the "A.D. Trust") and 1,693,928 shares of common stock held directly by E&S Investments ("E&S"). Andre Danesh has shared voting power and shared dispositive power with respect to all of these shares of common stock, but otherwise disclaims beneficial ownership. The address of Andre Danesh, the A.D. Trust and E&S is Allied Financial Corp. P.O. Box 1271, Brookline, MA 02446.

## **EQUITY COMPENSATION PLAN INFORMATION**

The following table sets forth information as of December 31, 2010 regarding the number of securities to be issued upon exercise, and the weighted average exercise price of outstanding options, warrants, and rights under our equity compensation plans and the number of securities available for future issuance under our equity compensation plans.

#### **Equity Compensation Plan Information as of December 31, 2010**

	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	e	Veighted average exercise price of outstanding ptions, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column a)
Equity compensation plans approved by security				
holders(1)	2,897,214	\$	5.93	1,099,206(2)
Equity compensation plans not approved by security				
holders(3)	300,000		1.94	200,000
Totals	3,197,214	\$	5.56	1,299,206

- (1) Includes information related to our Amended and Restated 1996 Stock Option/Restricted Stock Plan, Amended and Restated 1998 Equity Incentive Plan, Third Amended and Restated 2004 Stock Option and Incentive Plan, and 2010 Employee Stock Purchase Plan.
- (2) As of December 31, 2010, there were 1,099,206 shares available for future grant under the Third Amended and Restated 2004 Stock Option and Incentive Plan and 184,760 shares available under the 2010 Employee Stock Purchase Plan. No new stock grants or awards will be made under the Amended and Restated 1996 Stock Option/Restricted Stock Plan or the Amended and Restated 1998 Equity Incentive Plan.
- (3) Includes information related to our 2009 Non-Qualified Inducement Stock Plan, which is designed to provide equity grants to new employees.

# ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

#### TRANSACTIONS WITH RELATED PERSONS

Mr. Surgenor is a director of NeuroMetrix and was formerly the President and Chief Executive Officer and a director of Cyberkinetics Neurotechnology Systems, Inc. ("Cyberkinetics"). In November 2007, we made an investment of \$2.5 million in shares of Cyberkinetics common stock, agreed to negotiate the terms of a joint venture with Cyberkinetics and received a warrant to purchase an additional \$1.25 million of Cyberkinetics common stock. We would have been required to exercise the warrant if Cyberkinetics received FDA approval of a Humanitarian Device Exemption filing for the Andara OFS device for acute spinal cord injuries by December 31, 2008, which they did not. In February 2008, we formed PNIR (Peripheral Nerve Injury Repair) LLC, a joint venture with initial ownership of 50% by us and 50% by Cyberkinetics, and entered into a Collaboration Agreement and Operating Agreement with Cyberkinetics. The focus of the joint venture was on the development and commercialization of a product for the treatment of peripheral nerve injury using the Andara<sup>TM</sup> OFS<sup>TM</sup> (Oscillating Frequency Stimulation) technology (the "Andara Technology") licensed by Cyberkinetics from Purdue University and using other technologies to be developed. Under the terms of our joint venture agreement with Cyberkinetics, we agreed to fund the first \$2.0 million of program costs under the joint venture and any required funding beyond the initial \$2.0 million was to be shared equally by us and Cyberkinetics. Cyberkinetics had agreed to contribute the Andara Technology and certain additional technology, know-how and intellectual property. During the fourth quarter of 2008, the joint venture with Cyberkinetics was dissolved, and in January 2009, we acquired certain technological and intellectual property assets from Cyberkinetics and Andara Life Science, Inc., a wholly-owned subsidiary of Cyberkinetics, for \$350,000 in cash. The acquired assets include all of Cyberkinetics' rights and regulatory filings for the Andara Technology, the rights to develop and commercialize a therapeutic product for peripheral nerve injury based on the Andara Technology, development and commercialization rights to certain derivatives of the pharmacological agent 4-aminopyridine that may be useful in the treatment of central and peripheral nervous system injury and disease, and certain other intellectual property and technology. During 2009, the Company paid Red Sky Partners, LLC, or Red Sky, a total of \$49,000 for various consulting services. Mr. Surgenor is a partner in Red Sky. There were no services provided by Red Sky to the Company during 2010 and no payments were made by the Company to Red Sky during 2010.

# Policy for Approval of Transactions with Related Persons

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

#### DIRECTOR INDEPENDENCE

Please see the "Board Matters and Corporate Governance" section of Item 10.

# ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

# **ACCOUNTING FEES**

Aggregate fees for professional services rendered by PricewaterhouseCoopers LLP for the years ended December 31, 2010 and 2009 are as follows:

### Audit Fees

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

The audit fees for PricewaterhouseCoopers LLP for professional services rendered for the 2009 audit of our annual financial statements and the review of the financial statements included in our quarterly reports on Form 10-Q totaled \$478,455, of which \$327,500 was billed in 2009 and \$150,955 was billed in 2010.

# Audit-Related Fees

There were no audit related fees for PricewaterhouseCoopers LLP in 2010 and 2009.

# All Other Fees

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

Fees for PricewaterhouseCoopers LLP for services other than audit-related services were \$28,000 for 2009 and included fees of \$21,500 in connection with our Corporate Integrity Agreement with the Office of Inspector General of the United States Department of Health and Human Services regarding the previously-disclosed investigation into certain of our past sales and marketing practices relating to our NC-stat System, \$5,000 for the review of the Proxy Statement, and \$1,500 for a software subscription used to review new accounting pronouncements.

# Pre-Approval Policies and Procedures

The Audit Committee approved all audit and non-audit services provided to us by PricewaterhouseCoopers LLP during the 2010 and 2009 fiscal years.

# **PART IV**

# ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULE

# (a) 1. Financial Statements

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

2. Financial Statement Schedule

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

# 3. Exhibit Index

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

10.6.1+ Third Amended and Restated 2004 Stock Option and Incentive Plan(13)

Exhibit Number	Description
2.1	Asset Purchase Agreement dated November 7, 2008 by and between NeuroMetrix, Inc. and Advanced Diagnostics, LLC(10)
3.1	Third Amended and Restated Certificate of Incorporation of NeuroMetrix, Inc.(8)
3.2	Certificate of Designations for Series A Junior Cumulative Preferred Stock, par value \$0.001 per share(6)
3.3	Second Amended and Restated By-laws of NeuroMetrix, Inc.(8)
3.4	Amendment No. 1 to Second Amended and Restated Bylaws of NeuroMetrix, Inc.(4)
4.1	Specimen Certificate for Shares of Common Stock(1)
4.2.1	Shareholder Rights Agreement, dated as of March 7, 2007, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent(6)
4.2.2	Amendment to Shareholder Rights Agreement, dated September 8, 2009, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent(14)
4.3	Form of Common Stock Purchase Warrant(14)
4.4	Form of First Addendum to Common Stock Purchase Warrant issued to investors pursuant to Securities Purchase Agreements dated September 8, 2009(16)
10.1.1	Lease Agreement, dated October 18, 2000, between Fourth Avenue LLC and NeuroMetrix, Inc.(1)
10.1.2	Amendment Number One to Lease, dated February 22, 2008, between Fourth Avenue LLC and NeuroMetrix, Inc.(19)
10.3+	Amended and Restated 1996 Stock Option/Restricted Stock Plan(1)
10.4.1+	Amended and Restated 1998 Equity Incentive Plan(1)
10.4.3+	Second Amendment to Amended and Restated 1998 Equity Incentive Plan(1)
10.5+	Second Amended and Restated 2004 Stock Option and Incentive Plan(11)

Exhibit Number	Description
10.6.2+	Form of Restricted Stock Agreement pursuant to the Third Amended and Restated 2004 Stock Option and Incentive Plan(20)
10.7+	2010 Employee Stock Purchase Plan(22)
10.8+	Form of Indemnification Agreement between NeuroMetrix, Inc. and each of its directors(1)
10.9.1+	Employment Agreement, dated June 21, 2004, by and between NeuroMetrix, Inc. and Shai N. Gozani, M.D., Ph.D.(1)
10.9.2+	First Amendment to Employment Agreement dated December 31, 2008, by and between NeuroMetrix, Inc. and Shai N. Gozani, M.D., Ph.D.(12)
10.9.3+	Indemnification Agreement dated June 21, 2004, by and between Shai N. Gozani, M.D., Ph.D., and NeuroMetrix, Inc.(1)
10.9.4+	NeuroMetrix, Inc. Non-Statutory Stock Option Agreement (pursuant to the Amended and Restated 1998 Equity Incentive Plan), dated as of June 21, 2004, by and between Shai N. Gozani M.D., Ph.D., and NeuroMetrix, Inc.(1)
10.10.1+	Letter Agreement, dated February 5, 2008 between NeuroMetrix, Inc. and Michael Williams, Ph.D.(18)
10.10.2+	First Amendment to Letter Agreement, dated December 31, 2008, between NeuroMetrix, Inc. and Michael Williams, Ph.D.(12)
10.11.1+	Letter Agreement, dated February 5, 2008, between NeuroMetrix, Inc. and Guy Daniello(18)
10.11.2+	First Amendment to Letter Agreement, dated December 31, 2008, between NeuroMetrix, Inc. and Guy Daniello(12)
10.12.1+	Letter Agreement, dated August 31, 2009, between NeuroMetrix, Inc. and Thomas T. Higgins(15)
10.12.2+	Indemnification Agreement, dated September 10, 2009, by and between NeuroMetrix, Inc. and Thomas T. Higgins(15)
10.13.1+	Letter Agreement, dated April 30, 2009, between NeuroMetrix, Inc. and Walter Christensen(21)
10.13.2+	Indemnification Agreement, dated May 4, 2009, by and between NeuroMetrix, Inc. and Walter Christensen(21)
10.14.1+	Letter Agreement, dated January 20, 2010, between NeuroMetrix, Inc. and Krishnamurthy Balachandran(20)
10.14.2+	Indemnification Agreement, dated April 19, 2010, by and between NeuroMetrix, Inc. and Krishnamurthy Balachandran(20)
10.15+	Separation Agreement, dated May 1, 2008, between NeuroMetrix, Inc. and Gary L. Gregory(9)
10.16	Form of Securities Purchase Agreement, dated September 8, 2009 between the Company and each investor(14)
10.17†	Manufacturing and Supply Agreement, dated as of August 2, 2006, by and between Parlex Polymer Flexible Circuits, Inc. and NeuroMetrix, Inc.(2)

(1)

(2)

Exhibit Description Number Deferred Prosecution Agreement dated February 5, 2009 by and between NeuroMetrix, Inc. and the United States Attorney's Office for the District 10.18 of Massachusetts(7) Settlement Agreement and Release dated February 9, 2009 by and among NeuroMetrix, Inc. and the United States of America acting through the 10.19 United States Attorney's Office for the District of Massachusetts and the Office of Inspector General of the United States Department of Health and Human Services(7) 20.1 Notice of Proposed Settlement of Shareholder Derivative Action, dated December 21, 2009(17) 20.2 Stipulation of Settlement of Shareholder Derivative Action, dated December 21, 2009(17) \*23.1 Consent of PricewaterhouseCoopers LLP, an independent registered public accounting firm \*31.1 Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 \*31.2 Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 \*32 Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 Filed herewith. Indicates management contract or any compensatory plan, contract or arrangement. Portions of this Exhibit were omitted and have been filed separately with the Secretary of the SEC pursuant to the Registrant's application requesting confidential treatment thereof. Incorporated herein by reference to NeuroMetrix, Inc.'s Registration Statement on Form S-1 filed on May 13, 2004, as amended (Registration No. 333-115440). Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on August 2, 2006 (File No. 000-50856). Confidential treatment has been granted with respect to certain portions of this Exhibit, which portions have been omitted and filed separately with the Securities and Exchange Commission as part of an application for confidential treatment pursuant to the Securities Exchange Act of 1934, as amended. Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on March 8, 2007 (File No. 001-33351). Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on September 17, 2007 (File No. 001-33351).

- (4)
- (5) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on December 28, 2007 (File No. 001-33351).
- (6)Incorporated herein by reference to NeuroMetrix, Inc.'s Form 8-A12(b) filed on March 8, 2007 (File No. 001-33351).
- (7) Incorporated hereby by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on February 10, 2009 (File No. 001-33351).
- (8) Incorporated herein by reference to NeuroMetrix, Inc.'s Registration Statement on Form S-8 filed on August 9, 2004 (File No. 333-118059).

- (9) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on May 2, 2008 (File No. 001-33351).
- (10) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on November 26, 2008 (File No. 001-33351).
- (11) Incorporated herein by reference to Appendix A to NeuroMetrix, Inc.'s Proxy Statement on Schedule 14A filed on April 25, 2008 (File No. 001-33351).
- (12) Incorporated herein by reference to NeuroMetrix, Inc.'s Annual Report on Form 10-K filed on March 20, 2009 (File No. 001-33351).
- (13) Incorporated herein by reference to Appendix A to NeuroMetrix, Inc.'s Proxy Statement on Schedule 14A filed on April 24, 2009 (File No. 001-33351).
- (14) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed September 14, 2009 (File No. 001-33351).
- (15) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed September 15, 2009 (File No. 001-33351).
- (16) Incorporated herein by reference to NeuroMetrix, Inc.'s Quarterly Report on Form 10-Q filed November 12, 2009 (File No. 001-33351).
- (17) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed December 31, 2009 (File No. 001-33351).
- (18) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on February 6, 2008 (File No. 001-33351).
- (19) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on February 27, 2008 (File No. 001-33351).
- (20) Incorporated herein by reference to NeuroMetrix, Inc.'s Quarterly Report on Form 10-Q filed on May 14, 2010 (File No. 001-33351).
- (21) Incorporated herein by reference to NeuroMetrix, Inc.'s Annual Report on Form 10-K filed on March 12, 2010 (File No. 001-33351).
- (22) Incorporated herein by reference to Appendix A to NeuroMetrix, Inc.'s Proxy Statement on Schedule 14A filed on April 8, 2010.

# **SIGNATURES**

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

NEUROMETRIX, INC.

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

Title

Date: March 7, 2011

Name

Chairman, President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant on March 7, 2011 in the capacities indicated below.

/s/ SHAI N. GOZANI, M.D., PH.D.	Chairman, President and Chief Executive Officer
Shai N. Gozani, M.D., Ph.D.	(Principal Executive Officer)
/s/ THOMAS T. HIGGINS	Senior Vice President, Chief Financial Officer and Treasurer  (Principal Financial Officer and Principal Accounting
Thomas T. Higgins	Officer)
/s/ DAVID E. GOODMAN, M.D.	
David E. Goodman, M.D.	Director
/s/ ALLEN J. HINKLE, M.D.	
Allen J. Hinkle M.D.	Director
/s/ NANCY E. KATZ	_
Nancy E. Katz	Director
/s/ CHARLES R. LAMANTIA	
Charles R. LaMantia	Director
/s/ TIMOTHY R. SURGENOR	_
Timothy R. Surgenor	Director
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# INDEX TO FINANCIAL STATEMENTS

# NeuroMetrix, Inc.

# Years ended December 31, 2010, 2009, and 2008

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# Report of Independent Registered Public Accounting Firm

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

In our opinion, the accompanying balance sheets and the related statements of operations and comprehensive loss, of changes in stockholders' equity, and of cash flows present fairly, in all material respects, the financial position of NeuroMetrix, Inc. at December 31, 2010 and December 31, 2009, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2010 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the accompanying index presents fairly, in all material respects, the information set forth therein when read in conjunction with the related financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts March 7, 2011

# **Balance Sheets**

Total current assets       21,677,193       38,855,8         Restricted cash       408,000       408,00         Fixed assets, net       731,975       906,6         Intangible assets, net       210,000       280,0         Deferred costs and other long-term assets       39,261       116,0         Total assets       \$ 23,066,429       \$ 40,566,5		December 31,			31,
Current assets:         Cash and cash equivalents       \$ 16,986,809       \$ 22,937,4         Short-term investments       -       7,495,0         Accounts receivable, net of allowances of \$405,965 and \$514,362 at December 31, 2010       1,592,564       3,326,3         Inventories       2,412,805       4,559,6         Prepaid expenses and other current assets       603,821       404,7         Current portion of deferred costs       81,194       132,7         Total current assets       21,677,193       38,855,8         Restricted cash       408,000       408,00         Fixed assets, net       731,975       906,6         Intangible assets, net       210,000       280,0         Deferred costs and other long-term assets       39,261       116,0         Total assets       \$ 23,066,429       \$ 40,566,5		_	2010	_	2009
Cash and cash equivalents       \$ 16,986,809       \$ 22,937,4         Short-term investments       -       7,495,0         Accounts receivable, net of allowances of \$405,965 and \$514,362 at December 31, 2010       1,592,564       3,326,3         Inventories       2,412,805       4,559,6         Prepaid expenses and other current assets       603,821       404,7         Current portion of deferred costs       81,194       132,7         Total current assets       21,677,193       38,855,8         Restricted cash       408,000       408,00         Fixed assets, net       731,975       906,6         Intangible assets, net       210,000       280,0         Deferred costs and other long-term assets       39,261       116,0         Total assets       \$ 23,066,429       \$ 40,566,5					
Short-term investments       —       7,495,0         Accounts receivable, net of allowances of \$405,965 and \$514,362 at December 31, 2010       1,592,564       3,326,3         Inventories       2,412,805       4,559,6         Prepaid expenses and other current assets       603,821       404,7         Current portion of deferred costs       81,194       132,7         Total current assets       21,677,193       38,855,8         Restricted cash       408,000       408,0         Fixed assets, net       731,975       906,6         Intangible assets, net       210,000       280,0         Deferred costs and other long-term assets       39,261       116,0         Total assets       \$23,066,429       \$40,566,5		Φ.	16.006.000	Φ.	22.025 44.0
Accounts receivable, net of allowances of \$405,965 and \$514,362 at December 31, 2010 and 2009, respectively       1,592,564       3,326,3         Inventories       2,412,805       4,559,6         Prepaid expenses and other current assets       603,821       404,7         Current portion of deferred costs       81,194       132,7         Total current assets       21,677,193       38,855,8         Restricted cash       408,000       408,0         Fixed assets, net       731,975       906,6         Intangible assets, net       210,000       280,0         Deferred costs and other long-term assets       39,261       116,0         Total assets       \$23,066,429       \$40,566,5	<del>-</del>	\$	16,986,809	\$	
and 2009, respectively       1,592,564       3,326,3         Inventories       2,412,805       4,559,6         Prepaid expenses and other current assets       603,821       404,7         Current portion of deferred costs       81,194       132,7         Total current assets       21,677,193       38,855,8         Restricted cash       408,000       408,0         Fixed assets, net       731,975       906,6         Intangible assets, net       210,000       280,0         Deferred costs and other long-term assets       39,261       116,0         Total assets       \$23,066,429       \$40,566,5			_		7,495,000
Inventories       2,412,805       4,559,6         Prepaid expenses and other current assets       603,821       404,7         Current portion of deferred costs       81,194       132,7         Total current assets       21,677,193       38,855,8         Restricted cash       408,000       408,0         Fixed assets, net       731,975       906,6         Intangible assets, net       210,000       280,0         Deferred costs and other long-term assets       39,261       116,0         Total assets       \$23,066,429       \$40,566,5			4 =00 =64		0.000.004
Prepaid expenses and other current assets       603,821       404,7         Current portion of deferred costs       81,194       132,7         Total current assets       21,677,193       38,855,8         Restricted cash       408,000       408,00         Fixed assets, net       731,975       906,6         Intangible assets, net       210,000       280,0         Deferred costs and other long-term assets       39,261       116,0         Total assets       \$23,066,429       \$40,566,5	, I 3				
Current portion of deferred costs       81,194       132,7         Total current assets       21,677,193       38,855,8         Restricted cash       408,000       408,0         Fixed assets, net       731,975       906,6         Intangible assets, net       210,000       280,0         Deferred costs and other long-term assets       39,261       116,0         Total assets       \$23,066,429       \$40,566,5			, ,		, ,
Total current assets       21,677,193       38,855,8         Restricted cash       408,000       408,0         Fixed assets, net       731,975       906,6         Intangible assets, net       210,000       280,0         Deferred costs and other long-term assets       39,261       116,0         Total assets       \$ 23,066,429       \$ 40,566,5			, -		,
Restricted cash       408,000       408,00         Fixed assets, net       731,975       906,6         Intangible assets, net       210,000       280,0         Deferred costs and other long-term assets       39,261       116,0         Total assets       \$ 23,066,429       \$ 40,566,5	•			_	132,774
Fixed assets, net       731,975       906,6         Intangible assets, net       210,000       280,0         Deferred costs and other long-term assets       39,261       116,0         Total assets       \$ 23,066,429       \$ 40,566,5					38,855,838
Intangible assets, net       210,000       280,0         Deferred costs and other long-term assets       39,261       116,0         Total assets       \$ 23,066,429       \$ 40,566,5			,		408,000
Deferred costs and other long-term assets         39,261         116,0           Total assets         \$ 23,066,429         \$ 40,566,5					906,625
Total assets \$ 23,066,429 \$ 40,566,5	· ·		,		280,000
	Deferred costs and other long-term assets		39,261		116,057
	Total assets	\$	23,066,429	\$	40,566,520
Liabilities and Stockholders' Equity	iabilities and Stockholders' Equity				
Current liabilities:	Current liabilities:				
		\$	259,155	\$	1,086,946
			683,049		1,369,257
			1,227,790		1,295,577
Current portion of deferred revenue 468,324 699,7	Current portion of deferred revenue		468,324		699,775
Current portion of capital lease obligation 19,093 30,3	Current portion of capital lease obligation		19,093		30,357
Total current liabilities 2,657,411 4,481,9	Total current liabilities		2,657,411		4,481,912
Deferred revenue, net of current portion 171,797 341,5	Deferred revenue, net of current portion		171,797		341,513
	Capital lease obligation, net of current portion				33,224
Total liabilities 2,867,457 4,856,6	Total liabilities		2,867,457		4,856,649
Commitments and contingencies (Note 12)	Commitments and contingencies (Note 12)				
Stockholders' equity	tockholders' equity				
Preferred stock, \$0.001 par value, 5,000,000 shares authorized, none outstanding	Preferred stock, \$0.001 par value, 5,000,000 shares authorized, none outstanding				_
Common stock, \$0.0001 par value; 50,000,000 authorized; 23,197,537 and 22,969,670	Common stock, \$0.0001 par value; 50,000,000 authorized; 23,197,537 and 22,969,670				
shares issued and outstanding at December 31, 2010 and 2009, respectively 2,320 2,2	shares issued and outstanding at December 31, 2010 and 2009, respectively		2,320		2,297
			138,800,937		137,420,711
Accumulated deficit (118,604,285) (101,713,1	Accumulated deficit		(118,604,285)		(101,713,137)
Total stockholders' equity 20,198,972 35,709,8	Total stockholders' equity	_	20,198,972		35,709,871
Total liabilities and stockholders' equity \$ 23,066,429 \$ 40,566,5	otal liabilities and stockholders' equity	\$	23,066,429	\$	40,566,520

# **Statements of Operations and Comprehensive Loss**

	Years Ended December 31,					
D.	_	2010	_	2009	_	2008
Revenues:	ф	2.454.250	ф	0.510.445	ф	2 500 101
Medical equipment	\$	2,151,258	<b>Þ</b>	2,713,445	<b>Þ</b>	2,709,104
Consumables	_	11,748,412	_	23,423,581	_	28,411,696
Total revenues		13,899,670		26,137,026		31,120,800
Cost of revenues		7,050,209		7,535,616		9,011,941
Gross margin		6,849,461		18,601,410		22,108,859
Operating expenses:						
Research and development		5,855,353		5,611,296		5,589,221
Sales and marketing		11,072,172		10,840,340		14,646,958
General and administrative		7,231,875		9,119,001		12,016,158
Goodwill impairment		_		_		5,833,464
Legal settlement		_		_		3,705,866
Intangible asset impairment		_		_		1,767,500
Gain from deconsolidation of joint venture		_		_		(2,100,000)
Total operating expenses		24,159,400		25,570,637		41,459,167
Loss from operations		(17,309,939)		(6,969,227)		(19,350,308)
Loss on available-for-sale investment		_		_		(2,500,000)
Interest and other income		298,301		226,863		720,932
Warrants fair value adjustment		_		(5,175,136)		_
Loss from continuing operations		(17,011,638)		(11,917,500)		(21,129,376)
Loss from discontinued operations		_		_		(6,600,673)
Net loss before taxes		(17,011,638)		(11,917,500)		(27,730,049)
Income tax benefit		120,490		_		_
Net loss	\$	(16,891,148)	\$	(11,917,500)	\$	(27,730,049)
Loss per common share from continuing operations:	_				_	
Basic	\$	(0.73)	\$	(0.71)	\$	(1.54)
Diluted	\$	(0.73)	\$	(0.71)	\$	(1.54)
Loss per common share from discontinued operations:						
Basic	\$	_	\$	_	\$	(0.48)
Diluted	\$	_	\$	_	\$	(0.48)
Net loss per common share:						
Basic	\$	(0.73)	\$	(0.71)	\$	(2.02)
Diluted	\$	(0.73)	\$	(0.71)	\$	(2.02)
Weighted average shares used to compute net loss per common share:						
Basic		23,025,493		16,783,837		13,733,733
Diluted		23,025,493		16,783,837		13,733,733
Comprehensive loss:						
Net loss	\$	(16,891,148)	\$	(11,917,500)	\$	(27,730,049)
Reclassification adjustment for recognized loss included in net loss		_				1,441,745
Comprehensive loss	\$	(16,891,148)	\$	(11,917,500)	\$	(26,288,304)

# Statements of Changes in Stockholders' Equity

	Common	Stock	Additional		Accumulated Other	
	Number of Shares	Amount	Paid-In Capital	Accumulated Deficit	Comprehensive Items	Total
Balance at December 31, 2007	13,690,134	\$ 1,369	\$ 110,235,835	\$ (62,065,588)	\$ (1,441,745)	\$ 46,729,871
Issuance of stock from stock option plans	4,113	_	5,404	_	_	5,404
Stock-based compensation expense	_	_	2,228,839	_	_	2,228,839
Issuance of common stock under employee stock						
purchase plan	164,550	17	156,724	_	_	156,741
Realized loss on available-for-sale investment					1,441,745	1,441,745
Net loss	_	_	_	(27,730,049)	_	(27,730,049)
Balance at December 31, 2008	13,858,797	1,386	112,626,802	(89,795,637)		22,832,551
Stock issued in private placement	8,816,521	882	17,217,139	`	_	17,218,021
Issuance of stock from stock option plans	12,436	1	23,670	_	_	23,671
Stock-based compensation expense	_	_	2,035,335	_	_	2,035,335
Issuance of common stock under employee stock						
purchase plan	122,009	12	80,513	_	_	80,525
Other issuances of stock from our option plan	109,907	11	164,621	_	_	164,632
Issuance of stock to consultants	50,000	5	97,495	_	_	97,500
Warrants fair value adjustment	_	_	5,175,136	_	_	5,175,136
Net loss	_	_	_	(11,917,500)	_	(11,917,500)
Balance at December 31, 2009	22,969,670	2,297	137,420,711	(101,713,137)		35,709,871
Issuance of stock from stock option plans	5,868	1	10,272			10,273
Stock-based compensation expense	_	_	1,184,570	_	_	1,184,570
Issuance of common stock under employee stock						
purchase plan	116,772	12	162,551	_	_	162,563
Other issuances of stock from our option plan	105,227	10	22,833	_	_	22,843
Net loss	_	_	_	(16,891,148)	_	(16,891,148)
Balance at December 31, 2010	23,197,537	\$ 2,320	\$ 138,800,937	\$ (118,604,285)	<u> </u>	\$ 20,198,972

# **Statements of Cash Flows**

	Years Ended December 31,		
	2010	2009	2008
Cash flows for operating activities: Net loss	¢ (16 001 140)	¢ (11 017 E00)	¢ (27 720 040)
Adjustments to reconcile net loss to net cash used in operating activities:	\$ (10,891,148)	\$ (11,917,500)	φ (2/,/30,049)
Depreciation and amortization	523,756	578,666	1,593,467
Stock-based compensation Inventory charges	1,184,570 2,075,494	2,132,835 363,902	2,228,839
Accretion of discount on investments	2,073,494	303,902	(38,158)
Loss on available-for-sale investment	_	_	2,500,000
Goodwill impairment			5,833,464
Charge for legal settlement	_		3,705,866
Intangible assets impairment			4,147,500
Assets impairment relating to discontinued operations	<u>_</u>	<u> </u>	2,227,104
Gain from deconsolidation of joint venture	<u></u>	<u></u>	(2,100,000)
Gain on disposal of fixed assets	<u> </u>	<u> </u>	(20,000)
Warrants fair value adjustment	_	5,175,136	(20,000)
Changes in operating assets and liabilities:		3,173,133	
Accounts receivable	1,733,767	103,123	2,136,600
Inventories	71,308	683,298	(252,469)
Prepaid expenses and other current assets	(199,105)	(90,921)	(171,399)
Accounts payable	(827,791)	885,671	(2,426,614)
Legal settlement		(3,705,866)	_
Accrued expenses and compensation	(753,995)	(120,035)	(1,485,596)
Deferred revenue, deferred costs, and other	(223,970)	(225,396)	(837,018)
Net cash used in operating activities	(13,307,114)	(6,137,087)	(10,688,463)
Cash flows for investing activities:	, , , ,	(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	( , , , ,
Purchases of investments	_	(7,495,000)	(8,545,598)
Maturities of investments	7,495,000	7,495,000	23,710,497
Purchases of fixed assets	(306,451)	(342,115)	(509,872)
Purchase of technological and intellectual property		(350,000)	
Release of restricted cash	_	<u> </u>	1,095,598
Net cash provided by (used in) investing activities	7,188,549	(692,115)	15,750,625
Cash flows from financing activities:		( , ,	, ,
Net proceeds from issuance of common stock and warrants, including			
private placement and equity plans	195,679	17,486,849	162,145
Payments on capital lease	(27,715)	(22,521)	(19,262)
Net cash provided by financing activities	167,964	17,464,328	142,883
Net (decrease) increase in cash and cash equivalents	(5,950,601)	10,635,126	5,205,045
Cash and cash equivalents, beginning of year	22,937,410	12,302,284	7,097,239
	\$ 16,986,809	\$ 22,937,410	\$ 12,302,284
Cash and cash equivalents, end of year	\$ 10,900,009	Ψ 22,937,410	ψ 12,302,204
Supplemental disclosure of cash flow information:		_	
Equipment acquired under capital lease, net	\$ 60,410	\$ <u> </u>	\$ 89,244
Common stock issued to consultants	\$ —	\$ 97,500	\$ —
Warrants issued in Securities Purchase Agreement	\$ —	\$ 14,496,627	\$ —
	<u>-</u>		

#### **Notes to Financial Statements**

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

NeuroMetrix, Inc., or the Company, a Delaware corporation, was founded in June 1996. It is a science-based health care company transforming patient care through neurotechnology. The Company develops and markets innovative products for the detection, diagnosis, and monitoring of peripheral nerve and spinal cord disorders such as those associated with diabetes, carpal tunnel syndrome, lumbosacral disc disease, and spinal stenosis.

The Company's primary focus has shifted to diabetes, specifically detection and monitoring of diabetic neuropathy which is a common complication of the disease. The Company views diabetes as representing the largest and fastest growing opportunity for its proprietary technology. Neuropathy is a common and serious complication of the disease that may lead to foot ulcers and limb amputation. The Company has over a decade of experience in neuropathy detection and believes it is uniquely positioned to address the unmet need for a rapid, cost-effective, objective test for diabetic neuropathy. The Company is working towards a mid-2011 launch of NC-stat SL, which is a modified version of its NC-stat device designed specifically for assessment of diabetic neuropathy at the point-of-care.

The Company's ADVANCETM NCS/EMG System, or the ADVANCE System, is a comprehensive platform for the performance of traditional nerve conduction studies and invasive electromyography procedures. The Company focuses its sales efforts for the ADVANCE System on physician offices and clinics. 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 the Company's servers for data archiving, report generation, and other network services. The Company sold a predecessor device, the NC-stat System, to a broad group of physicians from its initial market launch in May 1999 through September 2010. The Company's NC-stat System is a point-of-care device for the performance of nerve conduction studies. The Company does not intend to support the NC-stat System beyond 2011 and therefore it is transitioning its NC-stat customers to the ADVANCE System. The Company's neurodiagnostic equipment is used in over 3,800 physicians' offices, clinics, and hospitals. Over 1.5 million patient studies have been performed with its neurodiagnostic devices since 1999.

The Company believes that its current cash and cash equivalents, and the cash to be generated from expected product sales will be sufficient to meet its projected operating requirements into 2012. The Company is currently facing significant challenges and uncertainties and, as a result, the Company's available capital resources may be consumed more rapidly than currently expected due to (a) changes in future revenues; (b) changes the Company makes to its ongoing operating expenses; (c) changes in the Company's business strategy; (d) regulatory developments affecting the Company and its products; (e) changes the Company makes to research and development spending plans; (f) the outcome of the class action lawsuit against the Company; and (g) other items affecting the Company's forecasted level of expenditures and use of cash resources. Accordingly, the Company may need to raise additional funds to support its operating and capital needs. The Company may attempt to obtain additional funding through public or private financing, collaborative arrangements with strategic partners, or through additional credit lines or other debt financing sources to increase the funds available to fund its operations. However, the Company may not be able to secure such financing on favorable terms, if at all. Without additional funds, the Company may be forced to delay, scale back or eliminate some of its sales and marketing efforts, research and development activities, or other

# **Notes to Financial Statements (Continued)**

# 1. Description of Business and Basis of Presentation (Continued)

operations and potentially delay product development in an effort to provide sufficient funds to continue its operations.

# 2. Summary of Significant Accounting Policies

# Use of Estimates and Assumptions

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

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

# Cash and Cash Equivalents

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

# Held-to-Maturity Investments

Investments are classified as held-to-maturity, and such investments are stated at amortized cost. Interest earned on investments held-to-maturity is included in interest income. The amortized cost of investments held-to-maturity is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income. At December 31, 2009, the Company invested only in bank certificates of deposit that were fully insured by FDIC. The Company had no such investments at December 31, 2010.

# Long-Term Available-for-Sale Investment

The Company's investment in Cyberkinetics Neurotechnology Systems, Inc. ("Cyberkinetics") was classified as available-for-sale and was carried at fair value, with any unrealized gains and losses, net of taxes, reported in accumulated other comprehensive income, a separate component of stockholders' equity. The Company marked this investment to market as of December 31, 2008 and recorded a realized year to date loss of \$2.5 million because it believed the decline in the value of this investment was other-than-temporary. Accordingly, as of December 31, 2008 this investment was written down to zero.

# **Restricted Cash**

Long-term restricted cash of \$408,000 at December 31, 2010 and 2009 is associated with a facility lease (See Note 12—Commitments and Contingencies).

# **Notes to Financial Statements (Continued)**

# 2. Summary of Significant Accounting Policies (Continued)

# Concentrations of Credit Risk

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

Through December 31, 2010, the Company distributed its products through its direct sales force and independent sales representatives. After that date, the Company shifted distribution to independent sales representatives for new customer acquisition plus telemarketing by its customer service representatives for sales to its installed base of active accounts. At December 31, 2010 and 2009 and for the years ended December 31, 2010, 2009, and 2008, no single customer accounted for more than 10% of accounts receivable or revenue.

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

#### Inventories

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

#### Fair Value

The carrying amounts of the Company's financial instruments, which include cash equivalents, accounts receivable, accounts payable, and accrued expenses approximate their fair value at December 31, 2010 and 2009.

#### Revenue Recognition

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

When multiple elements are contained in a single arrangement, the Company allocates revenue between the elements based on their relative fair value, provided that each element meets the criteria for treatment as a separate unit of accounting. An element is considered a separate unit of accounting if it has value to the customer on a stand-alone basis, there is objective, reliable evidence of the fair value of the undelivered elements, and delivery or performance of the undelivered elements is considered probable and substantially in the control of the Company. Fair value is determined based upon the price charged when the element is sold separately.

Medical equipment revenues consist of the ADVANCE and NC-stat Systems, related modules, and extended service agreement revenues. Revenues associated with the sale of the ADVANCE and NC-stat devices are recognized upon shipment provided that the fee is fixed or determinable, evidence of a

# **Notes to Financial Statements (Continued)**

# 2. Summary of Significant Accounting Policies (Continued)

persuasive arrangement exists, collection of receivables is reasonably assured, product returns are reasonably estimable, and no continuing obligations exist. The revenues from the sale of an ADVANCE communication hub, as well as the NC-stat docking station together with access to NeuroMetrix information systems are considered one unit of accounting and deferred and recognized on a straight-line basis over the estimated period of time the Company provides the service associated with the information systems of three years. The resulting deferred revenue and deferred costs are presented as separate line items on the accompanying balance sheet. Revenues related to extended service agreements for the devices are recognized ratably over the term of the extended service agreement.

The Company's payment terms extended to customers with traditional payment terms generally require payment within 30 days from invoice date. In addition, from the fourth quarter of 2009 through July 2010, the Company offered extended payment terms of up to one year for new customers placing large dollar value orders for a combination of medical equipment and consumables. Typically these sales involved installment payments in 12 equal monthly amounts. Revenues were recognized upon shipment provided the selling price was fixed or determinable, persuasive evidence of an arrangement existed, delivery had occurred and risk of loss had passed, collection of the resulting receivables was reasonably assured, and product returns were reasonably estimable. In developing parameters for revenue recognition, the Company relied on its historical experience for similar arrangements. During 2010 and 2009, the Company recognized gross revenue of \$1.2 million and \$0.6 million, respectively, on sales with extended payment terms. As of December 31, 2010, accounts receivable, net included \$467,000, net of accounts under extended payment terms.

Consumables revenues consist of single use nerve specific electrodes, EMG needles, and other accessories. Consumables revenues are recognized upon shipment provided that the fee is fixed or determinable, persuasive evidence of an arrangement exists, collection of receivables is reasonably assured, and product returns are reasonably estimable.

Certain product sales are made with a 30-day right of return. Because the Company can reasonably estimate future returns, the Company recognizes revenues associated with product sales that contain a right of return upon shipment and at the same time reduces revenue and accounts receivable by the amount of estimated returns.

Proceeds received in advance of product shipment are recorded as deferred revenues.

# Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. Accounts receivable on the balance sheet are recorded net of the allowance for doubtful accounts receivable and the reserve for estimated returns. The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses in its existing accounts receivable. The Company reviews its allowance for doubtful accounts and determines the allowance based on an analysis of customer past payment history, product usage activity, and recent communications between the Company and the customer. Past due balances are reviewed individually for collectibility. Account balances are written-off against the allowance when the Company feels it is probable the receivable will not be recovered. The Company does not have any off-balance sheet credit exposure related to its customers.

# **Notes to Financial Statements (Continued)**

# 2. Summary of Significant Accounting Policies (Continued)

#### Income Taxes

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

Ownership changes, as defined in the Internal Revenue Code, have limited the amount of net operating loss carry-forwards that can be utilized annually to offset future taxable income. The Company anticipates that these limitations will have no material impact on its ability to utilize the affected loss carry-forwards in future years. Subsequent ownership changes could further impact the limitation in future years.

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

# Research and Development

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

# **Product Warranty Costs**

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

# **Notes to Financial Statements (Continued)**

# 2. Summary of Significant Accounting Policies (Continued)

The following is a rollforward of the Company's accrued warranty liability for the years ended December 31, 2010, 2009, and 2008:

	Years Ended December 31,				31,
	2010		2009		2008
Balance at beginning of period	\$ 48,355	\$	136,170	\$	251,948
Accrual for warranties	6,499		9,182		16,053
Settlements made	(9,848)		(96,997)		(131,831)
Balance at end of period	\$ 45,006	\$	48,355	\$	136,170

# Fixed Assets and Long-Lived Assets

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

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

# **Intangible Assets**

Intangible assets with estimable useful lives are amortized over their estimated useful lives to their estimated residual values, if any, and are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable.

Determining the economic lives of acquired intangible assets requires the Company to make significant judgments and estimates, and can materially impact the Company's operating results.

# Accounting for Stock-Based Compensation

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

# **Notes to Financial Statements (Continued)**

# 2. Summary of Significant Accounting Policies (Continued)

# Net Loss per Common Share

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

	Years	Years Ended December 31,				
	2010	2009	2008			
Options	3,206,832	3,065,700	2,248,929			
Warrants	8,375,694	2,615,970	_			
Total	11,582,526	5,681,670	2,248,929			

# Advertising and Promotional Costs

Advertising and promotional costs are expensed as incurred. Advertising and promotion expense was \$256,000, \$274,000, and \$475,000 in the years ended December 31, 2010, 2009, and 2008, respectively.

# Accumulated Other Comprehensive Items

In November 2007, the Company entered into a strategic alliance with Cyberkinetics, a medical device company focused on neurological conditions. The Company made an investment of \$2.5 million in shares of Cyberkinetics common stock and accounted for the investment as an available-for-sale security. During 2008, the Company recorded a realized loss of \$2.5 million on the investment in Cyberkinetics as a result of a change in fair market value and the determination that the loss was other-than-temporary. For the years ended December 31, 2010 and 2009, the Company had no components of other comprehensive income or loss other than net loss.

# Segments

The Company operates in one segment for the sale of medical equipment and consumables. Substantially all of the Company's assets, revenues, and expenses for the years ended December 31, 2010, 2009, and 2008 were located at or derived from operations in the United States. Revenues from sales outside the United States accounted for approximately 2% of total revenues in each of 2010 and 2009, and less than 1% of total revenues for the year ended December 31, 2008.

# **Notes to Financial Statements (Continued)**

# 2. Summary of Significant Accounting Policies (Continued)

# Risks and Uncertainties

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

The Company is developing a rapid, cost-effective, objective test for diabetic neuropathy. The Company is working toward a mid-2011 launch of NC-stat SL, which is a modified version of its NC-stat device designed specifically for assessment of diabetic neuropathy at the point of care. The future prospects of the Company are closely tied to its success with NC-stat SL which, in turn, depends upon successful and timely completion of the development process, market acceptance, and growth in future revenues.

# Reclassification

Certain prior year amounts have been reclassified to conform to the current year's presentation.

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

In September 2009, the Emerging Issues Task Force, or EITF, issued new rules pertaining to the accounting for revenue arrangements with multiple deliverables. The new rules provide an alternative method for establishing fair value of a deliverable when vendor specific objective evidence cannot be determined. The guidance provides for the determination of the best estimate of selling price to separate deliverables and allows the allocation of arrangement consideration using this relative selling price model. The guidance supersedes the prior multiple element revenue arrangement accounting rules that are currently used by the Company. The new guidance can be prospectively applied by the Company beginning January 1, 2011 or can be early or retrospectively adopted. The Company does not believe adoption will have a material effect on its financial statements.

In September 2009, the EITF issued new rules to exclude (a) non-software components of tangible products and (b) software components of tangible products that are sold, licensed, or leased with tangible products when the software components and non-software components of the tangible product function together to deliver the tangible product's essential functionally. The new guidance can be prospectively applied by the Company beginning January 1, 2011 or can be early or retrospectively adopted. The Company does not believe adoption will have a material effect on its financial statements.

In January 2010, the Financial Accounting Standards Board issued Accounting Standards Update No. 2010-06, "Fair Value Measurements and Disclosures (Topic 820)—Improving Disclosures about Fair Value Measurements" ("ASU 2010-06"). ASU 2010-06 requires new disclosures regarding significant transfers in and out of Levels 1 and 2, as well as information about activity in Level 3 fair value measurements, including presenting information about purchases, sales, issuances, and settlements on a gross versus a net basis in the Level 3 activity rollforward. In addition, ASU 2010-06 also clarifies existing disclosures regarding input and valuation techniques, as well as the level of disaggregation for each class of assets and liabilities. ASU No. 2010-06 is effective for interim and annual periods beginning after December 15, 2009, except for the disclosures pertaining to purchases, sales, issuances, and settlements in the roll forward of Level 3 activity, which are effective for interim and annual periods beginning after December 15, 2010. The adoption of ASU 2010-06 had no current impact and is expected to have no subsequent impact on the Company's financial statements.

# **Notes to Financial Statements (Continued)**

# 3. Stock-Based Compensation and Equity

# Stock-Based Compensation

During 2004, the Company adopted the 2004 Stock Option and Incentive Plan, as amended and restated in 2006 and 2008 (the "2004 Stock Plan"). The 2004 Stock Plan, among other things, provides for granting of incentive and nonqualified stock option and stock bonus awards to officers, employees and outside consultants. Outstanding options under the 2004 Stock Plan generally vest over three or four years and terminate 10 years after the grant date, or earlier if the option holder is no longer an executive officer, employee, consultant, advisor or director, as applicable, of the Company. As of December 31, 2010, 3,946,022 shares of common stock were authorized for issuance under the 2004 Stock Plan, of which 333,742 shares had been issued, 2,418,883 shares were subject to outstanding options at a weighted average exercise price of \$4.70 per share and 1,099,206 shares were available for future grant. In March 2006, the Company's Board of Directors voted to discontinue the provision of the 2004 Stock Plan which automatically increased the number of options available for grant under the 2004 Stock Plan based on the net increase in the total number of outstanding shares of common stock during the year.

During May 2009, the Company adopted the 2009 Non-Qualified Inducement Stock Plan (the "2009 Inducement Plan"). The 2009 Inducement Plan is intended to encourage and enable employees, including prospective employees, of the Company upon whose judgment, initiative, and efforts the Company largely depends for the successful conduct of its business to acquire a proprietary interest in the Company. The 2009 Inducement Plan, among other things, provides for the granting of awards, including non-qualified stock options, restricted stock, and unrestricted stock. As of December 31, 2010, 500,000 shares of common stock were authorized for issuance under the 2009 Inducement Plan, of which no shares had been issued, 300,000 shares were subject to outstanding options at a weighted average exercise price of \$1.94 per share, and 200,000 shares were available for future grant.

The exercise price of each stock option issued under the 1996 and 1998 Stock Plans was specified by the Board of Directors at the time of grant. The exercise price of stock options awarded under the 2004 Stock Plan and the 2009 Inducement Plan may not be less than the fair market value of the common stock on the date of the option grant. For holders of more than 10% of the Company's total combined voting power of all classes of stock, incentive stock options may not be granted at less than 110% of the fair market value of the Company's common stock at the date of grant and for a term not to exceed five years.

In June 2004, the Company adopted the 2004 Employee Stock Purchase Plan (the "2004 ESPP"). All of the Company's employees who had been employed by the Company for at least 60 days and whose customary employment is for more than 20 hours per week and for more than five months in any calendar year were eligible to participate and any employee who owned 5% or more of the voting power or value of the Company's stock was not eligible to participate. The 2004 ESPP authorized the issuance of up to a total of 375,000 shares of the Company's common stock to participating employees.

Under the 2004 ESPP, participating employees could authorize the Company to withhold up to 10% of their earnings during consecutive six-month payment periods for the purchase of the shares. At the conclusion of each period, participating employees could purchase shares at 85% of the lower of their fair market value at the beginning or end of the period. The 2004 ESPP was regarded as a compensatory plan in accordance with the provisions of the Compensation—Stock Compensation topic of the Codification. Under this plan, the Company issued 122,009 and 164,550 shares of its common

#### Notes to Financial Statements (Continued)

# 3. Stock-Based Compensation and Equity (Continued)

stock during the years ended December 31, 2009 and 2008, respectively. As of December 31, 2009, there were no remaining shares to be issued under the 2004 ESPP

In May 2010, the Company adopted the 2010 Employee Stock Purchase Plan (the "2010 ESPP"). The 2010 ESPP authorizes the issuance of up to a total of 250,000 shares of the Company's common stock to participating employees plus an annual increase on the first day of each of the Company's fiscal years beginning in 2011, equal to the lesser of (i) 250,000 shares, (ii) 1 percent of the shares of common stock outstanding on the last day of the immediately preceding fiscal year, or (iii) such lesser number of shares as is determined by the Board. All of the Company's full-time employees and certain part-time employees are eligible to participate in the 2010 ESPP. For part-time employees to be eligible, they must have customary employment of more than five months in any calendar year and more than 20 hours per week. Employees who, after exercising their rights to purchase shares under the 2010 ESPP, would own shares representing 5% or more of the voting power of the Company's common stock, are also ineligible to participate.

Under the 2010 ESPP, participating employees can authorize the Company to withhold up to 10% of their earnings during consecutive six-month payment periods for the purchase of the shares. At the conclusion of each period, participating employees can purchase shares at 85% of the lower of their fair market value at the beginning or end of the period. The 2010 ESPP is regarded as a compensatory plan in accordance with the provisions of the Compensation—Stock Compensation topic of the Codification. For the year ended December 31, 2010 the Company issued 65,240 shares of its common stock under the 2010 ESPP. As of December 31, 2010, there were 184,760 remaining shares to be issued under the 2010 ESPP.

The Company uses the Black-Scholes option pricing model for determining the fair value of shares of common stock issued or to be issued under the 2004 ESPP and 2010 ESPP. The following assumptions are used in determining fair value: The risk-free interest rate assumption is based on the United States Treasury's constant maturity rate for a six month term (corresponding to the expected option term) on the date the option was granted. The expected dividend yield is zero because the Company does not currently pay dividends nor expects to do so during the expected option term. An expected term of six months is used based on the duration of each plan offering period. The volatility assumption is based on stock price volatility over the most recent period of time corresponding to the expected term and is also based on expected future stock price volatility.

The weighted average grant-date fair value used in the calculation of stock-based compensation expense in the accompanying statement of operations for the years ended December 31, 2010, 2009, and 2008 is calculated using the following assumptions:

		Years Ended December 3	31,
	2010	2009	2008
Risk-free interest rate	1.0%-2.8%	1.6%-2.6%	1.3%-3.5%
Expected dividend yield	_	_	_
Expected option term	5 years	5 years	5 years
Volatility	70.0%	70.0%-120.0%	85.0%-120.0%

The risk-free interest rate assumption is based on the United States Treasury's constant maturity rate for a five year term (corresponding to the expected option term) on the date the option was

# **Notes to Financial Statements (Continued)**

# 3. Stock-Based Compensation and Equity (Continued)

granted. The expected dividend yield is zero as the Company does not currently pay dividends nor expects to do so during the expected option term. The expected option term of five years is estimated based on an analysis of actual option exercises and a review of comparable medical device companies. The volatility assumption is based on weekly historical volatility during the time period that corresponds to the expected option term, a review of comparable medical device companies and expected future stock price volatility. The pre-vesting forfeiture rate is based on the historical and projected average turnover rate of employees.

A summary of option activity for the year ended December 31, 2010 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	ggregate insic Value
Outstanding at December 31, 2009	3,278,880	\$ 5.30		
Granted	678,220	1.33		
Exercised	(5,868)	1.75		
Forfeited	(550,528)	3.04		
Expired	(203,490)	5.80		
Outstanding at December 31, 2010	3,197,214	4.82	6.5	\$ 30,060
Vested or expected to vest at December 31, 2010	3,045,545	4.99	6.4	24,447
Exercisable at December 31, 2010	1,842,518	7.14	5.6	1,138

Expected to vest options are determined by applying the pre-vesting forfeiture rate to the total outstanding options. Aggregate intrinsic value represents the total pre-tax intrinsic value (the aggregate difference between the closing stock price of the Company's common stock as of December 31, 2010, as applicable, and the exercise price for the in-the-money options) that would have been received by the option holders if all the in-the-money options had been exercised on December 31, 2010.

The weighted average grant-date fair values of options granted during the years ended December 31, 2010, 2009, and 2008 was \$0.79, \$1.45, and \$1.44, respectively.

The aggregate intrinsic value of options issued or exercised during the years ended December 31, 2010, 2009, and 2008 was \$3,000, \$11,000, and \$5,000, respectively.

Total unrecognized stock-based compensation costs related to non-vested stock options was \$1,355,151, which related to 1,448,887 shares with a per share weighted fair value of \$0.94 as of December 31, 2010. This unrecognized cost is expected to be recognized over a weighted average period of approximately 1.1 years.

Stock options granted to non-employees are recorded at fair value and adjusted to market over the vesting period in accordance with the provisions of Equity topic of the Codification. The Company determines fair value using the Black-Scholes option pricing model, an expected term equal to the option term, a risk-free interest rate corresponding to the expected term, an expected volatility of 70% and a dividend yield of zero.

#### Notes to Financial Statements (Continued)

# 3. Stock-Based Compensation and Equity (Continued)

Beginning in 2010, certain employees have been granted restricted stock. There was no issuance of restricted stock in 2009 and 2008. The fair value of restricted stock is calculated based on the closing sale price of our common stock on the date of issuance. No restricted shares vested during the years ended December 31, 2010, 2009, or 2008.

A summary of restricted stock activity for the year ended December 31, 2010 is presented below:

	Restricted Shares	Weighted Av Grant Date Value	
Unvested at December 31, 2009	_		
Granted	94,191	\$	1.35
Vested	_		
Canceled	_		
Unvested at December 31, 2010	94,191	\$	1.35

During 2010, certain employees received bonus payments in the form of common stock. A total of 11,036 such shares were issued with a total intrinsic value of \$23,000.

Cash received from option exercises and purchases under the 2004 ESPP and the 2010 ESPP for the years ended December 31, 2010, 2009, and 2008 was \$163,000, \$104,000, and \$162,000, respectively. We issue new shares upon option exercises, purchases under our ESPPs, and vesting of restricted stock.

The Company recorded stock-based compensation expense of \$1.2 million, \$2.1 million, and \$2.2 million for the years ended December 31, 2010, 2009, and 2008, respectively.

# **Equity**

On September 8, 2009, the Company entered into securities purchase agreements in connection with a private placement of its securities to certain institutional and other accredited investors pursuant to which the Company agreed to sell and issue (i) an aggregate of 8,816,521 newly issued shares of its common stock, par value \$0.0001 per share and (ii) warrants to purchase an aggregate of 8,375,694 shares of common stock. The sale of securities resulted in aggregate gross proceeds of approximately \$18.7 million. The net proceeds, after deducting offering expenses (including fees to the placement agent and coagent), were approximately \$17.2 million. In addition, the placement agents were issued warrants to purchase an aggregate of 207,188 shares of common stock. The placement agents' warrants are in the same form as those issued to participants in the private placement but the shares acquired upon exercise are not entitled to registration rights.

The common stock and warrants were sold as a unit for a price of \$2.12. The warrants are exercisable at any time from six months after the closing date through the fifth anniversary of the closing date. The warrants have an exercise price of \$2.20 per share, reflecting a 10% premium over the consolidated closing bid price for the Company's common stock as reported on the NASDAQ Global Market on September 4, 2009. The warrants contain certain limitations that prevent the holder of any warrants from acquiring shares upon exercise of a warrant that would result in the number of shares beneficially owned by it and its affiliates to exceed 19.99% of the total number of shares of the Company's common stock then issued and outstanding (with a separate threshold of 9.99% of the total number of shares outstanding for any shareholder who has not exceeded that threshold as of the date

# **Notes to Financial Statements (Continued)**

# 3. Stock-Based Compensation and Equity (Continued)

of closing). The number of shares for which the warrants are exercisable and the associated exercise prices are subject to certain adjustments as set forth in the warrants. The holder has the right to net exercise any outstanding warrants for shares of the Company's common stock. In addition, upon certain changes in control of the Company, to the extent the warrants are not assumed by the acquiring entity, the holder could elect to receive, subject to certain limitations and assumptions, cash equal to the Black-Scholes value of the outstanding warrants.

The warrants issued in connection with the private offering are within the scope of the Distinguishing Liabilities from Equity Topic of the Codification. This Codification topic requires issuers to classify as liabilities (or assets under certain circumstances) free-standing financial instruments which, at inception, require or may require an issuer to settle an obligation by transferring assets. Accordingly, the Company reflected these warrants as a liability in the Balance Sheet. The fair value of the warrants at the issuance date was estimated using the Black-Scholes model. The estimated fair value of the warrants, including the warrants issued to the placement agents, was \$14.5 million on the date of issuance and was recorded as a reduction of additional paid-in capital. In addition, the warrants were revalued at September 30, 2009 using the Black-Scholes model and the change in the fair value of the warrants was recognized in the warrants fair value adjustment line item in the Company's consolidated statement of operations.

At September 30, 2009, the estimated fair value of the warrants increased to \$21.9 million and was presented as a long term liability in the balance sheet as of that date. The increase in the fair value of the warrants from the date of issuance to September 30, 2009 required the Company to record an increase in the value of the liability of \$7.4 million.

In October 2009, the Company executed addenda to the warrants issued in connection with the securities purchase agreements of September 8, 2009. The addenda revised the rights of warrant holders such that upon a change in control, as defined, the warrant holders will receive the Black-Scholes value of the warrants in the same currency and same proportions as will be received by the common stockholders of the Company, thereby removing the criteria in the agreements that required liability classification of the warrants. Following the addenda, the warrant liability was revalued at fair value resulting in a \$2.2 million credit to warrants fair value adjustment that was recorded in the Statement of Operations in October 2009. The remaining liability for common stock warrants of \$19.7 million was then reclassified to additional paid-in capital.

As of December 31, 2010, the Company had 50,000,000 shares of common stock authorized and 23,197,537 shares issued and outstanding. Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are not entitled to receive dividends unless declared by the Board of Directors.

At December 31, 2010, the Company has reserved authorized shares of common stock for future issuance as follows:

Warrants	8,375,694
Outstanding stock options	3,197,214
Possible future issuance under stock option plans	1,299,206
Possible future issuance under employee stock purchase plan	184,760
Total	13,056,874

#### Notes to Financial Statements (Continued)

# 3. Stock-Based Compensation and Equity (Continued)

On March 7, 2007, the Company's Board of Directors adopted a Shareholder Rights Plan and declared a dividend distribution of one preferred stock purchase right for each outstanding share of the Company's common stock to shareholders of record as of the close of business on March 8, 2007. As of December 31, 2010 and 2009, there was no preferred stock outstanding.

# 4. Long-Term Investment, Joint Venture, and Acquisition

# Long-Term Investment and Joint Venture

In November 2007, the Company purchased approximately 13% of Cyberkinetics' outstanding common stock for an aggregate purchase price of \$2.5 million. Cyberkinetics was a company in the business of developing products to restore function for people with spinal cord and other nerve injuries. In February 2008, the Company and Cyberkinetics formed PNIR (Peripheral Nerve Injury Repair) LLC ("PNIR"), a joint venture with initial ownership of 50% by the Company and 50% by Cyberkinetics, and entered into a Collaboration Agreement and Operating Agreement. Under the terms of the joint venture, the Company agreed to fund the initial \$2.0 million in product development costs and the Company and Cyberkinetics shared equally in all costs in excess of the initial \$2.0 million. Cyberkinetics contributed technology, know-how, and intellectual property to the joint venture. The joint venture was considered to be a variable interest entity under the provisions of the Consolidation topic of the Codification. The Company determined that it was the primary beneficiary based on a review of the relative economic risks of the two parties to the joint venture. As a result, the Company consolidated the joint venture and recorded the \$2.1 million contribution of technology and intellectual property by Cyberkinetics to intangible assets and a noncontrolling interest of \$2.1 million at the formation date of the joint venture. In November 2008, Cyberkinetics disclosed that it was in the process of winding down its operations due to declining cash reserves. During December 2008, the Company re-evaluated the value of the joint venture intangible assets and determined them to be fully impaired as a result of the Cyberkinetics announcement in November and a strategic change in direction with the development of the intangible assets. Therefore, the Company recorded an impairment charge of \$1.8 million within the Statement of Operations. The joint venture was legally dissolved effective as of December 31, 2008, and was deconsolidated from the Company's books, resulting in a gain on deconsolidation in the Statement of Operations of \$2.1 million recognized within continuing operations in the fourth quarter of the year ended December 31, 2008. Since the value of the Company's investment in Cyberkinetics was adversely affected, the Company then marked this investment to market as of December 31, 2008 and recorded charges during 2008 of \$2.5 million to write down this investment to zero.

# Acquisition

On December 26, 2007, the Company acquired substantially all of the assets of EyeTel Imaging, Inc. ("EyeTel") for total consideration of 1,050,297 shares of the Company's common stock, \$175,000 in cash, and the assumption of certain specified liabilities totaling \$804,916. EyeTel was a company that manufactured the DigiScope, a digital retinal imaging device. Assets acquired and liabilities assumed were recorded at their estimated fair value. Goodwill totaling \$5.8 million was recorded in connection with the acquisition, representing the excess of the purchase price over the estimated fair value of the acquired tangible and intangible assets. A total of \$2.8 million was allocated to intangible assets, representing the fair value of existing technology, to be amortized on a straight-line basis over the estimated life of five years. In February 2008, the Company's common stock price declined significantly such that as of March 31, 2008, the Company's publicly traded market value was

#### Notes to Financial Statements (Continued)

# 4. Long-Term Investment, Joint Venture, and Acquisition (Continued)

below its net book value. Based on this, the Company performed an interim goodwill impairment test. As the net book value of the Company's assets exceeded the enterprise value, the Company performed step two of its impairment test in which it assessed the fair value of all recorded and unrecorded tangible and intangible assets and liabilities. The Company determined that no assets were impaired and determined that there was no residual value of goodwill. Accordingly, the Company recorded a charge of \$5.8 million to write off goodwill during the quarter ended March 31, 2008. On September 30, 2008, the Company approved a plan for the closure of its facility in Columbia, Maryland and the discontinuance of sales and support of DigiScopes and DigiScope related services, effective November 1, 2008. As a result of the discontinuance of the DigiScope business operation, the Company recorded an impairment charge of approximately \$2.4 million for the remaining balance of intangible assets related to DigiScope in the third quarter of 2008 included in Discontinued Operations in the Statement of Operations. On November 7, 2008, the Company signed an Asset Purchase Agreement with Advanced Diagnostics, LLC relating to the sale of substantially all of its EyeTel/DigiScope assets in exchange for the assumption of certain identified commitments of approximately \$400,000 and a cash payment of \$50,000. The CEO and President of Advanced Diagnostics, LLC is a former executive of the Company who continued to receive payments under a separation agreement with the Company through February 2009. During 2008, the Company incurred a net loss of approximately \$4.6 million on the sale of discontinued operations to the related party which has been included in loss on discontinued operations in the Statements of Operations. All revenues and costs related to the sale of the DigiScope have been recast to discontinued operations for 2008. Loss from discontinued operations includes loss on operations and sale of assets relating to the Company's d

Net revenue, operating loss from discontinued operations, loss on sale of discontinued operations, and loss from discontinued operations for the year ended December 31, 2008 was as follows:

	December 31, 2008
Net revenue	\$ 1,095,754
Operating loss from discontinued operations	\$ (1,999,937)
Loss on sale of discontinued operations	(4,600,736)
Loss from discontinued operations	\$ (6,600,673)

# 5. Intangible Assets

In January 2009, the Company acquired certain technological and intellectual property assets from Cyberkinetics and Andara Life Science, Inc., a wholly-owned subsidiary of Cyberkinetics, for \$350,000 in cash. The assets acquired in January 2009 include all of Cyberkinetics' rights and regulatory filings for the Andara<sup>TM</sup> Oscillating Field Stimulator (OFS<sup>TM</sup>) technology for treatment of acute spinal cord injury, an investigational device designed to stimulate spinal cord repair and restore sensation; the rights to develop and commercialize a therapeutic product for peripheral nerve injury based on the Andara OFS neurostimulation technology; development and commercialization rights to certain derivatives of the pharmacological agent 4-aminopyridine that may have an alternative future use in central and peripheral nervous system injury and disease; and certain other intellectual property and technology, which has been capitalized. The Company had previously pursued some of these product development efforts through the PNIR joint venture.

# **Notes to Financial Statements (Continued)**

# 5. Intangible Assets (Continued)

See Note 4—Long-Term Investment, Joint Venture, and Acquisition for information regarding the intangible assets in 2008.

Changes in intangible assets for the years ended December 31, 2010 and 2009 were as follows:

	December 31, 2010 Dece				December 31, 2009		
	Gross	Accumulated	Net	Gross	Accumulated	Net	
	Intangibles	Amortization	Intangibles	Intangibles	Amortization	Intangibles	
Technological and intellectual property	\$ 350,000	\$ (140,000)	\$ 210,000	\$ 350,000	\$ (70,000)	\$ 280,000	
rechnological and intellectual property	\$ 350,000	\$ (140,000)	\$ 210,000	\$ 350,000	\$ (70,000)	\$ 280,000	

The Company's intangible assets are being amortized over their estimated useful lives of 5 years, with no estimated residual values. Amortization expense for the years ended December 31, 2010, 2009, and 2008 was \$70,000, \$70,000, and \$752,000, respectively.

The estimated future amortization expense for intangible assets as of December 31, 2010 is as follows:

	I	d Amortization Expense ember 31,
2011	\$	70,000
2012		70,000
2013		70,000
	\$	210,000

# 6. Inventories

The reduction in inventories during 2010 resulted largely from inventory charges of \$2.1 million during 2010, of which \$1.8 million related to the business restructuring in December 2010. See Note 17—Subsequent Event for more information regarding this restructuring.

At December 31, 2010 and 2009, inventories consist of the following:

	Decem	December 31,			
	2010	2009			
Purchased components	\$ 457,852	\$ 1,346,267			
Finished goods	1,954,953	3,213,340			
	\$ 2,412,805	\$ 4,559,607			

# **Notes to Financial Statements (Continued)**

# 7. Investments

# **Short-Term Investments**

There were no short-term investments as of December 31, 2010. Short-term investments as of December 31, 2009 are shown below.

	An	nortized Cost	U	Gross nrealized Gains	Uı	Gross nrealized Losses	Estimated Fair Value
2009							
Certificates of deposit	\$	7,495,000	\$	_	\$	_	\$ 7,495,000
	\$	7,495,000	\$	_	\$	_	\$ 7,495,000

The amortized cost and fair value of fixed maturity securities at December 31, 2009, by contractual maturity, are shown below.

		December 31, 2009			
	Am	ortized Cost	Fair Value		
Due in one year or less	\$	7,495,000	\$ 7,495,000		
3					

# 8. Fixed Assets

Fixed assets consist of the following:

	Estimated Useful Life		31,		
	(Years)	2010 2009			2009
Computer and laboratory equipment	3	\$	2,531,340	\$	2,416,952
Furniture and equipment	3		730,174		630,855
Production equipment	7		1,061,186		1,061,186
Leasehold improvements	*		179,997		176,497
			4,502,697		4,285,490
Less—accumulated depreciation			(3,770,722)		(3,378,865)
		\$	731,975	\$	906,625
		_			

Lesser of life of lease or estimated useful life.

Depreciation expense was \$453,756, \$508,666, and \$840,967 for the years ended December 31, 2010, 2009, and 2008, respectively.

A capital lease is included as a component of furniture and equipment at December 31, 2010 and 2009. Amortization of assets under this capital lease is included in depreciation expense.

# **Notes to Financial Statements (Continued)**

# 9. Accrued Expenses

Accrued expenses consist of the following for the years ended December 31, 2010 and 2009:

	 December 31,			
	2010	2009		
Professional services	\$ 284,290	\$	488,191	
Patent fees	250,000			
Customer overpayments	212,302		306,251	
Supplier obligations	195,000			
Sales taxes	76,805		191,601	
Other	209,393		309,534	
	\$ 1,227,790	\$	1,295,577	

# 10. Restructuring Related Activity

In January 2011, the Company announced it had restructured its neurodiagnostic activities to more efficiently focus its efforts on its installed base of active accounts, to shift distribution to independent sales representatives, and to reduce cash consumption. During December 2010, one employee was notified that his position was being eliminated in conjunction with this business restructuring. As a result, the Company recorded a charge of \$208,000 during the fourth quarter of 2010 related to severance expense. The remaining employees affected by the restructuring were notified in January 2011 and, in accordance with generally accepted accounting principles, the related severance cost of approximately \$0.3 million will be recorded in the first quarter of 2011. See Note 17—Subsequent Event for more information regarding this restructuring.

During the third quarter of 2010, the Company implemented a reduction in workforce that resulted in the elimination of 25 positions and recorded a charge of \$172,000 primarily related to severance expenses. The full amount of the charge was paid as of September 30, 2010.

In May 2008, the Company reduced the size of its direct sales force and took certain other actions to reduce its operating expenses. These actions affected 24 positions, substantially all of which were in sales. The total cost associated with these actions, primarily severance, was \$319,000.

Effective May 31, 2008, the Chief Operating Officer of the Company entered into a separation agreement with the Company. Under the terms of the separation agreement, he received continuation of his salary, car allowance, and health benefits for nine months following the effectiveness of his resignation, equal to \$217,970, which was recorded during the quarter ended March 31, 2008. In addition, he received a lump sum payment equal to three months salary and car allowance totaling \$69,810, which the Company recorded during the quarter ended June 30, 2008.

The following table provides a rollforward of the liability balance for the actions taken in 2010 and 2009, substantially all of which were recorded as sales and marketing expense in the Company's

# **Notes to Financial Statements (Continued)**

# 10. Restructuring Related Activity (Continued)

Statement of Operations. The balance as of December 31, 2010 will be paid out in semi-monthly installments through October 31, 2011.

	Years Ended December 31					
	2010			2009		
Balance at beginning of period	\$	_	\$	48,438		
Accrual for severance		380,223				
Severance payments made		(171,890)		(48,438)		
Balance at end of period	\$	208,333	\$			

# 11. Income Taxes

Current income tax expense (benefit) attributable to continuing operations consists of the following for the years ended December 31, 2010, 2009, and 2008.

	Years Ended	Years Ended December 31,		
	2010	2009 2008		
Federal	\$ (120,490)	\$ — \$ —		
State	_			
Total	\$ (120,490)	<del>\$ -</del> <del>\$ -</del>		

The Company's effective income tax rate differs from the statutory federal income tax rate as follows for the years ended December 31, 2010, 2009, and 2008.

	Years Ended December 31,		
	2010	2009	2008
Federal tax provision (benefit) rate	(34.0)%	(34.0)%	(34.0)%
State tax provision, net of federal provision	(3.5)	(1.6)	(2.1)
Permanent items	1.4	20.8	19.2
Federal research and development credits	(0.6)	(0.6)	(0.3)
Valuation allowance	36.0	15.4	17.2
Effective income tax rate	(0.7)%	_%	%

# **Notes to Financial Statements (Continued)**

# 11. Income Taxes (Continued)

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

	December 31,			
	2010		2009	
Deferred tax assets:				
Net operating loss carryforwards	\$	23,802,670	\$	17,951,109
Research and development credit carryforwards		1,408,830		1,129,548
Alternative minimum tax credit		_		120,490
Accrued expenses		539,150		642,692
Stock-based compensation		1,772,181		1,557,902
Other		1,147,204		1,111,476
Total gross deferred tax assets		28,670,035		22,513,217
Valuation allowance		(28,670,035)		(22,513,217)
Net deferred tax assets	\$	_	\$	

At December 31, 2010, the Company has federal and state net operating loss carryforwards ("NOL") of approximately \$70.7 million and \$44.1 million, respectively, as well as federal and state tax credits of approximately \$905,000 and \$763,000, respectively, which may be available to reduce future taxable income and the related taxes thereon. This amount includes tax benefits of \$3.7 million and \$71,000 attributable to NOL and tax credit carryforwards, respectively, that result from the exercise of employee stock options. The tax benefit of these items will be recorded as a credit to additional paid-in capital upon realization of the deferred tax asset or reduction in income taxes payable. The federal NOL's begin to expire in 2019 and the state NOL's began to expire in 2010.

In accordance with the provisions of the Income Taxes topic of the Codification, the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating losses. Management has determined that it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets and, as a result, a valuation allowance of approximately and \$28.7 million and \$22.5 million has been established at December 31, 2010 and 2009, respectively. Ownership changes, as defined in the Internal Revenue Code, have limited the amount of net operating loss carryforwards that can be utilized annually to offset future taxable income. The Company anticipates that these limitations will have no material impact on their ability to utilize the affected loss carryforwards in future years. Subsequent ownership changes could further impact the limitation in future years.

# 12. Commitments and Contingencies

# **Operating Leases**

# Lease Agreement with Fourth Avenue LLC

In February 2008, the Company amended the Lease Agreement dated October 18, 2000 between Fourth Avenue LLC and the Company for office and engineering laboratory space. The amendment extends the term of the lease through March 31, 2013. Base rent for the period January 2011 through March 2013 will increase from \$705,000 annually to \$765,000 annually.

# **Notes to Financial Statements (Continued)**

# 12. Commitments and Contingencies (Continued)

Future minimum lease payments under noncancelable operating leases as of December 31, 2010 are as follows:

2011	\$ 727,500
2012	757,500
2013	191,250
Total minimum lease payments	\$ 1,676,250

Total recorded rent expense was \$764,754, \$764,754, and \$719,568 for the years ended December 31, 2010, 2009, and 2008, respectively. The Company records rent expense on its facility lease on a straight-line basis over the lease term.

# Capital Lease

In October 2010, the Company entered into a non-cancelable capital lease for copiers located at its corporate headquarters valued at \$60,410, expiring in September 2013.

Future minimum lease payments under the capital lease as of December 31, 2010 are as follows:

2011	\$ 22,136
2012	22,136
2013	18,446
Total minimum lease payments	62,718
Less: Amount representing imputed interest	5,376
Present value of future minimum lease payments	\$ 57,342

# **Other Commitments**

At December 31, 2010, other commitments, comprised of purchase orders, totaled approximately \$1.3 million.

# **Restricted Time Deposit**

In connection with the Company's facility lease, the Company is required to maintain, for the benefit of the lessor, an irrevocable standby letter of credit stating the lessor as the beneficiary over the term of the lease, which is secured by a certificate of deposit in an amount equal to 102% of the letter of credit as security. The lease expires in March 2013. The certificate of deposit is renewable in 30-day increments. At December 31, 2010 and 2009, the Company has reflected \$408,000 as restricted cash associated with this lease on the accompanying balance sheet.

# Legal Matters

As previously disclosed in the Company's filings with the Securities and Exchange Commission, or SEC, on March 17, 2008, a putative securities class action complaint was filed in the United States District Court for the District of Massachusetts against the Company and certain of its current and former officers. On March 27, 2008, a related putative securities class action complaint was filed in the

#### Notes to Financial Statements (Continued)

# 12. Commitments and Contingencies (Continued)

same court, against the same defendants. These two actions were subsequently consolidated, and the court appointed a lead plaintiff. On November 10, 2008, a consolidated amended class action complaint was filed, which alleged, among other things, that between October 27, 2005 and February 12, 2008, the defendants violated the federal securities laws by allegedly making false and misleading statements and failing to disclose material information to the investing public. The plaintiffs sought unspecified damages. On January 30, 2009, the Company filed a motion to dismiss the consolidated amended complaint on the grounds, among others, that it failed to state a claim on which relief can be granted. On December 8, 2009, the Court entered an order granting defendants' motion to dismiss and dismissing the consolidated amended complaint in its entirety with prejudice. The plaintiffs filed a notice of appeal with the United States Court of Appeals for the First Circuit on January 6, 2010. Oral arguments on the plaintiffs' appeal were conducted on September 15, 2010. The appeal is currently pending.

The litigation process is inherently uncertain, and the Company cannot guarantee that the outcome of the above lawsuit will be favorable for the Company or that it will not be material to its business, results of operations, or financial position. However, the Company does not believe that a loss related to this litigation is probable. Accordingly, no accrual relating to this matter has been recorded at December 31, 2010.

As previously disclosed in the Company's filings with the SEC, on April 22, 2008, a shareholder derivative action was filed in the United States District Court for the District of Massachusetts against a number of the Company's current and former directors and officers. On December 10, 2008, a verified amended shareholder derivative complaint was filed, alleging, among other things, that, between August 2004 and the date the action was filed, the defendants breached various fiduciary duties to the Company based on conduct similar to that alleged in the putative securities class actions, including that the defendants caused the Company to make false and misleading statements, to fail to disclose material information to the public and to engage in improper business practices. The plaintiff sought various forms of monetary and non-monetary relief. The parties reached an agreement to resolve the shareholder derivative action, subject to Court approval, and executed a formal stipulation of settlement on December 21, 2009. On February 23, 2010, the Court entered an order approving the parties' settlement and entered a judgment dismissing the case in its entirety, with prejudice. In conjunction with the settlement, the Company's insurance carrier paid directly to third parties \$350,000 for the plaintiff's counsel's attorneys fees and reimbursement of expenses. No payment was required by the Company.

As previously disclosed in the Company's filings with the SEC, on February 9, 2009, the Company announced that it had reached a resolution with the United States Department of Justice, or DOJ, and the Office of Inspector General, or OIG, of the United States Department of Health and Human Services regarding the previously-disclosed investigation into certain of the Company's past sales and marketing practices relating to its NC-stat System.

As part of the resolution, the Company entered into a Deferred Prosecution Agreement, or the Deferred Prosecution Agreement, dated February 5, 2009, with the DOJ related to its operation of marketing referral programs. Pursuant to the Deferred Prosecution Agreement, the Company agreed to a \$1.2 million payment, and the DOJ has agreed not to prosecute the Company in return for compliance with the terms of the three-year Deferred Prosecution Agreement.

#### Notes to Financial Statements (Continued)

# 12. Commitments and Contingencies (Continued)

In addition, the Company entered into a civil Settlement Agreement with the DOJ and OIG, or the Settlement Agreement, dated February 9, 2009. The Settlement Agreement involves the referral programs and allegations that, where physicians performed a nerve conduction study using the NC-stat System and did not obtain an F-wave measurement, in limited circumstances, the Company caused physicians to seek reimbursement using the slightly higher valued 95903 CPT code payable for nerve conduction studies where an F-wave measurement is obtained, rather than the 95900 CPT code. While the Company did not admit to the allegations with respect to the F-wave coding issue, the Company agreed to pay \$2.5 million to settle this dispute and enter into a five-year Corporate Integrity Agreement with OIG. The Company remains fully eligible to participate in all federal health care programs.

The settlement payments discussed above in the total amount of \$3.7 million were paid in the first quarter of 2009.

# 13. Fair Value Measurements

The Fair Value Measurements and Disclosures Topic of the Codification defines fair value, establishes a framework for measuring fair value in applying generally accepted accounting principles, and expands disclosures about fair value measurements. This Codification topic identifies two kinds of inputs that are used to determine the fair value of assets and liabilities: observable and unobservable. Observable inputs are based on market data or independent sources while unobservable inputs are based on the Company's own market assumptions. Once inputs have been characterized, this Codification topic requires companies to prioritize the inputs used to measure fair value into one of three broad levels. Fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values identified by Level 2 inputs utilize observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities. Fair values identified by Level 3 inputs are unobservable data points and are used to measure fair value to the extent that observable inputs are not available. Unobservable inputs reflect the Company's own assumptions about the assumptions that market participants would use at pricing the asset or liability.

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

### NeuroMetrix, Inc.

## **Notes to Financial Statements (Continued)**

### 13. Fair Value Measurements (Continued)

unobservable data points for the asset or liability, and include situations where there is little, if any, market activity for the asset or liability.

			alue Measuremen	
		Decei	mber 31, 2010 Usi	ng
			Significant	
		Quoted Prices in	Other	Significant
		Active Markets	Observable	Unobservable
	December 31,	for Identical Assets	Inputs	Inputs
	2010	(Level 1)	(Level 2)	(Level 3)
Assets:				
Cash equivalents	\$ 13,010,213	\$ 13,010,213	\$ —	\$ —
Total	\$ 13,010,213	\$ 13,010,213	\$ —	\$ —

			llue Measuremen nber 31, 2009 Usi	
	December 31, 2009	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	\$ 22,233,503	\$ 22,233,503	\$ —	\$ —
Total	\$ 22,233,503	\$ 22,233,503	\$ —	\$ —

### 14. Retirement Plan

The Company established a 401(k) defined contribution savings plan for its employees who meet certain service period and age requirements. Contributions are permitted up to the maximum allowed under the Internal Revenue Code of each covered employee's salary. The savings plan permits the Company to contribute at its discretion. For the years ended December 31, 2010, 2009, and 2008 the Company made no contributions to the plan.

# 15. Related Party

During 2009, the Company paid Red Sky Partners, LLC, or Red Sky, a total of \$49,000 for various consulting services. One of the Company's current board members is a partner in Red Sky. The same board member was also the former President and CEO of Cyberkinetics. There were no services provided by Red Sky to the Company during 2010 and no payments were made to Red Sky by the Company during 2010.

# 16. Credit Facility

In order to supplement its access to capital, on March 5, 2010 the Company entered into a one year Loan and Security Agreement, "Credit Facility", with a bank, which permits the Company to borrow up to \$7.5 million on a revolving basis. Amounts borrowed under the Credit Facility will bear interest equal to the prime rate plus 0.5%. Any borrowings under the Credit Facility will be secured by

### NeuroMetrix, Inc.

# **Notes to Financial Statements (Continued)**

# 16. Credit Facility (Continued)

the Company's cash, accounts receivable, inventory, and equipment. The Company has not borrowed any funds under the Credit Facility. The Credit Facility expires in March 2012.

# 17. Subsequent Event—Business Restructuring

In January 2011, the Company announced it had restructured its neurodiagnostic activities to more efficiently focus its efforts on its installed base of active accounts, to shift distribution to independent sales representatives, and to reduce cash consumption. Twenty five employee positions were eliminated, primarily in sales. Charges totaled \$2.3 million related to severance costs and inventory. Approximately \$2.0 million, consisting of \$0.2 million in severance and \$1.8 million in inventory charges, was recorded as of December 31, 2010 and the balance of approximately \$0.3 million in severance will be recorded in 2011.

# NeuroMetrix, Inc.

# Schedule II—Valuation and Qualifying Accounts

Description	Balance at Beginning of Period	Charged to costs and expenses	Charged to other accounts	Recoveries/ (Deductions)	Balance at End of Period
December 31, 2010					
Allowance for Doubtful Accounts	\$ 370,000	\$ 657	\$ —	\$ 8,443(1)	\$ 379,100
Sales Returns Reserve	144,362	_	655,890	(773,387)(2)	26,865
Deferred Tax Asset Valuation Allowance	22,513,217	6,147,638		9,180(3)	28,670,035
December 31, 2009					
Allowance for Doubtful Accounts	650,000	114,683	_	(394,683)(2)	370,000
Sales Returns Reserve	231,394	_	960,397	(1,047,429)(2)	144,362
Deferred Tax Asset Valuation Allowance	21,191,712	1,420,233	_	(98,728)(3)	22,513,217
December 31, 2008					
Allowance for Doubtful Accounts	906,000	355,774		(611,774)(2)	650,000
Sales Returns Reserve	165,643	_	1,190,783	(1,125,032)(2)	231,394
Deferred Tax Asset Valuation Allowance	16,238,566	5,155,327		(202,181)(3)	21,191,712

<sup>(1)</sup> Net recoveries.

<sup>(2)</sup> Write-offs.

<sup>(3)</sup> Utilization and expiration of Federal and State Net Operating Loss Carryforwards.

Exhibit 23.1

# CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-118059, 333-135242, 333-151195, 333-159712, 333-159713 and 333-167180) and on Form S-3 (Nos. 333-150087, 333-162303 and 333-165784) of NeuroMetrix, Inc. of our report dated March 7, 2011 relating to the financial statements and financial statement schedule, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts March 7, 2011

Exhibit 23.1

#### CERTIFICATION

#### I, Shai N. Gozani, certify that:

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

Date: March 7, 2011	/s/ SHAI N. GOZANI, M.D., PH.D.
	Shai N. Gozani, M.D., Ph.D.
	Chairman, President and Chief Executive Officer

Exhibit 31.1

#### CERTIFICATION

### I, Thomas T. Higgins, certify that:

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

Date: March 7, 2011	/s/ THOMAS T. HIGGINS
	Thomas T. Higgins
	Senior Vice President, Chief Financial Officer and Treasurer

Exhibit 31.2

Exhibit 32

### CERTIFICATION

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

The Annual Report for the year ended December 31, 2010 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 7, 2011

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

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

Chairman, President and Chief Executive Officer

Date: March 7, 2011

/s/ THOMAS T. HIGGINS

Thomas T. Higgins

Senior Vice President, Chief Financial Officer and Treasurer

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

Exhibit 32