

# NEUROMetrix

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Transforming Patient Care through Neurotechnology

2008

ANNUAL REPORT

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

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**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, 2008**

**OR**



**TRANSITION REPORT PURSUANT TO SECTION 12 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from to**

**Commission File Number 001-33351**

**NEUROMETRIX, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or Other Jurisdiction of Incorporation or Organization)

**04-3308180**

(I.R.S. Employer Identification No.)

**62 Fourth Avenue Waltham, Massachusetts**  
(Address of Principal Executive Offices)

**02451**  
(Zip Code)

**(781) 890-9989**

(Registrant's Telephone Number, Including Area Code)

Securities Registered Pursuant To Section 12(b) of the Act:

Title of each class	Name of exchange on which registered
Common Stock, \$0.0001 par value per share Preferred Stock Purchase Rights	The NASDAQ Stock Market LLC
Securities Registered Pursuant to Section 12(g) of the Act None	

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ 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 ☐ 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 ☐

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

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☒  
(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 ☐ No ☒

As of June 30, 2008 the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately \$18,616,000 based on the closing sale price of the common stock as reported on the NASDAQ Global Market on June 30, 2008. For this computation, the registrant has excluded the market value of all outstanding shares beneficially owned by any director, executive officer or person known to the registrant to beneficially own 10% or more of the registrant's common stock; such exclusion shall not be deemed to constitute an admission that any such person is an affiliate of the registrant.

As of March 6, 2009, there were 13,858,797 shares of Common Stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive proxy statement for the registrant's 2009 annual meeting of stockholders, which is expected to be filed pursuant to Regulation 14A within 120 days of the registrant's year ended December 31, 2008, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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**NEUROMETRIX, INC.**  
**ANNUAL REPORT ON FORM 10-K**  
**FOR THE YEAR ENDED DECEMBER 31, 2008**  
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## PART I

The statements contained in this Annual Report on Form 10-K, including under the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and other sections of this Annual Report, include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including, without limitation, statements regarding our or our management’s expectations, hopes, beliefs, intentions or strategies regarding the future. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “plan” and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. The forward-looking statements contained in this annual report are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in the section titled “Risk Factors.” Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects 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.

### ITEM 1: BUSINESS

#### Our Business—An Overview

We are a science-based medical device company advancing patient care through the development and commercialization of innovative products that aid physicians in the assessment, treatment, and repair of peripheral nerve and spinal cord injuries and disorders, and that provide regional anesthesia and pain control. Currently, our core mission is to develop and market products in three clinical areas related to the nervous system. The first is diagnosis and monitoring of peripheral nerve and spinal cord dysfunction. The second is the delivery of anesthetic and therapeutic agents to peripheral nerves and the spine. The third is neurostimulation to promote repair and regeneration of peripheral nerves and the spinal cord. These three areas have a common core scientific theme, which is the measurement, modulation, and repair of neural conduction.

To date, our focus has been on products that help physicians with the diagnosis or detection of neuropathies. Neuropathies affect the peripheral nerves and parts of the spine and are frequently caused by or associated with carpal tunnel syndrome, or CTS, diabetes, sciatica, and other clinical disorders. We market systems for the performance of nerve conduction studies and needle electromyography procedures. We have two medical devices cleared by the United States Food and Drug Administration, or FDA, that are used for the assessment of neuropathies. The first device is the ADVANCE™ NCS/EMG System, a comprehensive platform for the performance of traditional nerve conduction studies and needle electromyography procedures. This system is used primarily by neurologists, physical medicine and rehabilitation, or PM&R, physicians, neurosurgeons, orthopedic and hand surgeons and pain medicine physicians. We believe that the ADVANCE System offers these specialists an effective tool for performing traditional nerve conduction studies and needle electromyography procedures. The ADVANCE System was cleared by the FDA through the pre-market notification or process in May 2008. We began shipping the ADVANCE System immediately following FDA clearance. The second device is the NC-stat System, an automated device for the performance of nerve conduction studies. We believe that the NC-stat System improves the quality and efficiency of patient care by offering primary care and internal medicine physicians the ability to objectively evaluate

patients with neuropathies at the point-of-service, that is, in the physician's office at the time the patient is examined, resulting in earlier and more accurate detection, greater patient comfort and convenience, and, in many cases, improved clinical and economic outcomes. We market the ADVANCE and NC-stat Systems domestically and internationally in the United Kingdom and various countries in Latin America. Our neurodiagnostic equipment is used in over five thousand physician offices, clinics and hospitals. Over one and a half million patients have been tested with our neurodiagnostic equipment since 1999.

The second area we are leveraging our core technology into is the minimally invasive delivery of commercially available therapeutic agents using a proprietary delivery system for regional anesthesia, pain control and the treatment of neuropathies. We are currently in the clinical stage of development of a nerve localization system, which we refer to as ASCEND™. We submitted a 510(k) application to the FDA on one component of the system in December 2008, and expect to submit another 510(k) application on the second component in the first half of 2009.

The third area we are focused on is neural repair and restoration of neural conduction through certain technological and intellectual property assets acquired from Cyberkinetics Neurotechnology Systems, Inc., or Cyberkinetics, and Andara Life Science, Inc., a wholly-owned subsidiary of Cyberkinetics. The assets acquired in January 2009 include all of Cyberkinetics' rights and regulatory filings for the Andara™ Oscillating Field Stimulator (OFS™) 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 be useful in the treatment of central and peripheral nervous system injury and disease; and certain other intellectual property and technology. We had previously pursued some of these product development efforts through a joint venture established in February 2008 with Cyberkinetics which was dissolved in the fourth quarter of 2008.

As of December 31, 2008, we sold our products through a sales force of approximately 28 regional sales managers, three regional sales directors and a Vice President of Sales to physician offices, medical specialists and clinics.

Our revenues declined 28.7% to \$31.1 million in 2008, after decreasing 21.0% to \$43.7 million in 2007 from \$55.2 million in 2006. The decline in revenues was primarily attributable to challenges experienced with reimbursement of nerve conduction studies performed using the NC-stat System. The American Medical Association CPT Editorial Panel, which we refer to as the CPT Panel, has been reviewing the reimbursement coding for nerve conduction studies and formed a work group in early 2007 to examine the reimbursement coding of nerve conduction studies performed using nerve conduction equipment, including the NC-stat System. The findings of this work group were presented to the CPT Panel at a meeting in February 2008. At this meeting, the CPT Panel approved a Category III code describing nerve conduction studies performed with pre-configured electrode arrays. However, prior to publishing a new Category III CPT code for nerve conduction studies, the CPT Panel decided to reconsider its decision. In October 2008, the CPT Panel again considered nerve testing as an agenda item and at this meeting voted on a new Category I CPT code for nerve conduction studies performed with pre-configured electrode arrays, such as are utilized with the NC-stat System. The outcome of the most recent vote was first made public in January 2009, when the CPT Panel minutes from its October 2008 meeting were reported by a financial analyst. We expect that the new code will be published in the Federal Register in the second half of 2009 for implementation on January 1, 2010. Before this new CPT code is implemented, the amount of reimbursement that physicians will receive under the code will need to be determined. The Centers for Medicare & Medicaid Services, or CMS, will determine the Relative Value Units, or RVUs, on which the amount of reimbursement is based and publish the final RVUs in the Federal Register—usually in October for

implementation January 1 the next year. This CPT code, when issued, may improve our customers' ability to submit claims efficiently and for these claims to be processed expeditiously and may help to stabilize the process for obtaining reimbursement under Medicare for nerve conduction studies performed using the NC-stat System.

The majority of our revenues in 2008 were derived from sales of the NC-stat and ADVANCE Systems. Approximately 91% of our revenues were attributable to sales of electrodes, which we refer to as consumables that physicians use to perform nerve conduction studies and needle electromyography procedures with our systems. We recorded net losses of \$27.7 million in 2008, \$8.4 million in 2007 and net income of \$4.3 million in 2006. Our net loss in 2008 was primarily a result of the decline in revenues, charges related to the settlement of an investigation conducted by 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 and asset impairments.

## Neuropathies

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

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

### *NC-stat System*

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

### *ADVANCE System*

The ADVANCE System is a comprehensive platform for the performance of traditional nerve conduction studies and needle electromyography procedures. The ADVANCE System is comprised of: (1) single use surface 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 our onCall Information System for data archiving, report generation and other network services. The technical specifications include a precision electrical stimulator and dual recording channels for acquiring nerve conduction responses. A third channel is available for recording needle electromyography signals. The ADVANCE System introduces several important technological improvements into the market, including a small form factor and power from a high capacity lithium-ion battery making use of the device convenient in many environments. The amplification and digitization hardware is embedded in the cable connector thereby providing digital signal transmission from the recording electrodes to the device. This technology reduces susceptibility to electrical interference and makes the device suitable for all settings, even challenging applications such as nerve function assessment in intensive care units. The device is designed around a high-resolution color touch screen that facilitates real-time review and editing of nerve conduction waveforms. Integrated Bluetooth® provides convenient wireless communication with data management and report generation servers. This wireless link also enables expansion of system capabilities with the introduction of modules in the future. Finally, several enhancements have been made to the proprietary NeuroMetrix neurophysiological analysis software, which is resident on ADVANCE devices.

### *Consumables*

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

proximal locations. We also market EMG needles and various cables and other accessories for performing nerve conduction studies and needle electromyography procedures.

### **Customers**

We market our products directly to physicians, clinics and hospitals. The NC-stat System is marketed primarily to primary care and internal medicine physicians. The ADVANCE System is marketed primarily to neurologists, PM&R physicians, neurosurgeons, orthopedic and hand surgeons and pain medicine physicians. As of December 31, 2008, we had over 5,000 active NC-stat and ADVANCE customers. No single customer accounted for more than 10% of our revenues in 2008, 2007 or 2006.

### **Geographic Information**

Substantially all of our assets, revenues and expenses for the years ended December 31, 2008, 2007 and 2006 were located at or derived from operations in the United States. As a result of the launch of the NC-stat and ADVANCE Systems in the United Kingdom and various countries in Latin America, which has been on a limited basis to date, we had initial revenues from sales outside the United States which accounted for less than 1% of total revenues for the years ending December 31, 2008 and 2007, respectively.

### **Strategic Alliance**

In February 2008, we entered into a joint venture with Cyberkinetic for the development and commercialization of a product for the treatment of peripheral nerve injury using the Andara™ OFS™ (Oscillating Frequency Stimulation) technology licensed by Cyberkinetics from Purdue University and using other technologies to be developed. The Andara OFS technology utilizes an oscillating electrical field to stimulate the regeneration of injured nerves and has been shown in initial human clinical studies to provide a statistically significant improvement in sensory function of patients with acute spinal cord injuries.

During the fourth quarter of 2008, the joint venture with Cyberkinetics as described above 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™ Oscillating Field Stimulator (OFS™) technology and 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 be useful in the treatment of central and peripheral nervous system injury and disease; and certain other intellectual property and technology.

### **Discontinued Operations**

In December 2007, we acquired substantially all of the assets of EyeTel Imaging, Inc., or EyeTel, and their product, the DigiScope, a product used for the detection of eye disorders such as diabetic retinopathy, an eye disease prevalent in patients with diabetes for total consideration of approximately 1.1 million shares of our newly issued common stock and \$175,000 in cash. Prior to acquiring EyeTel and during 2007, we had previously entered into an exclusive licensing agreement with EyeTel pursuant to which we had sales and marketing rights to the DigiScope in the primary diabetes care physician market. On September 30, 2008, as part of our ongoing focus on cost-efficiencies in all areas of our business, and our refocused efforts towards our core business, which is the sale of the ADVANCE System and support for our existing NC-stat System customers, we approved a plan for the closure of our facility in Columbia, Maryland and 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 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. The CEO and President of Advanced Diagnostics, LLC is a former executive of ours who continues to receive payments under a separation agreement with us.

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

As of December 31, 2008 we employed 28 regional sales managers, three regional sales directors and a vice president of sales who sell directly to physicians. Our products are primarily marketed and distributed within the United States, although we have initiated sales efforts through independent distributors in the United Kingdom, Mexico, Brazil, Argentina, Chile and other markets in Latin America.

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

Our success is highly dependent on our ability to maintain our direct sales force. In markets outside the United States, we may be unable to enter into further agreements with qualified distributors on commercially reasonable terms or at all and we may not be successful in maintaining the existing sales and marketing infrastructure we have developed. Even if we are able to enter into further agreements with distributors outside the United States, these parties may not commit the necessary resources to effectively market and sell our products or ultimately be successful in selling our products.

Promotion and sales of medical devices are also 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.

Currently, we are in the process of splitting our U.S. sales operations into three sales channels:

- (1) neurology, which includes neurologists, PM&R physicians, and pain medicine physicians,
- (2) neurointerventional, which includes neurosurgeons, orthopedic surgeons and anesthesiologists, and
- (3) physician office, which includes primary care physicians, internal medicine physicians, endocrinologists, rheumatologists and occupational medicine physicians. We are pursuing this realignment in order to effectively distribute and commercialize our products as we continue to diversify our product offering. As a part of this realignment, our vice president of sales departed March 4, 2009, and we are looking to hire an experienced executive to oversee our overall sales function.

### **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 the ADVANCE or NC-stat devices, docking station/communication hubs or 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 and 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. We did not experience any inventory shortages on any established products in 2008, although we did experience some delays in production with Parlex Corporation, or Parlex, the manufacturer of our electrodes. Additionally, during 2008, we experienced slightly higher rates of defects in electrodes manufactured by Parlex, as we rejected approximately 3-5% of electrodes shipped to us by Parlex. We are continuing to work closely with Parlex to address these issues. 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 diagnostic devices. Sunburst manufactures the current generation of the NC-stat and the ADVANCE devices at a facility in Massachusetts.

We and our third-party manufacturers are registered with the FDA and subject to compliance with FDA quality system regulations. We are also ISO registered and undergo frequent quality system audits by European agencies. The NC-stat and ADVANCE Systems are cleared for marketing within the United States, Canada and the European Union. Our facility and the facilities of our manufacturers 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 manufacturers will undergo regularly scheduled FDA quality system inspections. However, additional FDA inspections may occur if deemed necessary by the FDA.

### **Products Under Development and Research and Development**

Our research and development efforts are focused in the near term on further enhancing our existing products, which includes enhancements to the ADVANCE System and new electrodes and other accessories for use with the ADVANCE System, developing the ASCEND platform, a system for the minimally invasive delivery of therapeutic agents for regional anesthesia, pain control and local treatment of neuropathies, and development of Andara OFS, an investigational device, for the treatment of acute spinal cord injuries.

Our research and development staff consists of 23 people, including seven who hold Ph.D. or M.D. degrees. Our research and development group has extensive experience in neurophysiology, biomedical instrumentation, signal processing, biomedical sensors and information systems. These individuals work closely with our marketing group, our clinical support group (led by a board-certified neurologist) and our customers to design products that are intended to improve clinical outcomes.

During 2008, 2007 and 2006, we spent \$5.3 million, \$4.9 million and \$5.0 million, respectively, on research and development.

#### *Neurodiagnostic Devices*

Most of our efforts are currently directed to the addition of certain functionality to the ADVANCE System. We are also developing new electrodes for performance of nerve conduction studies and needle electromyography procedures.

#### *Devices for Regional Anesthesia, Pain Control and the Treatment of Neuropathies*

We believe that our core technology can be adapted and extended to provide minimally invasive approaches to nerve localization and specifically to provide regional anesthesia, pain control and treatments for neuropathies. We are developing the ASCEND platform, a proprietary neuro-electrical guidance system, that is designed to help physician's position drug delivery devices such as hypodermic needles and catheters safely and quickly in very close proximity to specific nerves to optimize the therapeutic benefit.

The use of nerve localization instrumentation and needles is a standard of care for nerve block procedures which are increasingly the preferred form of anesthesia for many surgical procedures, particularly within orthopedics. This can effectively provide the physician with confirmation that the needle is in the proper location and can optimize the efficacy of anesthetic delivery.

We believe that neuropathies, that are focal in nature, can be safely and effectively treated if drugs can be delivered near the disease site without damaging the nerve in the process. Some of these types of treatments are performed today, but they are performed manually by a limited number of physicians. Our ASCEND development program is designing a product that we believe will reduce the risk involved in providing these treatments.

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

After establishing our technology in anesthesia, we plan to proceed into the broader market for select clinical conditions such as the treatment and management of CTS and common pain syndromes.

Our ASCEND products will resemble our diagnostic products in that there will be three key components:

- consumables that will include proprietary nerve localization and drug delivery needles;
- electrodes and other disposables; and
- an electronic instrument linked to local and/or remote information systems.

We have submitted a 510(k) application to the FDA on the signal detector portion of our ASCEND product in December 2008, and expect to file an application on the stimulator for the device in the first half of 2009.

There are no assurances that our devices for regional anesthesia, pain control and the treatment of neuropathies will receive 510(k) clearance from the FDA and that, if launched, sales and marketing efforts will be successful.

#### *Andara OFS Device*

The Andara OFS device for spinal cord injury is an investigational device, which is being developed as a single use implant to enhance neurological recovery in patients with devastating loss of movement and sensation from acute spinal cord injuries. The FDA is currently reviewing this device for market clearance as a Humanitarian Device. Cyberkinetics first filed a Humanitarian Device Exemption, or HDE, application for the Andara OFS device in February 2007. Since February 2007, Cyberkinetics has amended its HDE application twice in response to letters from the FDA requesting additional information, with the most recent amendment submitted in March 2008. 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 will 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 Andara OFS device is designed to be implanted in muscle tissue adjacent to the spinal column with electrical leads attached to the tissue next to the vertebrae, above and below the spinal cord injury. Testing indicates it can be implanted in an hour or less by a spine surgeon during the acute phase of treatment and is consistent with other surgical treatments for spinal cord injury. We believe that approximately one third of the estimated 11,000 individuals that suffer spinal cord injuries per year in the United States may be candidates for the Andara OFS device. Because currently there are no approved treatments for acute spinal cord injury, we believe that if it is approved for use in humans, the Andara OFS device may become the standard of care for such injuries.

#### **Competition**

There are a number of companies that sell neurodiagnostic devices. These companies include Cardinal Healthcare (acquired Viasys Healthcare Inc. in 2007), Cadwell Laboratories, Inc. Natus (acquired Xltec, Inc. in 2007) and Neumed, Inc. Cardinal Healthcare has substantially greater financial resources than we do. Cardinal Healthcare and Cadwell Laboratories, Inc. have established a reputation as an effective worldwide distribution channel 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, who we expect to work on our products, to agree to disclose and assign to us all inventions conceived during the work day, 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, 2008, we had 20 issued U.S. patents, 26 issued foreign patents and 42 pending patent applications, including 28 U.S. applications, seven International PCT applications and ten foreign national applications.

Our issued design patents begin to expire in 2015, and our issued utility patents begin to expire in 2017. In particular, seven of our issued U.S. utility patents covering important aspects of our current products will expire on the same date in 2017. Although the patent protection for material aspects of our products covered by the claims of the patents will be lost at that time, we have additional patents and patent applications directed to other novel inventions that will have patent terms extending beyond 2017.

In connection with the acquisition of certain technological and intellectual property assets of Cyberkinetics 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 a patent infringement claim 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**

Reimbursement from third-party payers is an important element of success for medical products companies. We anticipate that sales volumes and prices of our products will continue to be dependent in large part on the availability of reimbursement for our customers from third-party payers and on policies issued by governmental agencies. Third-party payers include governmental programs such as Medicare and Medicaid, private insurance plans, and workers' compensation plans. These organizations may deny coverage and refuse reimbursement for a diagnostic procedure or specific product such as our neuropathy diagnostic system, the NC-stat System, if they determine that the diagnostic test or product was not medically appropriate, reasonable or necessary. Tests will be considered not medically reasonable or necessary if they are deemed "investigational" (i.e. there is insufficient evidence of efficacy or accuracy.) The third-party payers may also attempt to place limitations on the types of physicians that can perform specific types of diagnostic procedures. Also, third-party payers are increasingly challenging the prices charged for medical products and services. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted payment ceilings on specific product lines and procedures. We cannot assure you that procedures using our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payers, that procedures performed using our products will be reimbursed as separate procedures under existing reimbursement codes, that an adequate level of reimbursement will be available or that the third-party payers' coverage and reimbursement policies will not adversely affect our ability to sell our products profitably.

As our presence in the market has expanded, we have experienced and are likely to continue to experience an increased focus from third-party payers and governmental agencies regarding the reimbursement of nerve conduction studies performed using the NC-stat System and an increased focus from these organizations regarding the professional requirements for performing nerve conduction studies in general. A number of third-party payers, including commercial payers, have taken and may continue to take the position of not reimbursing our customers for their use of the NC-stat System.

There are sixteen organizations serving as local insurance carriers that, on behalf of Medicare, process claims submitted by physician practice groups and other healthcare providers and establish what are called local coverage determinations, or LCDs. In the absence of a position issued by Medicare at the national level, the LCDs issued by these local insurance carriers govern the reimbursement of procedures performed using medical devices such as the NC-stat System. During the second half of 2006 and in 2007, several local Medicare carriers issued draft LCDs, final LCDs or coding articles specifically addressing coverage and reimbursement policies under Medicare for nerve conduction studies performed using the NC-stat System or other automated nerve conduction equipment. Several of these carriers indicated that they will not reimburse physicians under Medicare for nerve conduction studies performed using the NC-stat System under the three existing Current Procedural Terminology, or CPT, codes for conventional nerve conduction studies (95900, 95903 and 95904) but rather that physicians must submit claims for reimbursement for these procedures under a miscellaneous CPT code (95999), in which case the local carriers may determine the level of reimbursement to be paid, if any. CPT codes are used in the submission of claims to insurers, including the CMS, for reimbursement for medical services. CPT codes are assigned, maintained and revised by the CPT Panel. There are three local Medicare carriers with final LCDs, one local Medicare carrier with a draft LCD, and one local Medicare carrier with a coding article which address coverage and reimbursement policies under Medicare for nerve conduction studies performed using the NC-stat System. One additional Medicare carrier, which had previously issued a final LCD, reversed their position effective June 30, 2007. In certain regions impacted by these reimbursement decisions, our customers have experienced lower levels of reimbursement and higher levels of claims denials. If physicians do not receive adequate reimbursement under the miscellaneous CPT code from those local carriers, our existing customers may



continue to limit or curtail their use of the NC-stat System and we may be unable to obtain new customers, both of which could materially and adversely impact our revenues and profitability.

The CPT Panel has been reviewing the reimbursement coding for nerve conduction studies and formed a work group in early 2007 to examine the reimbursement coding of nerve conduction studies performed using nerve conduction equipment, including the NC-stat System. The findings of this work group were presented to the CPT Panel at a meeting in February 2008. At this meeting, the CPT Panel approved a Category III code describing nerve conduction studies performed with pre-configured electrode arrays. However, prior to publishing a new Category III CPT code for nerve conduction studies, the CPT Panel decided to reconsider its decision. In October 2008, the CPT Panel again considered nerve testing as an agenda item and, at this meeting voted on a new Category I CPT code for nerve conduction studies performed with pre-configured electrode arrays, such as are utilized with the NC-stat System. The outcome of the most recent vote was first made public in January 2009 when the CPT Panel minutes from the October 2008 meeting were reported by a financial analyst. We expect that the new code will be published in the Federal Register in the second half of 2009 for implementation on January 1, 2010. Before this new CPT code is implemented, the amount of reimbursement that physicians will receive under the code will need to be determined. CMS will determine the RVUs on which the amount of reimbursement is based and publish the final RVUs in the Federal Register—usually in October for implementation January 1 the next year. This CPT code, when issued, may improve our customers' ability to submit claims efficiently and for these claims to be processed expeditiously and may help to stabilize the process for obtaining reimbursement under Medicare for nerve conduction studies performed using the NC-stat System.

The LCDs and coding articles issued by local Medicare carriers have also addressed a number of other issues, including (1) the background and training of physicians supervising or performing nerve conduction studies, (2) the level of training requirements for technicians performing a nerve conduction study, (3) whether nerve conduction tests should be required to be performed concomitantly with a needle electromyography procedure and (4) whether the NC-stat System is comparable to conventional nerve conduction testing equipment. We do not believe that these LCDs prohibit physicians from receiving reimbursement under Medicare for medically necessary nerve conduction studies performed using the NC-stat System. However, these LCDs do appear to be targeted at limiting access to perform and/or reimbursement for nerve conduction studies. In certain cases, these LCDs are being interpreted or implemented in a manner that impacts the ability of physicians to receive reimbursement under Medicare, including lower levels of reimbursement and an increase in the number of claims being denied, for nerve conduction studies performed using the NC-stat System, which is having an adverse impact on our revenues.

Additionally, a significant number of commercial payers, including the majority of regional Blue Cross Blue Shield carriers, and other major private payers, have adopted general policies indicating that they will not provide reimbursement for the use of the NC-stat System. These general policies are not followed in every situation, and may be impacted by other factors such as specific arrangements with insured persons or physicians and any local or regional policies these payers have in place; however, we believe these general policies are negatively impacting the use of the NC-stat System by existing customers and our sales to new customers, both of which are having an adverse impact on our revenues. These commercial payers have cited various reasons for their reimbursement policies, including, among others, that the NC-stat System is experimental and investigational. We have been communicating with these payers, directly, through our customers or through our network of reimbursement consultants, to attempt to address their concerns. Third-party payers may also impose requirements on physicians to submit additional paperwork supporting the medical necessity of nerve conduction studies performed using the NC-stat System. We believe these requirements are negatively impacting the use of the NC-stat System by existing customers and our sales to new customers, both of which are having an adverse impact on our revenues.

Additional third-party payers, including local Medicare carriers and commercial payers, could potentially take a position that could reduce or eliminate the reimbursement procedures performed using our products and could have the impact of deterring usage by our customers and could have an adverse impact on our revenues.

In the United States, some insured individuals are receiving their medical care through managed care programs, which monitor and often require pre-approval of the services that a member will receive. Some managed care programs are paying their providers on a per capita basis, which puts the providers at financial risk for the services provided to their patients by paying these providers a predetermined payment per member per month, and consequently, may limit the willingness of these providers to use our products.

We believe that the overall escalating cost of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry to reduce the costs of products and services. We cannot assure you that third-party reimbursement and coverage will be available or 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. In addition, we believe that pressure is being applied to payer organizations by specialists, such as neurologists, who perform traditional nerve conduction studies and view the NC-stat System as competitive with their business.

Our success in selling the ADVANCE System will be dependent, among other things, on our customers' receiving, and our potential customers' belief that they will receive, sufficient reimbursement from third-party payers for performing procedures using the ADVANCE System. We do not believe that the final LCDs or policies adopted by major private payers impacting reimbursement for procedures performed using the NC-stat System will apply to procedures performed by specialists with peripheral nerve expertise using the ADVANCE System. However, these final LCDs and policies are subject to the interpretation of, and may be modified by, the applicable third-party payer, whose interpretations may differ from ours. Additionally, the outcome of the ongoing process with the CPT Panel regarding reimbursement coding of nerve conduction studies could impact future reimbursement of procedures performed 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 U.S. Federal Food, Drug, and Cosmetic Act, or FDCA, and the regulations promulgated thereto, as well as other regulatory bodies in the United States and abroad. The FDA classifies medical devices into one of three classes on the basis of 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 in intended use, safety and effectiveness 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 yet 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 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 510(k) clearance, *de novo* classification or PMA is obtained or take other action.

### *De Novo Review Process*

If a previously unclassified 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 yet 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 *de novo* classification into Class I or II. The FDA then has 60 days in which to classify the device. If the FDA grants *de novo* classification, the device will be placed into either Class I or Class II, and allowed to be marketed. If a product is classified into Class I or 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 file a PMA application. The PMA process generally requires more extensive pre-filing testing than is required in the 510(k) pre-market notification process and is more costly, lengthy and uncertain. 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 there is a reasonable assurance of the safety and effectiveness of the device to the FDA's satisfaction through extensive submissions, including pre-clinical and clinical trial data, and information about the device, its design, manufacture, labeling and components. Before granting 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 regulations.

If FDA grants 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 Quality System Regulation, or QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other 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 if their device 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 governing 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 invasive electromyography procedures.

The NC-stat System has received six 510(k) clearances as a Class II medical device, the first of which was received in 1998, and the most recent in July 2006. The NC-stat System's stated intended use is to stimulate and measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies.

We believe that this intended use is consistent with the manner in which the NC-stat System is marketed and used by our customers.

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. We have recently responded to the third additional information request that we have received from the FDA relating to this filing.

#### *Manufacturing Facilities*

The facilities utilized by Parlex and Sunburst, two of our contract manufacturers, to supply our products have each been inspected by FDA in the past, and observations were noted. There were no findings that involved a significant violation of regulatory requirements. The responses to these observations have been accepted by FDA and we believe that we are in substantial compliance with the QSR. Like all manufacturers, we expect our contract manufacturers to be inspected by FDA again in the future. If FDA finds significant violations, we could be subject to fines, recalls, requirements to halt manufacturing or other administrative or judicial sanctions.

#### *U.S. Anti-Kickback and False Claims Laws*

In the United States, there are federal and state anti-kickback laws that 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 medical devices. Other provisions of state and federal law provide civil and criminal penalties for presenting, or causing to be presented, to third-party payers for reimbursement, claims that are false or fraudulent, or which are for items or services that were not provided as claimed. Under the federal civil 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. As described in more detail in the section titled “Legal Proceedings,” we have been subject to investigations by the OIG and the DOJ of various aspects of our practices related to the NC-stat System.

### **Employees**

As of December 31, 2008, we had a total of 95 employees. Of the total employees, 23 were in research and development, 48 in sales and marketing and 24 in general and administrative services. One employee holds both M.D. and Ph.D. degrees, six additional employees hold Ph.D. degrees and one additional employee holds an M.D. degree.

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

### **Available Information**

We were organized as a corporation in the state of Delaware in 1996. 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](http://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](http://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.



## 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.*

### **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, including net losses of approximately \$3.9 million in 2003 and \$4.7 million in 2004. In 2005 and 2006, we recorded net income of approximately \$0.3 million and \$4.3 million, respectively. However, we incurred a net loss of approximately \$8.4 million in 2007 and \$27.7 million in 2008 as a result of a decline in revenues and increases in operating expenses and other charges. At December 31, 2008, we had an accumulated deficit of approximately \$89.8 million. We cannot assure you that we will be able to reach profitability again and sustain profitability.

### **Disruption in global financial markets could have a negative effect on our business.**

Global financial markets have been experiencing extreme disruption in recent months, resulting in extreme volatility in security prices and severely diminished liquidity and availability of credit and equity capital. There can be no assurance that there will not be a further deterioration in financial markets, which may lead to challenges in the operation of our business including challenges to our manufacturers or suppliers. The current tightening of credit in financial markets adversely affects the ability of customers and suppliers to obtain financing for significant purchases and operations and could result in decrease in demand for our products and services. In the near-term we may seek to raise additional funds through alternative sources such as issuance of equity, debt or strategic alliance. Given the disruption in global financial markets these funds may not be available on favorable terms, or at all.

### **If physicians or other healthcare providers are unable to obtain sufficient reimbursement from third-party healthcare payers for procedures performed using our products, the adoption of our products and our future product sales will be severely harmed.**

Widespread adoption of our products by the medical community is unlikely to occur if physicians do not receive sufficient reimbursement from third-party payers for performing procedures using our products. If physicians are unable to obtain adequate reimbursement for procedures performed using our products, we may be unable to sell our products and our business would suffer significantly. Additionally, even if these procedures are reimbursed by third-party payers, adverse changes in payers' policies toward reimbursement for the procedures would harm our ability to market and sell our products. Third-party payers include those governmental programs such as Medicare and Medicaid, workers' compensation programs, private health insurers and other organizations. These organizations may deny coverage if they determine that a procedure was not reasonable or necessary, for example, if its use was not considered medically appropriate, or was experimental, or was performed for an unapproved indication. In addition, some health care systems are moving towards managed care arrangements in which they contract to provide comprehensive healthcare for a fixed cost per person, irrespective of the amount of care actually provided. These providers, in an effort to control healthcare costs, are increasingly challenging the prices charged for medical products and services and, in some

instances, have pressured medical suppliers to lower their prices. If we are pressured to lower our prices, our revenues may decline and our profitability could be harmed. CMS guidelines set the reimbursement rates for procedures covered by Medicare. Future regulatory action by CMS or other governmental agencies or negative clinical results may diminish reimbursement payments to physicians for performing procedures using our products. Medicaid reimbursement differs from state to state, and some state Medicaid programs may not reimburse physicians for performing procedures using our products in an adequate amount, if at all. Additionally, some private payers do not follow the CMS and Medicaid 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.

During the second half of 2006 and in 2007, several local Medicare carriers issued draft LCDs, final LCDs or coding articles particularly addressing coverage and reimbursement policies under Medicare for nerve conduction studies performed using the NC-stat System. Several of these carriers indicated that they will not reimburse physicians under Medicare for nerve conduction studies performed using the NC-stat System under the three existing Current Procedural Terminology, or CPT, codes for conventional nerve conduction studies (95900, 95903 and 95904), which provide for levels of reimbursement fixed by CMS, but rather that physicians must submit claims for reimbursement for these procedures under a miscellaneous CPT code (95999), in which case the local carriers may determine the level of reimbursement to be paid, if any. Currently, there are three local Medicare carriers with final LCDs, one local Medicare carrier with a draft LCD, and one local Medicare carrier with a coding article which address coverage and reimbursement policies under Medicare for nerve conduction studies performed using the NC-stat System. One additional Medicare carrier, which had previously issued a final LCD, reversed their position effective June 30, 2007. In certain regions impacted by these reimbursement decisions, our customers have experienced lower levels of reimbursement and higher levels of claims denials. If physicians do not receive adequate reimbursement under the miscellaneous CPT code from those local carriers, our existing customers may continue to limit or curtail their use of the NC-stat System and we may be unable to obtain new customers, both of which could materially and adversely impact our revenues and profitability.

The CPT Panel has been reviewing the reimbursement coding for nerve conduction studies and formed a work group in early 2007 to examine the reimbursement coding of nerve conduction studies performed using nerve conduction equipment, including the NC-stat System. The findings of this work group were presented to the CPT Panel at a meeting in February 2008. At this meeting, the CPT Panel approved a Category III code describing nerve conduction studies performed with pre-configured electrode arrays. However, prior to publishing a new Category III CPT code for nerve conduction studies, the CPT Panel decided to reconsider its decision. In October 2008, the CPT Panel again considered nerve testing as an agenda item and, at this meeting, voted on a new Category I CPT code for nerve conduction studies performed with pre-configured electrode arrays, such as are utilized with the NC-stat System. The outcome of this most recent vote was first made public in January 2009 when a financial analyst reported on the CPT Panel's minutes from its October 2008 meeting. We expect that the new code will be published in the Federal Register in the second half of 2009 for implementation on January 1, 2010. Before this new CPT code is implemented, the amount of reimbursement that physicians will receive under the code will need to be determined. CMS will determine the RVUs on which the amount of reimbursement is based and publish the final RVUs in the Federal Register—usually in October for implementation January 1 the next year. This CPT code, when issued, may improve our customers' ability to submit claims efficiently and for these claims to be processed expeditiously and may help to stabilize the process for obtaining reimbursement under Medicare for nerve conduction studies performed using the NC-stat System.

The final status and form of a new code that describes nerve conduction studies performed using the NC-stat System is uncertain until the CPT Panel formally publishes any new code or series of new

codes. Until a new code has been published and the reimbursement values established there could be an adverse impact on reimbursement by other third party payers and could have an adverse and material impact on our revenues and results of operations.

The LCDs and coding articles issued by local Medicare carriers have also addressed a number of other issues, including (1) the background and training of physicians supervising or performing nerve conduction studies, (2) the level of training requirements for technicians performing a nerve conduction study, (3) whether nerve conduction tests should be required to be performed concomitantly with a needle electromyography procedure and (4) whether the NC-stat System is comparable to conventional nerve conduction testing equipment. We do not believe that these LCDs prohibit physicians from receiving reimbursement under Medicare for medically necessary nerve conduction studies performed using the NC-stat System. However, these LCDs do appear to be targeted at limiting access to perform and/or reimbursement for nerve conduction studies. In certain cases, these LCDs are being interpreted or implemented in a manner that impacts the ability of physicians to receive reimbursement under Medicare, including lower levels of reimbursement and an increase in the number of claims being denied, for nerve conduction studies performed using the NC-stat System, which are having an adverse impact on our revenues.

Additionally, a significant number of commercial payers, including the majority of regional Blue Cross Blue Shield carriers, and other major private payers, have adopted policies indicating that they will not provide reimbursement for the use of the NC-stat System. These commercial payers have cited various reasons for their reimbursement policies, including, among others, that the NC-stat System is experimental and investigational. We are in the process of communicating with these payers, directly, through our customers or through our network of reimbursement consultants, to attempt to address their concerns. Third-party payers may also impose requirements on physicians to submit additional paperwork supporting the medical necessity of nerve conduction studies performed using the NC-stat System. We believe these requirements are negatively impacting the use of the NC-stat System by existing customers and our sales to new customers, both of which are having an adverse impact on our revenues.

Additional third-party payers, including local Medicare carriers and commercial payers, could potentially take a position that could reduce or eliminate the reimbursement for the NC-stat System and could have the impact of deterring usage by our customers and could have an adverse impact on our revenues.

If the LCDs adopted or reimbursement determinations adopted in the future relating to the reimbursement of nerve conduction studies place additional restrictions or qualifications on the performance of these procedures generally or using the NC-stat System, our business, revenues and profitability could be materially adversely affected. Additionally, in the short-term, the uncertainty caused by these changes, or other future changes, in third-party payers' reimbursement policies regarding nerve conduction studies may cause existing customers to reduce their use of the NC-stat System and potential new customers to defer a decision or decline to purchase the NC-stat System, which could materially adversely affect our business. We are expending and anticipate continuing to expend substantial resources to address potential reimbursement issues with third-party payers. Widespread adoption of the NC-stat System by the medical community is unlikely to occur if physicians do not receive satisfactory reimbursement from third-party payers for procedures performed with the NC-stat System. Our success in selling the ADVANCE System will be dependent, among other things, on our customers' receiving, and our potential customers' belief that they will receive, sufficient reimbursement from third-party payers for performing procedures using the ADVANCE System. We do not believe that the final LCDs or policies adopted by major private payers impacting reimbursement for procedures performed using the NC-stat System will apply to procedures performed by specialists with peripheral nerve expertise using the ADVANCE System. However, these final LCDs and policies are subject to the interpretation of, and may be modified by, the applicable third-party payer, whose

interpretations may differ from ours. Additionally, the outcome of the ongoing process with the CPT Panel regarding reimbursement coding of nerve conduction studies could impact future reimbursement of procedures performed using the ADVANCE System.

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

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

- third-party payers challenging, or the threat of third-party payers challenging, the necessity of increased levels of nerve conduction studies;
- third-party payers reducing or eliminating reimbursement for procedures performed by physicians using the NC-stat System;
- unfavorable experiences by physicians using the NC-stat or ADVANCE System;
- physicians' reluctance to alter their existing practices; and
- the failure of other companies' existing drug development programs to produce an effective treatment for DPN, which may limit the perceived need and the actual use of the NC-stat System in connection with this disease, and thereby limit or delay our growth in the DPN market, which we have estimated to be our largest potential market for our NC-stat System.

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

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

We are focusing our sales and marketing efforts for the NC-stat System on primary care physicians and the ADVANCE System to specialist physicians. We may be unable to convince these physicians that our products provide effective diagnostic solutions. In addition, these physicians may be reluctant to make the capital investment required to purchase the NC-stat System or ADVANCE System. If we are unable to successfully sell our products to primary care physicians and specialist physicians, our ability to increase our revenues will be severely limited.

**We are dependent on several single source manufacturers to produce the NC-stat and ADVANCE Systems and any changes in the relationships with these manufacturers could prevent us from delivering products to our customers in a timely manner and may adversely impact our future revenues or costs.**

We rely on third-party manufacturers to manufacture all of the components of the NC-stat and ADVANCE Systems. In the event that our manufacturers cease to manufacture sufficient quantities of our products in a timely manner and on terms acceptable to us, we would be forced to locate alternate manufacturers. Additionally, if our manufacturers experience a failure in their production process, are unable to obtain sufficient quantities of the components necessary to manufacture our products or otherwise fail to meet our quality requirements, we may be forced to delay the manufacture and sale of our products or locate an alternative manufacturer. We may be unable to locate suitable alternative manufacturers for our products, particularly our electrodes, for which the manufacturing process is relatively specialized, on terms acceptable to us, or at all. We have entered into an exclusive manufacturing and supply agreements with Parlex for the manufacture of the electrodes, and Sunburst for the manufacture of our NC-stat and ADVANCE monitors, docking stations and communication hubs.

We do occasionally experience transient inventory shortages on new products during the initial production ramp-up phase. If any of the changes in our relationships with these manufacturers as described above occurs, 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 our products in substantial quantities, 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 NC-stat and ADVANCE Systems 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 NC-stat System to the market in May 1999 and the ADVANCE System in May 2008. We derive substantially all of our revenues from sales of the products that comprise these two systems, and we expect that sales of these products 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 NC-stat and ADVANCE Systems, particularly electrodes, sales of which accounted for approximately 86-91% 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;
- decisions made by the CPT Panel relating to the reimbursement of nerve conduction studies performed using the NC-stat System;
- Medicare reimbursement rate established for a potential new Category I CPT Code for nerve conduction studies performed with pre-configured electrode arrays, such as are utilized with the NC-Stat 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 studies relating to our products or our competitors' products.

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



**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. Our patent position is generally uncertain and involves complex legal and factual questions. 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.

**We are subject to extensive regulation by the FDA, which could restrict the sales and marketing of the NC-stat or ADVANCE Systems 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 for 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 receive 510(k) clearance, grant of a *de novo* classification or pre-marketing approval from the FDA, unless an exemption applies. Medical devices may be marketed only for the indications for which they are approved or cleared. We may also be required to obtain a new 510(k) clearance, *de novo* classification or PMA for significant post-market modifications to our products including changes to the intended use. Each of these processes can be expensive and lengthy. The FDA's process for granting 510(k) clearance usually takes approximately three months, but it can be significantly longer. The process for obtaining *de novo* classification involves a level of scrutiny similar to the 510(k) clearance process, but may require more data. The process for obtaining PMA is much more costly and uncertain and it generally takes from one to three years, or longer, from the time the application is filed with the FDA.

Our clearances can be rescinded 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 occur or if the FDA takes other administrative or judicial actions, 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. In particular, our business could be adversely impacted in the event that we do not obtain 510(k) clearance for the portions of the onCall Information System that are the subject of our 510(k) filing in the fourth quarter of 2006. Because the portions of the onCall Information System under review are currently in use, if the FDA does not clear them, we may be required to modify or remove the portions of the onCall Information System that are under review. Any such modifications could make the NC-stat System more time consuming for physicians, which could adversely impact our ability to generate revenues from the NC-stat System, or more expensive for us to operate. Either of these could have a material adverse impact on our business.

We also are subject to numerous post-marketing regulatory requirements, including 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, which may include any of the following sanctions:

- warning letters, fines, injunctions, product seizures, consent decrees and civil penalties;
- requiring repair, replacement, refunds, notifications or recall of our products;
- imposing operating restrictions, suspension or shutdown of production;
- refusing our requests for 510(k) clearance or PMA of new products, new intended uses, or modifications to existing products;
- rescinding 510(k) clearances or withdrawing PMAs 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.

**If the FDA does not approve the HDE application for our recently acquired Andara™ OFS™ System, we will not be able to market this system in the United States.**

In September 2006, the FDA designated the Andara™ OFS™ device as a HUD, a designation based on a potential U.S. patient population of less than 4,000 patients per year. As the second of two steps in the HUD approval process, Cyberkinetics filed a HDE application in February 2007. Approval of the HDE by the FDA requires that we demonstrate the device would 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.

In May 2007, the FDA sent Cyberkinetics a letter informing them that it had completed an initial scientific review of the application and indicating that it required additional information to determine if the device meets the statutory criteria for approval. In response to the FDA's letter, Cyberkinetics amended the HDE application in July 2007. In December 2007, the FDA sent a letter indicating that it had completed an initial scientific review of the July amendment and that it required additional information to determine if the device met the statutory criteria for approval. The letter requested additional information related to clinical data, study analysis, biocompatibility, sterilization, device description, and labeling. In February 2008, Cyberkinetics met with members of the FDA review staff, including the Director and Deputy Director of the division responsible for the HDE review, regarding Cyberkinetics HDE application. Following this meeting, in March 2008, Cyberkinetics submitted an amendment addressing the specific questions contained in the December 2007 letter from the FDA.

The FDA's review of the HDE application is ongoing, and we cannot provide any assurance that (1) Cyberkinetics' responses will be satisfactory to the FDA or that we would not have to conduct additional significant, lengthy and expensive clinical trials or satisfy other requirements before the FDA would grant its approval to market the Andara™ OFS™ device, or (2) the FDA will ever grant such approval. If the FDA does not grant its approval, we will not be able to market the Andara™ OFS™ device in the United States.

**If we or the manufacturers of our products fail to comply with the FDA's quality system regulations, 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 regulations, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our devices. The FDA enforces its quality system regulations through periodic inspections. We cannot assure you that our facilities or the facilities of the manufacturers of our products would pass any future quality system inspection. If our or any of the facilities of the manufacturers of our products fail a quality system 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 quality system 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 bodies 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 NC-stat or ADVANCE Systems would be particularly harmful to our business and financial results because the products that comprise the NC-stat and ADVANCE Systems 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 Medicare/Medicaid anti-kickback law, and several similar state laws, prohibit 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 healthcare 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 healthcare programs. 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.

As described in more detail in the section titled “Legal Proceedings,” in February 2009, 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 NC-stat or ADVANCE Systems may be susceptible to claims of injury because they involve 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, President and Chief Executive Officer; 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 95 employees as of December 31, 2008, 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 do not effectively manage our future potential growth, our business resources may become strained, we may not be able to deliver our products in a timely manner and our results of operations may be adversely affected.**

Future potential growth of our business may provide challenges to our organization and may strain our management and operations. We may misjudge the amount of time or resources that will be required to effectively manage any anticipated or unanticipated growth in our business or we may not be able to attract, hire and retain sufficient personnel to meet our needs. If we cannot scale our business appropriately, maintain control over expenses or otherwise adapt to anticipated and unanticipated growth, our business resources may become strained, we may not be able to deliver our products in a timely manner and our results of operations may be adversely affected.

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

As of December 31, 2008, we employed approximately 28 regional sales managers, three regional sales directors and a Vice President of Sales. We are highly dependent on our regional sales managers to generate our revenues. Our ability to build and develop a strong sales force will be affected by a number of factors, including:

- our ability to attract, integrate and motivate sales personnel;
- our ability to effectively train our sales force;
- the ability of our sales force 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 sales organization;
- our ability to enter into agreements with prospective members of our sales force 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 sales force, our revenues may decline, our revenue growth may be limited and our expenses may increase.

**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, 2008, the majority of our revenues were derived from selling the NC-stat and ADVANCE Systems. Our future business and financial success will depend, in part, on our ability to continue to introduce or sell new products 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/nEMG equipment including Cardinal Healthcare, having acquired Viasys Healthcare Inc. in 2007, Cadwell Laboratories, Inc. and Natus, having acquired Xltec, Inc. in 2007. Additionally, we are aware of one company, Neumed, Inc., that markets a nerve conduction study system to the point-of-service market. Of these companies, Cardinal Healthcare, 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 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 future capital needs are uncertain and we may need to raise additional funds in the future, and these funds may not be available on acceptable terms or at all.**

We believe that our current cash and cash equivalents together with our short-term investments and the cash to be generated from expected product sales will be sufficient to meet our projected operating requirements for at least the next 12 months. However, we may seek additional funds from public and private stock offerings, borrowings under credit lines or other sources. Our capital requirements 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 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. On January 20, 2009, for example, we acquired certain assets of Cyberkinetics.

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.

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

We had our initial revenues in the United Kingdom in the third quarter of 2007, representing our initial launch in Europe and had initial revenues in Latin America in 2008, representing our initial launch in Latin America. If we continue to expand, or attempt 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.

**Our operating results may fluctuate due to various factors and, as a result, period-to-period comparisons of our results of operations will not necessarily be meaningful.**

Factors relating to our business make our future operating results uncertain and may cause them to fluctuate from period to period. These factors include:

- changes in the availability of third-party reimbursement in the United States or other countries;
- the timing of new product announcements and introductions by us or our competitors;
- market acceptance of new or enhanced versions of our products;
- changes in manufacturing costs or other expenses;
- competitive pricing pressures;
- the gain or loss of significant distribution outlets or customers;
- increased research and development expenses;
- the timing of any future acquisitions; or

- general economic conditions.

Because our operating results may fluctuate from quarter to quarter, it may be difficult for us or our investors to predict our future performance by viewing our historical operating results.

**Anti-takeover provisions in our organizational documents and Delaware law, and those anti-takeover provisions adopted by the Company 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 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 (an “acquiring person”) could suffer substantial dilution of its ownership interest under the terms of the Shareholder Rights Plan through the issuance of common stock to all shareholders 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.

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

We are currently involved in various pending and potential legal proceedings, including a class action lawsuit and a shareholders derivative 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 to engage in improper business practices. If we are ultimately unsuccessful in any of these matters, 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.

**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 any future debt or credit facility may preclude 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.

**Our shares may be delisted from the NASDAQ Global Market if the closing price for our shares is not maintained at \$1.00 per share or higher.**

NASDAQ imposes, among other requirements, listing maintenance standards as well as minimum bid and public float requirements. The price of our common stock must trade at or above \$1.00 per share to comply with NASDAQ's minimum bid requirement for continued listing on the NASDAQ Global Market. In recent months, our common stock has traded at below \$1.00 per share at closing for an extended period of time.

In response to current market conditions, NASDAQ has suspended its enforcement of the rules regarding a minimum closing bid price until April 20, 2009. If the closing bid price of our common stock fails to meet NASDAQ's minimum bid price requirement for 30 consecutive business days on or after April 20, 2009, or such later date to which NASDAQ may extend its suspension of this requirement, or if we otherwise fail to meet all other applicable requirements of the NASDAQ Global Market, NASDAQ may make a determination to delist our common stock. Any such delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease and could also adversely affect our ability to obtain financing for the continuation of our operations and/or result in the loss of confidence by stockholders.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

We have not received written comments from the SEC regarding our periodic or current reports under the Securities and Exchange Act of 1934, as amended, 180 days or more before December 31, 2008 that remain unresolved.

**ITEM 2. PROPERTIES**

Our headquarters is located in a 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 pursuant to Section 13 or 15(d) under the Securities Act, 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 alleges, among other things, that between October 27, 2005 and February 12, 2008, 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 are seeking 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. In March 2009, the parties mutually agreed to participate in mediation to attempt to resolve the litigation, and



the court entered an order staying the proceedings until the mediation is complete. A mediation is currently scheduled for June 2009.

As previously disclosed in our filings with the SEC pursuant to Section 13 or 15(d) under the Securities Act, 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. The complaint alleges, among other things, that, between August 2004 and the date the action was filed, the defendants engaged in the same conduct alleged in the putative securities class actions, causing us to make false and misleading statements, to fail to disclose material information to the public and to engage in improper business practices. The plaintiffs are seeking various forms of monetary and non-monetary relief. In March 2009, the parties agreed to participate in mediation to attempt to resolve the litigation, currently scheduled for June 2009.

The litigation process is inherently uncertain, and we cannot guarantee that the outcomes of the above lawsuits will be favorable for us or that they will not be material to our business, results of operations or financial position.

On February 9, 2009, we announced that we had reached a resolution with the DOJ and OIG regarding the previously-disclosed investigation into certain of our past sales and marketing practices relating to our NC-stat System. We had been cooperating with the investigation since it began in 2006.

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, or the Settlement Agreement, dated February 9, 2009, with the DOJ and OIG. 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 do 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 the OIG. We remain fully eligible to participate in all federal health care programs.

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

#### **ITEM 4: SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

No matters were submitted to a vote of our security holders during the fourth quarter of the year ended December 31, 2008, through the solicitation of proxies or otherwise.

## 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 closing sales prices of our common stock as reported by NASDAQ for the periods indicated.

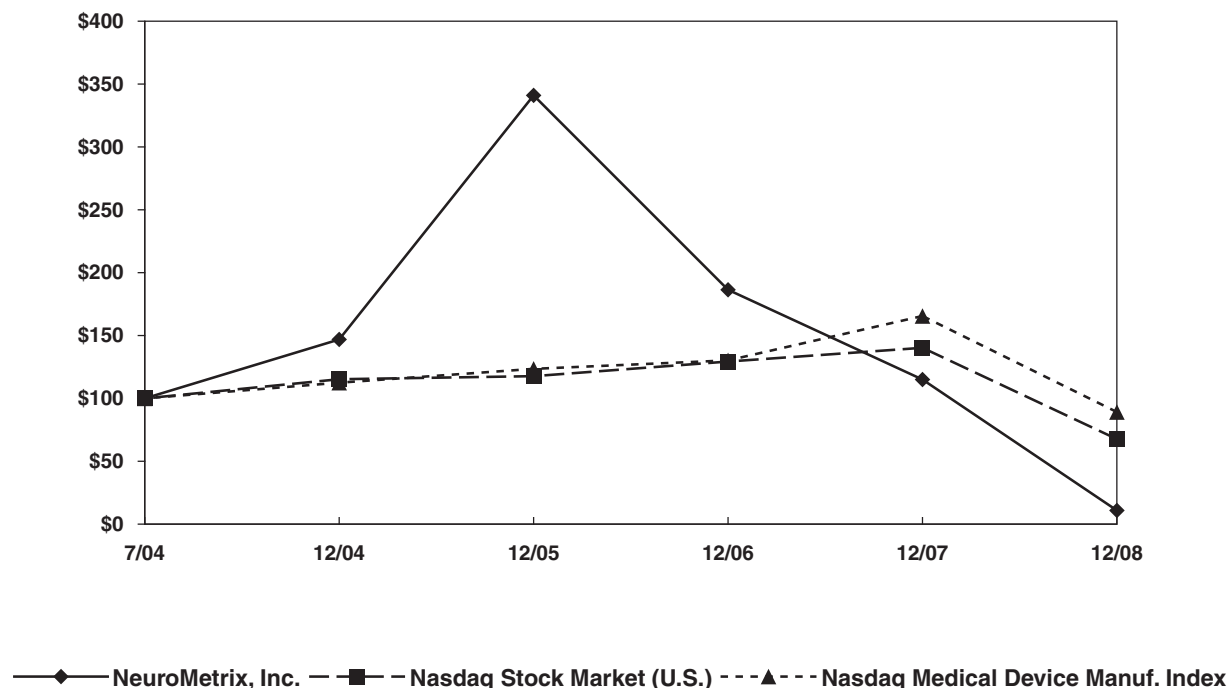
	Years ended December 31,			
	2008		2007	
	High	Low	High	Low
First quarter . . . . .	\$10.97	\$1.67	\$14.50	\$9.25
Second quarter . . . . .	\$ 2.83	\$1.40	\$10.76	\$8.62
Third quarter . . . . .	\$ 1.88	\$0.96	\$ 9.12	\$7.25
Fourth quarter . . . . .	\$ 1.30	\$0.52	\$10.25	\$7.79

On March 6, 2009, there were approximately 124 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 6, 2009, the last reported sale price per share of our common stock on the NASDAQ Global Market was \$1.20.

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.

## COMPARATIVE STOCK PERFORMANCE GRAPH

The following graph shows the cumulative stockholder return of our common stock from July 22, 2004 (the first trading day for our common stock) through December 31, 2008 as compared with that of the NASDAQ (U.S. Companies) Index and the NASDAQ Medical Device Manufacturers Index. The total stockholder return is measured by dividing the per share price change of the respective securities, plus dividends, if any, for each period shown by the share price at the end of the particular period. The graph assumes the investment of \$100 in our common stock and each of the comparison groups on July 22, 2004 and assumes the reinvestment of dividends. We have never declared a dividend on our common stock. The stock price performance depicted in the graph below is not necessarily indicative of future price performance.



	<u>07/22/04</u>	<u>12/31/04</u>	<u>12/31/05</u>	<u>12/31/06</u>	<u>12/31/07</u>	<u>12/31/08</u>
NeuroMetrix, Inc. . . . .	\$100.00	\$146.88	\$341.00	\$186.38	\$115.00	\$10.88
Nasdaq Stock Market (U.S.) . . . . .	\$100.00	\$115.25	\$117.69	\$129.32	\$140.24	\$67.63
Nasdaq Medical Device Manuf. Index . . . .	\$100.00	\$112.49	\$123.50	\$130.24	\$165.52	\$89.14

## 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, of which certain columnar subtotal amounts found in the table below may not sum due to rounding:

	Years Ended December 31,				
	2008	2007	2006	2005	2004
	(In thousands, except share and per share data)				
<b>Statement of Operations Data:</b>					
Revenues . . . . .	\$ 31,121	\$ 43,667	\$55,250	\$34,298	\$ 17,920
Costs and expenses:					
Cost of revenues, excluding amortization . . . . .	9,012	11,338	13,558	8,858	4,853
Research and development . . . . .	5,257	4,892	5,011	3,821	3,268
Sales and marketing . . . . .	14,647	22,837	22,014	14,150	8,488
General and administrative . . . . .	12,016	14,834	11,805	8,022	5,267
Charge for impaired goodwill . . . . .	5,833	—	—	—	—
Charge for legal settlement . . . . .	3,706	—	—	—	—
Charge for intangible asset impairment . . . . .	1,768	—	—	—	—
Gain on deconsolidation of joint venture . . . . .	(2,100)	—	—	—	—
Amortization of intangible assets . . . . .	333	—	—	—	—
Total costs and expenses . . . . .	50,471	53,901	52,388	34,851	21,876
Income (loss) from continuing operations . . . . .	(19,350)	(10,233)	2,862	(553)	(3,956)
Loss on available-for-sale investment . . . . .	(2,500)	—	—	—	—
Interest income (expense), net . . . . .	721	1,751	1,598	837	(750)
Income (loss) from continuing operations before provision for income taxes . . . . .	(21,129)	(8,482)	4,460	284	(4,706)
Provision for income taxes . . . . .	—	—	193	35	—
Income (loss) from continuing operations . . . . .	(21,129)	(8,482)	4,267	249	(4,706)
Income (loss) from discontinued operations . . . . .	(6,601)	104	—	—	—
Net income (loss) . . . . .	(27,730)	(8,378)	4,267	249	(4,706)
Accretion of dividend on redeemable convertible preferred stock . . . . .	—	—	—	—	(1,386)
Deemed dividend on redeemable convertible preferred stock . . . . .	—	—	—	—	(788)
Beneficial conversion feature associated with redeemable convertible preferred stock . . . . .	—	—	—	—	(7,051)
Net income (loss) attributable to common stockholders . . . . .	<u>\$(27,730)</u>	<u>\$(8,378)</u>	<u>\$ 4,267</u>	<u>\$ 249</u>	<u>\$(13,932)</u>
Net income (loss) per common share from continuing operations:					
Basic . . . . .	\$ (1.54)	\$ (0.67)	\$ 0.34	\$ 0.02	\$ (2.42)
Diluted . . . . .	\$ (1.54)	\$ (0.67)	\$ 0.33	\$ 0.02	\$ (2.42)
Net income (loss) per common share from discontinued operations:					
Basic . . . . .	\$ (0.48)	\$ 0.01	\$ —	\$ —	\$ —
Diluted . . . . .	\$ (0.48)	\$ 0.01	\$ —	\$ —	\$ —
Net income (loss) per common share:					
Basic . . . . .	\$ (2.02)	\$ (0.66)	\$ 0.34	\$ 0.02	\$ (2.42)
Diluted . . . . .	\$ (2.02)	\$ (0.66)	\$ 0.33	\$ 0.02	\$ (2.42)

	As of December 31,				
	2008	2007	2006	2005	2004
	(in thousands)				
<b>Balance Sheet Data:</b>					
Cash and cash equivalents . . . . .	\$ 12,302	\$ 7,097	\$ 7,910	\$ 8,170	\$ 1,936
Short-term investments . . . . .	7,495	22,622	32,411	24,082	18,575
Working capital . . . . .	21,632	33,304	41,894	33,268	21,774
Long-term investments . . . . .	—	1,058	—	—	9,497
Total assets . . . . .	31,378	56,375	55,706	42,897	37,953
Long-term debt and other long-term liabilities . .	52	33	73	131	189
Accumulated deficit . . . . .	(89,796)	(62,066)	(53,687)	(57,955)	(58,204)
Total stockholders' equity . . . . .	22,833	46,730	43,409	34,833	33,330

## 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. As a result of many factors, such as those set forth under the section titled "Risk Factors" and elsewhere in this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements.*

### Overview

NeuroMetrix was founded in June 1996. We are a science-based medical device company advancing patient care through the development and commercialization of innovative products that aid physicians in the assessment, treatment, and repair of peripheral nerve and spinal cord injuries and disorders, and that provide regional anesthesia and pain control. To date, our focus has been on products that help physicians with the diagnosis or detection of neuropathies and neurovascular disorders. Neuropathies affect the peripheral nerves and parts of the spine and are frequently caused by or associated with CTS, diabetes, sciatica, and other clinical disorders. We market systems for the performance of nerve conduction studies and needle electromyography procedures.

We have two medical devices cleared by FDA that are used for the assessment of neuropathies. The first device is the ADVANCE™ NCS/EMG System a comprehensive platform for the performance of traditional nerve conduction studies and invasive electromyography procedures. This system is used primarily by neurologists, physical medicine and rehabilitation (PM&R) physicians, neurosurgeons, orthopedic and hand surgeons and pain medicine physicians. The ADVANCE System is a system for the performance of traditional nerve conduction studies and needle electromyography procedures. The ADVANCE System is comprised of: (1) single use surface 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 our onCall Information System for data archiving, report generation and other network services. The second device is the NC-stat System, an automated device for the performance of nerve conduction studies. The NC-stat System, our first product for the assessment of neuropathies, has been sold historically to a broad group of physicians, including primary care physicians and specialists since its initial market launch in May 1999. The NC-stat System is comprised of: (1) disposable single use electrodes, (2) the NC-stat monitor and related components and (3) the NC-stat docking station, an optional device that enables the physician's office to transmit data to our onCall Information System. Our neurodiagnostic equipment is used in over five thousand physician offices, clinics and hospitals. Over one and a half million patients have been tested with our neurodiagnostic equipment since 1999.

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

Substantially all of our revenues to date have been derived from sales of the NC-stat System. Due to reimbursement uncertainty described in further detail below, we are presently focusing our medical equipment sales efforts primarily on sales of the ADVANCE System to specialist physicians with peripheral nerve expertise. We continue to sell electrodes to and support our NC-stat System customer base, work with our existing NC-stat System customers in specialty practices to convert them to the ADVANCE System and provide solutions that enable our customers to provide this important diagnostic service to their patients.

### *Business Developments*

Our revenues declined to \$31.1 million for the twelve months ended December 31, 2008 compared to \$43.7 million for the same period in 2007. Additionally, we incurred a net loss of \$27.7 million for the twelve months ended December 31, 2008 compared to net loss of \$8.4 million for the same period in 2007. We believe that the decline in our revenues has been caused primarily by the current environment relating to the reimbursement by third-party payers of nerve conduction studies performed using the NC-stat System and we expect that our revenues from sales of the NC-stat System may continue to be adversely affected by the uncertainty regarding reimbursement.

As of the year ended December 31, 2008, significant developments impacting and relating to our financial condition and results of operations which we expect to impact future periods, include:

- Reimbursement developments relating to nerve conduction studies on our revenues as described below, including the outcome of the CPT Panel review of reimbursement coding for nerve conduction studies performed using equipment such as the NC-stat System and the Medicare reimbursement rate to be established for a potential new Category I CPT Code for nerve conduction studies performed with pre-configured electrode arrays, such as are utilized with the NC-Stat System.
- The launch of the ADVANCE System, a system for the performance of traditional nerve conduction studies and needle electromyography procedures, which occurred in May 2008 following the 510(k) clearance by the FDA. We are primarily focusing our sales and marketing efforts for the ADVANCE System on specialist physicians with peripheral nerve expertise, including neurologists, physical medicine and rehabilitation physicians, neurosurgeons, orthopedic and hand surgeons and pain medicine physicians in the United States.
- The discontinuance of sales, support and marketing efforts for the DigiScope effective November 1, 2008.
- The reduction in the size of the sales force from 50 regional sales managers to approximately 30 regional sales managers and certain other cost reduction steps taken during the second quarter of 2008. These steps were taken largely as a result of a decline in revenues we have experienced. We expect that our operating expenses will be reduced by approximately \$5.0 million on an annualized basis, as a result of these actions, compared to operating expense levels prior to these actions being taken. In addition, our decision to terminate the relationships with our independent sales agencies in the second half of 2007, which we believe has adversely impacted our revenues, but has resulted in the elimination of commissions on recurring revenues from accounts originally sourced through our independent sales agencies. Total commissions relating to independent sales agencies were \$0 and \$3.0 million for the twelve months ended December 31, 2008 and 2007, respectively. Our sales and marketing expenses have declined



\$8.2 million in the twelve months ended December 31, 2008 as compared to the same period in 2007. We believe these cost reduction programs were the primary drivers.

- The government investigations by the OIG and DOJ, that we were subject to, which resulted in significantly increased legal expenses from historical levels in 2007 and in the twelve months of 2008. On February 9, 2009, the Company announced that it had reached a resolution with the OIG and DOJ regarding the previously-mentioned investigation into certain of the Company's past sales and marketing practices relating to its NC-stat System.

For a more detailed description of the resolution, see the section titled "Legal Proceedings."

- Continued progress developing a product designed to precisely deliver pharmacologic agents such as anesthetics and corticosteroids in close proximity to nerves for regional anesthesia, pain control and the treatment of focal neuropathies such as CTS for which we have submitted a 510(k) application to the FDA on the signal detector in December 2008, and expect to file an application on the stimulator for the device in the first quarter of 2009. We continue to invest resources on the development of this product.
- The investment we made in Cyberkinetics in the fourth quarter of 2007, which included the purchase of \$2.5 million of Cyberkinetics common stock and the receipt of 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 an HDE filing for the Andara OFS device for acute spinal cord injuries by December 31, 2008, which they did not. Cyberkinetics, in its Form 8-K filed on November 3, 2008, disclosed that its existing cash and cash equivalents were only sufficient to meet their projected operating requirements for approximately 30 days. As Cyberkinetics was in the process of winding down operations, the value of the Company's investment in Cyberkinetics was adversely affected. We believe that this decline is not temporary in nature, and have therefore taken a charge of \$2.5 million to earnings for the decline in value through December 31, 2008. We had entered into a joint venture with Cyberkinetics for the development of a treatment for peripheral nerve injury, for which we had committed to fund the first \$2.0 million in development expenses and 50% of any development costs exceeding the initial \$2.0 million. During the fourth quarter of 2008 the joint venture with Cyberkinetics was dissolved which resulted in deconsolidation of the entity from the consolidated financial statements. In January 2009, we acquired certain technological and intellectual property assets from Cyberkinetics for \$350,000 in cash.

Reimbursement from third-party payers is an important element of success for medical device companies. As our presence in the market over the last several years has expanded with the use of the NC-stat System, physicians using NC-stat have experienced and may continue to experience an increased focus from third-party payers and governmental agencies regarding the reimbursement of nerve conduction studies performed using this device and an increased focus from these organizations regarding the professional requirements for performing nerve conduction studies in general. A number of third-party payers, including commercial payers, have taken and may continue to take the position of not reimbursing our customers for procedures performed using the NC-stat System.

During the second half of 2006 and in 2007, several local Medicare carriers issued draft local coverage determinations, or LCDs, final LCDs or coding articles particularly addressing coverage and reimbursement policies under Medicare for nerve conduction studies performed using the NC-stat System. Several of these carriers indicated that they will not reimburse physicians under Medicare for nerve conduction studies performed using the NC-stat System under the three existing Current Procedural Terminology, or CPT, codes for conventional nerve conduction studies (95900, 95903 and 95904), which provide for levels of reimbursement fixed by the CMS but rather that physicians must submit claims for reimbursement for these procedures under a miscellaneous CPT code (95999), in which case the local carriers may determine the level of reimbursement to be paid, if any. Currently,

there are four local Medicare carriers with final LCDs which address coverage and reimbursement policies under Medicare for nerve conduction studies performed using the NC-stat System. In certain regions impacted by these reimbursement decisions, our customers have experienced lower levels of reimbursement and higher levels of claims denials. If physicians do not receive adequate reimbursement under the miscellaneous CPT code from those local carriers, our existing customers may continue to limit or curtail their use of the NC-stat System and we may be unable to obtain new customers, both of which could materially and adversely impact our revenues and profitability.

The CPT Panel has been reviewing the reimbursement coding for nerve conduction studies and formed a work group in early 2007 to examine the reimbursement coding of nerve conduction studies performed using nerve conduction equipment, including the NC-stat System. The findings of this work group were presented to the CPT Panel at a meeting in February 2008. At this meeting, the CPT Panel approved a Category III code describing nerve conduction studies performed with pre-configured electrode arrays. However, prior to publishing a new Category III CPT code for nerve conduction studies, the CPT Panel decided to reconsider its decision. In October 2008, the CPT Panel again considered nerve testing as an agenda item and, at this meeting, approved a new Category I CPT code for nerve conduction studies performed with pre-configured electrode arrays, such as are utilized with the NC-stat System. This most recent decision was first made public in February 2009 when the CPT Panel released the final approved minutes from its October 2008 meeting. We expect that the new code will be published in the Federal Register in the second half of 2009 for implementation on January 1, 2010. Before this new CPT code is implemented, the amount of reimbursement that physicians will receive under the code will need to be determined. CMS will determine the RVUs on which the amount of reimbursement is based and publish the final RVUs in the Federal Register—usually in October for implementation January 1 the next year. This CPT code, when issued, may improve our customers' ability to submit claims efficiently and for these claims to be processed expeditiously and may help to stabilize the process for obtaining reimbursement under Medicare for nerve conduction studies performed using the NC-stat System.

The LCDs and coding articles issued by local Medicare carriers have also addressed a number of other issues, including (1) the background and training of physicians supervising or performing nerve conduction studies, (2) the level of training requirements for technicians performing a nerve conduction study, (3) whether nerve conduction tests should be required to be performed concomitantly with a needle electromyography procedure and (4) whether the NC-stat System is comparable to conventional nerve conduction testing equipment. We do not believe that these LCDs prohibit physicians from receiving reimbursement under Medicare for medically necessary nerve conduction studies performed using the NC-stat System. However, these LCDs do appear to be targeted at limiting access to perform and/or reimbursement for nerve conduction studies. In certain cases, these LCDs are being interpreted or implemented in a manner that impacts the ability of physicians to receive reimbursement under Medicare, including lower levels of reimbursement and an increase in the number of claims being denied, for nerve conduction studies performed using the NC-stat System, which are having an adverse impact on our revenues.

Our success in selling the ADVANCE System will be dependent, among other things, on our customers' receiving, and our potential customers' belief that they will receive, sufficient reimbursement from third-party payers for performing procedures using the ADVANCE System. We do not believe that the final LCDs or policies adopted by major private payers impacting reimbursement for procedures performed using the NC-stat System will apply to procedures performed by specialists with peripheral nerve expertise using the ADVANCE System. However, these final LCDs and policies are subject to the interpretation of, and may be modified by, the applicable third-party payer, whose interpretations may differ from ours. Additionally, the outcome of the ongoing process with the CPT Panel regarding reimbursement coding of nerve conduction studies could impact future reimbursement of procedures performed using the ADVANCE System.

Additionally, a significant number of commercial payers, including the majority of regional Blue Cross Blue Shield carriers, and other major private payers, have adopted policies indicating that they will not provide reimbursement for the use of the NC-stat System. These commercial payers have cited various reasons for their reimbursement policies, including, among others, that the NC-stat System is experimental and investigational. We are in the process of communicating with these payers directly, through our customers or through our network of reimbursement consultants, to attempt to address their concerns. Third-party payers may also impose requirements on physicians to submit additional paperwork supporting the medical necessity of nerve conduction studies performed using the NC-stat System. We believe these requirements are negatively impacting the use of the NC-stat System by existing customers and our sales to new customers, both of which are having an adverse impact on our revenues.

Additional third-party payers, including local Medicare carriers and commercial payers, could potentially take a position that could reduce or eliminate the reimbursement for nerve conduction studies performed with the NC-stat System and could have the impact of deterring usage by our customers which could have an adverse impact on our revenues.

In the second quarter of 2008, we received 510(k) clearance from the FDA for the marketing in the United States of the ADVANCE System, a system for the performance of traditional nerve conduction studies and needle electromyography procedures. The ADVANCE System was cleared by the FDA with the primary predicate, or comparable, device being the Keypoint device originally manufactured and marketed by Medtronic, Inc. to neurologists and physical medicine and rehabilitation physicians for the performance of nerve conduction studies and needle electromyography procedures. The ADVANCE System is a traditional system that supports nerve conduction testing with any electrode methodology, real-time waveform review and cursor editing, needle electromyography procedures and conventional reports with the results of the testing. We launched our sales and marketing efforts for the ADVANCE System to specialists with peripheral nerve expertise such as neurologists, physical medicine and rehabilitation physicians, neurosurgeons, orthopedic and hand surgeons and pain medicine physicians in May 2008. Our success in selling the ADVANCE System will be dependent, among other things, on our customers' receiving, and our potential customers' belief that they will receive, sufficient reimbursement from third-party payers for performing procedures using the ADVANCE System. We do not believe that the final LCDs or policies adopted by major private payers impacting reimbursement for procedures performed using the NC-stat System will apply to procedures performed by specialists with peripheral nerve expertise using the ADVANCE System. However, these final LCDs and policies are subject to the interpretation of, and may be modified by, the applicable third-party payer, whose interpretations may differ from ours. Additionally, the outcome of the ongoing process with the CPT Panel regarding reimbursement coding of nerve conduction studies could impact future reimbursement of procedures performed using the ADVANCE System.

One of the primary challenges we face in our business is successfully expanding the market for nerve conduction studies and needle electromyography procedures. A successful market expansion will depend upon, in part, our targeting of specialist physicians with peripheral nerve expertise. Historically, our strategy had been to sell our neuropathy assessment systems through a combination of independent sales agencies and a direct sales force of experienced sales representatives. Due to a significant decline in the percentage of new customers being sourced through our independent sales agency network in 2007, we eliminated the independent sales agencies in the second half of 2007 and focused our selling efforts exclusively through our direct sales force. We believe the decision to terminate the independent sales agency relationships has contributed to the decline in revenues and could potentially have an adverse impact on our revenues and our ability to secure new customers in future periods as well.

We reduced the size of our direct sales force in the second quarter of 2008 to approximately 30 regional sales managers from the previous level of approximately 50 regional sales managers. We took this action to reduce our sales and marketing expenses as a result of the decline in revenues we have

experienced and due to our expectation that there will be further declines in revenues over the next several quarters. This action resulted in a charge for severance and benefit costs of \$318,981 in the second quarter of 2008 and we expect that this action, coupled with other cost reduction steps taken, will reduce our operating expenses by approximately \$5.0 million on an annualized basis compared to operating expense levels prior to these actions being taken. During the remainder of 2008, our direct sales force was primarily focused on sales of our ADVANCE System to specialist physicians with peripheral nerve expertise and on sales of electrodes to, and account management of, our existing customer base. In March 2009, we reorganized our sales force into three market segments: (1) neurology, which includes neurologists and PM&R physicians, (2) neurointerventional, which includes neurosurgeons, orthopedic surgeons, pain medicine physicians, and anesthesiologists, and (3) physician office, which includes primary care physicians, internal medicine physicians, endocrinologists, rheumatologists and occupational medicine physicians. We are pursuing this realignment in order to effectively distribute and commercialize our products as we continue to diversify our product offering. As a part of this realignment, our vice president of sales departed March 4, 2009, and we are looking to hire an experienced executive to oversee our overall sales function.

Our business is currently facing significant challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected due to changes in our estimated future revenues, changes we make to our ongoing operating expenses, future changes in our business strategy, decisions we make regarding the size of our sales force and the magnitude of our sales and marketing programs, research and development spending plans and other items affecting our level of expenditures and our use of existing cash and cash equivalents and short-term investments. Accordingly, we may need to raise additional funds to support our operating and capital needs. Without additional funds, we may be forced to delay, scale back or eliminate some of our sales and marketing efforts, research and development activities or other operations and potentially delay our product development efforts. We may attempt to obtain additional funding through public or private financing, collaborative arrangements with strategic partners or through credit lines or other debt financing sources to increase the funds we have available to us to fund our operations. However, there are no assurances that we will be able to secure such financing on favorable terms, if at all.

#### *Discontinued Operations*

In December 2007, we acquired substantially all of the assets of EyeTel and their product, the DigiScope, a product used for the detection of eye disorders such as diabetic retinopathy, an eye disease prevalent in patients with diabetes for total consideration of approximately 1.1 million shares of our newly issued common stock and \$175,000 in cash. Prior to acquiring EyeTel and during 2007, we had previously entered into an exclusive licensing agreement with EyeTel pursuant to which we had sales and marketing rights to the DigiScope in the primary diabetes care physician market. On September 30, 2008, as part of our ongoing focus on cost-efficiencies in all areas of our business, and our refocused efforts towards our core business, which is the sale of the ADVANCE System and support for our existing NC-stat System customers, we approved a plan for the closure of our facility in Columbia, Maryland and 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 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. The CEO and President of Advanced Diagnostics, LLC is a former executive of ours who continues to receive payments under a separation agreement with us.

Net revenue, income (loss) from operations, and (loss) on sale for discontinued operations for the years ended December 31, 2008 and 2007 are as follows:

	<u>Years Ended December 31,</u>	
	<u>2008</u>	<u>2007</u>
Net revenue . . . . .	\$ 1,095,754	\$954,935
Operating income (loss) from discontinued operations . . . . .	(1,999,937)	103,986
Loss on sale of discontinued operations . . . . .	(4,600,736)	—
Net income (loss) from discontinued operations . . . . .	<u>\$(6,600,673)</u>	<u>\$103,986</u>

### *Business Focus*

Our long-term financial objectives are to grow our business through the sale of proprietary medical equipment and to achieve and sustain profitability. However, during 2009 our revenues are likely to remain flat or decrease from total revenues recognized in the year 2008, we are likely to continue to incur losses as a result of the reimbursement and other issues we are currently facing and there are no assurances that we will achieve these objectives over the longer term. We expect to focus our efforts for 2009 on (1) sales of the ADVANCE System to specialist physicians with peripheral nerve expertise, (2) sales of the NC-stat System, including sales of electrodes to, and on-going account management of, our existing NC-stat System customer base, (3) efforts to stabilize third-party reimbursement for procedures performed with the NC-stat System, (4) seeking regulatory clearance from the FDA for portions of the onCall Information System, and (5) our ongoing research and development programs.

Our launch of the ADVANCE System took place in May 2008 following 510(k) clearance by the FDA for marketing the ADVANCE System in the United States. In September 2008, we also received 510(k) clearance for our Universal Electrodes which are consumables designed to be used in conjunction with our ADVANCE System. During the fourth quarter of 2006, at the request of the FDA, we submitted a 510(k) filing relating to the onCall Information System which is currently in use. The 510(k) is still pending before the FDA. If 510(k) clearance for the portions of the onCall Information System that are under review is not obtained, it may require additional product development and potential changes in the configuration of the NC-stat System and onCall Information System, and the status of our currently distributed products using the onCall Information System may be uncertain. The portions of the onCall System under review through this 510(k) filing do not impact use of the ADVANCE System.

During 2009, we expect our research and development programs to (1) make improvements to and develop accessories and new consumables for our existing products, (2) continue to develop our system for regional anesthesia and pain control, for which we have submitted a 510(k) application to the FDA on the signal detector in December 2008 and expect to file on the stimulator for the device in the first quarter of 2009, and (3) to develop our neural repair and regeneration pipeline which includes the Andara OFS device for treatment of acute spinal cord injury, a device to stimulate peripheral nerve regeneration, and derivatives of the pharmacologic agent 4-aminopyridine, depending on the amount of R&D funding available during 2009.



## Results of Operations

The following table presents certain statement of operations information stated as a percentage of total revenues, of which certain columnar subtotal amounts found in the table below may not sum due to rounding:

	Years Ended December 31,		
	2008	2007	2006
Revenues:			
Medical equipment . . . . .	8.7%	9.7%	13.6%
Consumables . . . . .	91.3	90.3	86.4
Total revenues . . . . .	100.0	100.0	100.0
Costs and expenses:			
Cost of revenues, excluding amortization . . . . .	29.0	26.0	24.5
Research and development . . . . .	16.9	11.2	9.1
Sales and marketing . . . . .	47.1	52.3	39.8
General and administrative . . . . .	38.6	34.0	21.4
Charge for impaired goodwill . . . . .	18.7	—	—
Charge for settlement . . . . .	11.9	—	—
Charge for intangible asset impairment . . . . .	5.7	—	—
Gain from deconsolidation of joint venture . . . . .	(6.7)	—	—
Amortization of intangible assets . . . . .	1.1	—	—
Total operating expenses . . . . .	162.2	123.4	94.8
Income (loss) from continuing operations . . . . .	(62.2)	(23.4)	5.2
Loss on available-for-sale investment . . . . .	(8.0)	—	—
Interest income, net . . . . .	2.3	4.0	2.9
Income (loss) from continuing operations before provision for income taxes . . . . .	(67.9)	(19.4)	8.1
Provision for income taxes . . . . .	—	—	0.3
Income (loss) from continuing operations . . . . .	(67.9)	(19.4)	7.7
Income (loss) from discontinued operations . . . . .	(21.2)	0.2	—
Net income (loss) . . . . .	(89.1)%	(19.2)%	7.7%

## Comparison of Years Ended December 31, 2008 and December 31, 2007

### Continuing Operations

#### Revenues

The following tables present a breakdown of our customers, consumables units used, revenues, costs and expenses and net loss, of which certain columnar subtotal amounts found in the table below may not sum due to rounding:

	Years Ended December 31,			
	2008	2007	Change	% Change
Active NC-stat and ADVANCE Customers . . . . .	5,189	5,555	(366)	(6.6)%
Nerve specific electrode units used . . . . .	809,900	1,055,500	(245,600)	(23.3)



	Years Ended December 31,			
	2008	2007	Change	% Change
	(in thousands, except percentage data)			
Revenues:				
Medical equipment . . . . .	\$ 2,709.1	\$ 4,254.0	\$ (1,544.9)	(36.3)%
Consumables . . . . .	28,411.7	39,413.3	(11,001.6)	(27.9)
Total revenues . . . . .	\$31,120.8	\$43,667.3	\$(12,546.5)	(28.7)

Medical equipment revenues consisting of the NC-stat devices, NC-stat docking stations and ADVANCE devices and related modules, which we began to market and sell in May 2008, were \$2.7 million and \$4.3 million for the years ended December 31, 2008 and 2007, respectively, representing a decrease of \$1.5 million, or 36.3%. This decrease is primarily attributable to a lower number of NC-stat Systems sold and a decrease in the average selling price of the NC-stat System, which we believe resulted primarily from uncertainty and adverse developments relating to the reimbursement for procedures performed, partially offset by ADVANCE System sales. Also contributing to this decline was our decision to reduce our direct sales force by approximately 40% in May 2008, and our decision to terminate our relationships with all independent sales agencies during the second half of 2007. Medical equipment revenues accounted for 8.7% and 9.7% of our total revenues for the years ended December 31, 2008 and 2007, respectively.

Consumables revenues consisting of single use nerve specific electrodes which are used with our NC-stat System and our ADVANCE System and disposable EMG concentric needles, which are used with our ADVANCE System, were \$28.4 million and \$39.4 million for the years ended December 31, 2008 and 2007, respectively, representing a decrease of \$11.0 million, or 27.9%. This decrease is attributable to lower sales of consumables and average selling price of the electrodes and needles, which we believe resulted primarily from uncertainty and adverse developments relating to the reimbursement for procedures performed with the NC-stat System, partially offset by ADVANCE System electrodes sales. Consumables revenue accounted for 91.3% and 90.3% of our total revenues for the years ended December 31, 2008 and 2007, respectively.

Our customers used 809,900 nerve specific electrodes in the year ended December 31, 2008, compared to 1,055,500 nerve specific electrodes in the year ended December 31, 2007, a decrease of 245,600 nerve specific electrodes, or 23.3%. This decrease in nerve specific electrodes usage is primarily the result of a decline in the average usage per customer and a decrease in our active customer base. During the 12-month period ending December 31, 2008, a total of 5,189 customers used our NC-stat and ADVANCE Systems compared to 5,555 customers for the same period in 2007. This represents a 6.6% year-over-year decrease in the number of customers that used our NC-stat or ADVANCE Systems. The average usage per account declined 17.9% to 156 nerve specific electrodes for the year ended December 31, 2008 from 190 nerve specific electrodes for the same period in 2007.

We anticipate that total revenues in 2009 will remain flat or decrease from total revenues recognized in the year 2008. Our revenues for 2009 are likely to be impacted by (a) the level of reimbursement established for procedures performed using the NC-stat System by insurance carriers and other third-party payers; (b) the level of reimbursement for procedures performed using the ADVANCE System; (c) whether final LCDs are applied in a manner that places additional restrictions or qualifications on the performance of these procedures; (d) any other reimbursement determinations relating to nerve conduction studies that may be issued by third-party payers; and (e) any other events causing uncertainty as to the existence or amount of reimbursement physicians are likely to receive for performing procedures using our nerve conduction product offerings. Separately, we expect revenues to be positively impacted by expanded sales and marketing efforts for our launch of the ADVANCE System and the anticipated launch of our ASCEND product. Overall, revenues could be impacted by a

variety of factors, including the level of demand for our products, potential for changes in third-party reimbursement for nerve conduction studies, the overall economy, competitive factors and the factors described in the section of this Annual Report on Form 10-K titled “Risk Factors.”

### *Costs and Expenses*

The following table presents our costs and expenses and net loss of which certain columnar subtotal amounts found in the table below may not sum due to rounding:

	<b>Years Ended December 31,</b>			
	<b>2008</b>	<b>2007</b>	<b>Change</b>	<b>% Change</b>
	<b>(in thousands, except percentage data)</b>			
Cost of revenues:				
Cost of medical equipment revenues . . . . .	\$ 1,232.6	\$ 915.8	\$ 316.8	34.6%
Cost of consumables revenues . . . . .	7,779.4	10,422.1	(2,642.7)	(25.4)
Research and development . . . . .	5,256.7	4,891.9	364.8	7.5
Sales and marketing . . . . .	14,646.9	22,836.9	(8,189.9)	(35.9)
General and administrative . . . . .	12,016.1	14,834.1	(2,817.9)	(19.0)
Charge for impaired goodwill . . . . .	5,833.5	—	5,833.5	N/A
Charge for legal settlement . . . . .	3,705.9	—	3,705.9	N/A
Charge for intangible assets impairment . . . . .	1,767.5	—	1,767.5	N/A
Gain from deconsolidation of joint venture . . . . .	(2,100.0)	—	(2,100.0)	N/A
Amortization of intangible assets . . . . .	332.5	—	332.5	N/A
Total costs and expenses . . . . .	50,471.1	53,900.7	(3,429.6)	(6.4)
Loss from continuing operations . . . . .	(19,350.3)	(10,233.4)	(9,116.9)	89.1
Loss from available-for-sale investment . . . . .	(2,500.0)	—	(2,500.0)	N/A
Interest income . . . . .	720.9	1,751.0	(1,030.0)	(58.8)
Loss from continuing operations . . . . .	(21,129.4)	(8,482.5)	(12,646.9)	149.1
Income (loss) from discontinued operations . . . . .	(6,600.7)	104.0	(6,704.7)	(6,447.7)
Net loss . . . . .	<u>\$(27,730.0)</u>	<u>\$ (8,378.5)</u>	<u>\$(19,351.6)</u>	<u>231.0%</u>

### *Cost of Revenues*

Cost of medical equipment revenues increased to \$1.2 million, or 45.5% of medical equipment revenues, for the year ended December 31, 2008, as compared to \$915,800, or 21.5% of medical equipment revenues, for the same period in 2007. The increase in the cost of medical equipment revenues and the cost of medical equipment revenues as a percentage of medical equipment revenues is primarily attributable to increased discounting, in part, resulting from our introduction of the ADVANCE System, particularly related to the transition of existing NC-stat System customers to the ADVANCE System and the higher cost of revenues of the ADVANCE System as compared to the NC-stat System.

Cost of consumables revenue decreased to \$7.8 million, or 27.4% of consumables revenue, for the year ended December 31, 2008, as compared to \$10.4 million, or 26.4% of consumables revenue, for the same period in 2007. The decrease in the cost of consumables revenue is primarily attributable to lower sales volumes. The increase in the cost of consumables revenues as a percentage of consumables revenue is primarily attributable to higher discounting resulting in a decrease of their average selling price.

Our overall cost of revenues decreased to \$9.0 million, or 29.0% of revenues, for the year ended December 31, 2008, compared to \$11.3 million, or 26.0% of revenues for the same period in 2007.

Our cost of revenues as a percentage of revenues may continue to increase during 2009 compared to the corresponding period in 2008 due to the continued transition of existing NC-stat System customers to the ADVANCE System and its higher cost of revenues as compared to the NC-stat System.

#### *Research and Development*

Our research and development (R&D), expenses include expenses associated with our research, product development, clinical, regulatory, and quality assurance departments.

R&D expenses increased \$364,800, or 7.5%, to \$5.3 million for the year ended December 31, 2008 from \$4.9 million for the same period in 2007. As a percentage of revenues, R&D expenses were 16.9% and 11.2% for the years ended December 31, 2008 and 2007, respectively. The increase in expenses was primarily due to an increase of \$242,400 in employee compensation and benefit costs primarily attributable to the hiring of additional employees for our product development efforts. Also contributing to the change in expenses are (a) an increase of \$98,900 in outside development costs; (b) an increase of \$25,000 in recruiting expenses attributable to the hiring of additional employees; and (c) an increase of \$19,700 in stock-based compensation expense. These amounts were offset by a decrease of \$130,600 in consulting expenses.

We expect our spending on R&D will be relatively unchanged in 2009 as compared to the level of expenses for 2008. This amount may vary, however, depending on the opportunities and challenges that arise during the year of 2009 as well as availability of funding.

#### *Sales and Marketing*

Our sales and marketing expenses include expenses from the marketing, field sales, sales administration and inside sales departments.

Sales and marketing expenses decreased \$8.2 million, or 35.9%, to \$14.6 million for year ended December 31, 2008 from \$22.8 million for the year ended December 31, 2007. As a percentage of revenues, sales and marketing expenses were 47.1% and 52.3% for the years ended December 31, 2008 and 2007, respectively. The decrease in expenses was primarily due to (a) a decrease of \$3.5 million in employee compensation and benefit costs primarily attributable to the decrease in commissions, bonuses and salaries resulting from the reduction of the size of our direct sales force in May 2008; (b) a decrease of \$3.0 million in third-party sales commissions due to our decision to terminate our relationships with all independent sales agencies and focus our selling efforts exclusively through our direct sales force; (c) a decrease of \$450,500 in stock compensation expense; (d) a decrease of \$409,300 in consulting services due to less activity involving our reimbursement matters; (e) decreases of \$269,800 in recruiting expenses and \$266,500 in travel expenses both attributable to the reduction of our direct sales force; (f) a decrease of \$243,400 in advertising costs, largely attributable to a 2007 sales promotion; and (g) a decrease of \$139,600 in telephone related expenses.

We expect sales and marketing expenses to remain relatively unchanged during 2009 as compared to the level of expenses for 2008. However, as a significant portion of our sales and marketing expenses is comprised of commissions to our direct sales force, this may vary depending on our revenues for 2009. Additionally, sales and marketing expenses may increase slightly as a result of our realignment of our U.S. sales operations.

#### *General and Administrative*

Our general and administrative expenses include expenses from the executive, finance, administrative, customer service, and information technology departments.

General and administrative expenses decreased \$2.8 million, or 19.0%, to \$12.0 million for the year ended December 31, 2008 from \$14.8 million for the year ended December 31, 2007. As a percentage of revenues, general and administrative expenses were 38.6% and 34.0% for the years ended December 31, 2008 and 2007, respectively. The decrease in expenses was primarily due to a decrease of \$3.4 million in professional fees primarily resulting from decreased legal fees, particularly relating to the government investigations by the OIG and the DOJ that we were subject to, a decrease of \$411,500 in stock compensation expense and a decrease of \$132,400 in credit card fees. These amounts were offset by increased sales tax expense of \$1.2 million partially attributable to the reversal of a \$1.7 million sales tax liability as a result of receiving amnesty from a number of states and receiving relief from other states in the form of a limited look back period and waiver of penalties that occurred during the second quarter of 2007.

We believe our general and administrative expenses will decrease in 2009, due to reduced legal fees, as a result of the DOJ and OIG settlement.

#### *Charge for Impaired Goodwill*

We perform impairment tests related to our goodwill, which resulted from our acquisition of EyeTel in December 2007, under Statement of Financial Accounting Standards No. 142, “*Goodwill and Other Intangible Assets*,” or SFAS No. 142, annually and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable, such as the decline in the market capitalization of our common stock that occurred during the first quarter of 2008. Subsequent to the AMA CPT Panel meeting in February 2008, our common stock price declined significantly such that as of March 31, 2008, our publicly traded market value was significantly below our net book value. We determined that an interim goodwill impairment test was required. As the net book value of our assets exceeded the enterprise value, we performed step two of the SFAS No. 142 impairment test in which we assessed the fair value of all recorded and unrecorded tangible and intangible assets and liabilities. EyeTel’s operations were incorporated into our one segment and we determined that we are comprised of a single reporting unit for goodwill impairment testing. We determined that there was no residual value of goodwill. Accordingly, we recorded a charge of \$5.8 million to write off goodwill during the first quarter of 2008.

#### *Charge for Settlement*

As of December 31, 2008, we accrued \$3.7 million for the settlement with the DOJ and OIG which is included in “Accrued expenses” on our Balance Sheet at that date and which was subsequently paid in the first quarter of 2009. For a more detailed description of the settlement, see the section titled “Legal Proceedings.”

#### *Asset impairment, gain from deconsolidation of Joint Venture and amortization of intangible assets*

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. The joint venture was included in our consolidated financial statements. Together with Cyberkinetics, we were in the preclinical stage of development of a product for the treatment of peripheral nerve injury using the Andara™ OFS™ (Oscillating Frequency Stimulation) technology licensed by Cyberkinetics. Under the terms of our joint venture agreement with Cyberkinetics, we had 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. Cyberkinetics had agreed to contribute the Andara OFS technology and certain additional technology, know-how and intellectual property. During the fourth quarter of 2008, the joint venture was dissolved and we took a charge of approximately \$1.8 million for the remaining balance of intangible assets representing the value of the technology and intellectual property of the joint venture, which was being amortized over

5 years and as of December 31, 2008, had accumulated amortization of approximately \$0.3 million and booked a gain of \$2.1 million representing our share in the assets of the joint venture on deconsolidation.

#### *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 the Cyberkinetics' issued and outstanding shares at the time of the investment, at a price of \$0.46 per share for a total consideration of \$2.5 million. We also received a warrant to purchase up to approximately 2.7 million shares of Cyberkinetics common stock. The warrant is exercisable at \$0.46 per share and has a term of five years, expiring in November 2012 and would have been required to be exercised if Cyberkinetics received FDA approval of an HDE filing for the Andara OFS device for acute spinal cord injuries by December 31, 2008, which did not occur.

We review the carrying value of this investment periodically to determine whether an other-than-temporary decline in market value exists. We consider factors such as the length of time the value of the investment has been below its original purchase price, the financial condition of the investee and near-term prospects for the investee's recovery to original purchase price and our intent with regard to the underlying investment. Cyberkinetics, in its Form 8-K filed on November 3, 2008, disclosed that its existing cash and cash equivalents were only sufficient to meet their projected operating requirements for approximately 30 days. As Cyberkinetics was in the process of winding down operations, the value of the Company's investment in Cyberkinetics was adversely affected. The Company marked this investment to market as of December 31, 2008 and, taking into account the factors noted above, have recorded year-to-date charges of \$2.5 million because it is believed that the decline in the value of this investment is other-than-temporary. Accordingly, as of December 31, 2008 this investment has been written down to zero.

#### *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 includes loss on operations and sale of assets relating to our discontinued operations. The loss on discontinued operations will not have any income tax benefit.

#### *Interest Income*

Interest income was \$720,900 and \$1.8 million for the years ended December 31, 2008 and 2007, 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, 2008, as compared to the same period a year ago is primarily due to lower average invested balances and lower rates of return.

#### *Provision for Income Taxes*

We recorded no tax provision for the years ended December 31, 2008 and 2007 due to the net loss incurred.

## Comparison of Years Ended December 31, 2007 and December 31, 2006

### Continuing Operations

#### Revenues

The following tables present a breakdown of our customers, consumables units used and revenues of which certain columnar subtotal amounts found in the table below may not sum due to rounding:

	Years Ended December 31,		Change	% Change
	2007	2006		
Active NC-stat and ADVANCE Customers . . . . .	5,555	4,929	626	12.7%
Nerve specific electrode units used . . . . .	1,055,500	1,155,300	(99,800)	(8.6)

	Years Ended December 31,			
	2007	2006	Change	% Change
	(in thousands, except percentage data)			
Revenues:				
Medical equipment . . . . .	\$ 4,254.0	\$ 7,538.3	\$ (3,284.3)	(43.6)%
Consumables . . . . .	39,413.3	47,711.4	(8,298.1)	(17.4)
Total revenues . . . . .	\$43,667.3	\$55,249.7	\$(11,582.4)	(21.0)

Medical equipment revenues were \$4.3 million and \$7.5 million for the years ended December 31, 2007 and 2006, respectively, a decrease of \$3.3 million, or 43.6%. This decrease is primarily attributable to a lower number of units sold, which we believe resulted primarily from uncertainty and adverse developments relating to the reimbursement for procedures performed with the NC-stat System. Medical equipment revenues accounted for 9.5% and 13.6% of our total revenues for the years ended December 31, 2007 and 2006, respectively.

Consumables revenues were \$39.4 million and \$47.7 million for the years ended December 31, 2007 and 2006, respectively, a decrease of \$8.3 million, or 17.4%. This decrease is attributable to lower sales of consumables, which we believe resulted primarily from uncertainty and adverse developments relating to the reimbursement for procedures performed with the NC-stat System. Consumables revenues accounted for 88.3% and 86.4% of our total revenues for the years ended December 31, 2007 and 2006, respectively.

Our customers used 1,055,500 consumables units in the year ended December 31, 2007, compared to 1,155,300 units in the year ended December 31, 2006, a decrease of 99,800 units, or 8.6%. This decrease in consumables usage is primarily the result of a decline in average usage per customer offset in part by an increase in our customer base. During the 12-month period ended December 31, 2007, a total of 5,555 customers used the NC-stat System compared to 4,929 customers for the same period in 2006. This represents a 12.7% year-over-year increase in the number of customers that used our NC-stat System. The average usage per account declined to 190 consumables for the year ended December 31, 2007 from 234 consumables for the same period in 2006.

Our total revenues were \$43.7 million and \$55.2 million for the years ended December 31, 2007 and 2006, respectively, a decrease of \$11.6 million, or 21%. The decline in our total revenues is attributable to the previously mentioned lower number of NC-stat Systems and consumables sold, which we believe resulted primarily from uncertainty and adverse developments relating to the reimbursement for nerve conduction studies performed with the NC-stat System.



### Costs and Expenses

The following table presents our costs and expenses and net income (loss) of which certain columnar subtotal amounts found in the table below may not sum due to rounding:

	Years Ended December 31,			
	2007	2006	Change	% Change
	(in thousands)			
Cost of revenues:				
Cost of medical equipment revenues . . . . .	\$ 915.8	\$ 1,320.5	\$ (404.7)	(30.7)%
Cost of consumables revenues . . . . .	10,422.1	12,237.6	(1,815.5)	(14.8)
Research and development . . . . .	4,891.9	5,010.5	(118.6)	(2.4)
Sales and marketing . . . . .	22,836.9	22,013.7	823.2	3.7
General and administrative . . . . .	14,834.1	11,805.1	3,029.0	25.7
Total costs and expenses . . . . .	53,900.7	52,387.4	1,513.3	2.9
(Loss) income from continuing operations . . . . .	(10,233.4)	2,862.4	(13,095.8)	(457.5)
Interest income . . . . .	1,751.0	1,598.4	152.6	9.5
(Loss) income from continuing operations . . . . .	(8,482.5)	4,460.8	(12,943.3)	(290.2)
Income from discontinued operations . . . . .	104.0	—	104.0	100.0
Provision for income taxes . . . . .	—	193.0	(193.0)	(100.0)
Net (loss) income . . . . .	\$ (8,378.5)	\$ 4,267.8	\$(12,646.3)	(296.3)

### Costs of Revenue

Medical equipment gross margin decreased to \$3.3 million, or 78.5% of medical equipment revenue, for the year ended December 31, 2007, as compared to \$6.2 million, or 82.5% of medical equipment revenue, for same period in 2006. The decrease in the gross margin percentage is primarily attributable to a decrease in the average selling price and the number of devices sold.

Consumables gross margin decreased to \$29.0 million, or 73.6% of consumables revenue, for the year ended December 31, 2007, as compared to \$35.5 million, or 74.4% of consumables revenue, for the same period in 2006. The decrease in the consumables gross margin percentage is primarily due to higher discounts on sales and higher product warranty costs.

### Research and Development

Our R&D expenses include expenses associated with our research, product development, clinical, regulatory, and quality assurance departments.

R&D expenses decreased \$118,600, or 2.4%, to \$4.9 million for the year ended December 31, 2007 from \$5.0 million for the year ended December 31, 2006. As a percentage of revenues, R&D expenses were 11.0% and 9.1% for the years ended December 31, 2007 and 2006, respectively. The decrease in R&D expenses for the year ended December 31, 2007 compared with the same period in 2006 was primarily due to a decrease of \$178,400 related to developmental costs expended on the ADVANCE System and on new biosensors. This decrease was offset in part by an increase of \$81,000 in personnel costs resulting from the hiring of additional employees in our R&D department and related to increases in employee compensation.

### Sales and Marketing

Our sales and marketing expenses include expenses from the marketing, field sales, sales administration and reimbursement departments.

Sales and marketing expenses increased \$0.8 million, or 3.7%, to \$22.8 million for year ended December 31, 2007 from \$22.0 million for the year ended December 31, 2006. As a percentage of revenues, sales and marketing expenses were 52.2% and 39.8% for the years ended December 31, 2007 and 2006, respectively. The increase in expenses was primarily due to (a) an increase of \$1.3 million in employee compensation and benefit costs attributable to the expansion of our sales force; (b) an increase of \$511,100 in consulting services, primarily to assist us with the reimbursement challenges we are facing; (c) an increase of \$245,400 in stock-based compensation expense; and (d) an increase of \$335,400 in advertising and promotional expenses. These amounts were partially offset by a decrease in third-party sales commissions of \$2.0 million, primarily due to our decision to terminate our relationships with all independent sales agencies and focus our selling efforts exclusively through our direct sales force and also due to decreased revenues.

#### *General and Administrative*

Our general and administrative expenses include expenses from the executive, finance, administrative, customer service, and information technology departments.

General and administrative expenses increased \$3.0 million, or 25.7%, to \$14.8 million for year ended December 31, 2007 from \$11.8 million for the year ended December 31, 2006. As a percentage of revenues, general and administrative expenses were 33.2% and 21.4% for the years ended December 31, 2007 and 2006, respectively. The increase in expenses was primarily due to an increase of \$5.2 million in professional fees, mainly legal services, an increase of \$425,000 in consulting expenses and an increase of \$191,800 in stock-based compensation expense. The increases in professional fees and consulting services are both primarily related to the government investigations previously disclosed by us and to reimbursement matters. Partially offsetting these increases was a reversal of \$1.7 million of sales tax liability as a result of receiving amnesty from a number of states and receiving relief from other states in the form of a limited look back period and waiver of penalties and a \$585,200 decrease in bad debt expense.

#### *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. Income from discontinued operations for the year 2007 includes net operating income relating to our discontinued operations.

#### *Interest Income*

Interest income was \$1.8 million and \$1.6 million during the years ended December 31, 2007 and 2006, respectively. Interest income was earned from cash equivalents and short-term investments. The increase in interest income for the year ended December 31, 2007, as compared to the same period in 2006, was primarily due to higher average invested cash balances combined with an increase in the average portfolio yield, attributable to a shift in the portfolio mix to higher yielding fixed maturities, and the prevailing interest rate environment primarily during the first half of 2007.

#### *Provision for Income Taxes*

We recorded no tax provision for the year ended December 31, 2007 due to the net loss incurred. We recorded a tax provision related to the alternative minimum tax of \$193,000 for the year ended December 31, 2006.

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

Our principal source of liquidity is our current cash and cash equivalents and short-term held-to-maturity investments. As of December 31, 2008, the weighted average maturity of our

short-term held-to-maturity investments was 223 days. 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. A 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:

	December 31,		Change	% Change
	2008	2007		
	(in thousands)			
Cash and cash equivalents . . . . .	\$12,302.32	\$ 7,097.2	\$ 5,205.0	73.3%
Short-term held-to-maturity investments . . . . .	7,495.0	22,621.7	(15,126.7)	(66.9)
Total cash, cash equivalents and short-term held-to-maturity investments . . . . .	<u>\$ 19,797.3</u>	<u>\$29,718.9</u>	<u>\$ (9,921.7)</u>	<u>(33.4)%</u>

During 2008, our cash and cash equivalents and short-term held-to-maturity investments decreased by \$9.9 million, primarily due to \$10.7 million of cash used in operations and \$0.5 million of cash used for capital expenditures, offset partially by a release of \$1.0 million of restricted cash resulting from the February 2008 amendment to our property lease and \$0.2 million of proceeds received from the issuance of common stock under our employee stock purchase plan. In first quarter of 2009, \$3.7 million was paid for the DOJ and OIG legal settlement.

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, 2008 and December 31, 2007:

	Years Ended December 31,	
	2008	2007
Days' sales outstanding (days) . . . . .	54	55
Inventory turnover rate (times per year) . . . . .	1.6	2.5

Our payment terms extended to our customers generally require payment within 30 days from invoice date. At December 31, 2008, we experienced a small decrease in DSO to 54 days from 55 days at December 31, 2007.

Our inventory turnover for the year ended December 31, 2008 was 1.6 times, compared with 2.5 times for the year ended December 31, 2007. The decrease in the inventory turnover rate for the year ended December 31, 2008, as compared to the year ended December 31, 2007, was primarily due to decreased demand for the NC-stat System and an increase in inventories of consumables and the ADVANCE System in support of our introduction of the ADVANCE System.

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

	Years Ended December 31,		
	2008	2007	2006
	(in thousands)		
Net cash provided by (used in) operating activities . . . . .	\$(10,688.5)	\$(7,989.1)	\$ 7,297.9
Net cash provided by (used in) investing activities . . . . .	\$ 15,750.6	\$ 6,898.2	\$(9,133.4)
Net cash provided by financing activities . . . . .	\$ 142.9	\$ 278.3	\$ 1,575.3

Our operating activities used approximately \$10.7 million and \$8.0 million of cash in 2008 and 2007, respectively, while providing cash of \$7.3 million in 2006.

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 working capital of \$3.4 million. The primary drivers for the uses of cash in our investment in working capital during 2008 were a decrease in accounts payable and accrued expense of \$3.8 million, a \$0.7 million decrease in deferred revenue and cost, an increase in our inventories of approximately \$0.3 million primarily related to an increase in consumables inventories, partially offset by a \$1.7 million decrease in accounts receivable, excluding the provision for doubtful accounts, mainly due to a decline in revenues and a \$0.3 million decrease in prepaid and other assets. Our net loss excluding the \$6.6 million of loss attributed to discontinued operations and excluding non-cash items was approximately \$0.7 million.

In 2007, a net loss of \$8.4 million and a net use of cash of \$3.4 million for our investment in working capital were offset by \$3.8 million in non-cash items, mainly compensation expense associated with stock options. The primary driver for the use of cash in our investment in working capital was a decrease in accrued expenses of \$3.4 million. This decrease was primarily due to the reversal of \$1.7 million of sales tax liability as a result of receiving amnesty from a number of states and receiving relief from other states in the form of a limited look back period and waiver of penalties. Also impacting working capital was an increase in our inventories of \$1.7 million primarily for the production of the ADVANCE System. These items were offset by a \$1.6 million decrease in accounts receivable, excluding the provision for doubtful accounts, due to a decline in revenues.

As a result of the decline in revenues and increase in operating expenses, we incurred a net loss in 2008 and we expect to incur net losses for 2009. In addition, in the first quarter of 2009, we paid \$3.7 million for the DOJ and OIG settlements. This is expected to have an adverse impact on our cash flows from operating activities for 2009.

Our investing activities provided \$15.8 million and \$6.9 million of cash in 2008 and 2007, respectively, and used \$9.1 million of cash in 2006. In 2008, the primary sources of cash from investment activities were a \$23.7 million in investment maturities, a release of \$1.1 million of restricted cash and proceeds from the sale of our discontinued operation. Primary uses of cash in investment activities were \$8.5 million in purchase of investments and \$0.5 million for purchases of fixed assets, primarily related to computer equipment and tooling equipment for new products. In 2007, \$37.8 million in investment maturities provided cash which was offset in part by \$28.0 million in investment purchases, \$2.5 million used to fund our investment in Cyberkinetics, \$257,500 used to fund purchases of fixed assets, primarily related to computer equipment and tooling equipment for new products and \$175,000 used to fund the acquisition of EyeTel. In 2006, \$42.1 million in investment purchases and \$620,500 used to fund purchases of fixed assets, primarily related to computer equipment, were partially offset by \$33.6 million in cash provided from investment maturities.

Our financing activities provided approximately \$0.1 million, \$0.3 million and \$1.6 million of cash in 2008, 2007 and 2006, respectively. Cash provided by financing activities in 2008, 2007 and 2006 primarily represent the proceeds from the issuance of shares under our employee stock purchase plan and the exercise of stock options. In 2008 and 2007, the main use of cash in financing activities was payments on capital lease.

During 2009, we expect to continue to maintain our cash and investments in money market funds and certificates of deposit. We expect to continue to incur net losses and negative cash flows from operations for the foreseeable future. Based upon our current plans, we believe that our existing capital resources, including cash and cash equivalents, as of December 31, 2008 are sufficient to finance our ongoing operations into 2010, including the anticipated operating expenses and capital expenditures described above. However, our business is 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 our estimated future revenues; (b) changes we make to our ongoing operating expenses; (c) future changes in our business strategy; (d) decisions we make regarding the size of our

sales force and the magnitude of our sales and marketing programs; (e) research and development spending plans; (f) the outcome of the class action lawsuits that we are currently subject to; and (g) other items affecting our level of expenditures and our use of existing cash and cash equivalents. Accordingly, we may need to raise additional funds to support our operating and capital needs. Without additional funds, we may be forced to delay, scale back or eliminate some of our sales and marketing efforts, research and development activities or other operations and potentially delay our product development efforts. We may attempt to obtain additional funding through public or private financing, collaborative arrangements with strategic partners or through additional credit lines or other debt financing sources to increase the funds we have available to us to fund our operations. However, there are no assurances that we will be able to secure such financing on favorable terms, if at all.

As of December 31, 2008, we have federal and state net operating loss carryforwards available to offset future taxable income of \$49.3 million and \$28.2 million, respectively, and federal and state research and development credits of \$651,000 and \$575,000, 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 expire at various dates beginning in 2019 for federal and 2009 for state. 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, 2008, we did not have any off-balance sheet financing arrangements.

The following table summarizes our principal contractual obligations as of December 31, 2008 and the effects such obligations are expected to have on our liquidity and cash flows in future periods.

<u>Contractual Obligations</u>	<u>Payments due in</u>			
	<u>Total</u>	<u>2009</u>	<u>1-3 years</u>	<u>3-5 years</u>
Operating lease obligations . . . . .	\$3,112,500	\$ 738,750	\$2,182,500	\$191,250
Capital lease obligations . . . . .	125,400	45,600	79,800	—
Purchase order obligations . . . . .	1,668,794	1,321,594	347,200	—
Total contractual obligations . . . . .	<u>\$4,906,694</u>	<u>\$2,105,944</u>	<u>\$2,609,500</u>	<u>\$191,250</u>

As of December 31, 2008, we have no contractual obligations that extend beyond 5 years.

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

#### **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*

Our revenue recognition policy is to recognize revenues from our NC-stat System and ADVANCE 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 shorter of the estimated customer relationship period or the estimated useful life of the product, currently three years. We record revenue on a net basis for product sales made to distributors, based upon the amount billed to the distributors, when the distributor accepts the responsibility for invoicing the customer and the responsibility for the risk of collections and product returns from the customer.

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.

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 reduce revenue by the amount of estimated returns under the provisions of SFAS No. 48, *“Revenue Recognition When Right of Return Exists.”*

### *Accounts Receivable and Allowance for Doubtful Accounts*

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. 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. Past due balances over 90 days are reviewed individually for collectibility. Account balances are charged 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.

### *Warranty Costs*

We accrue for device warranty costs at the time of sale. While we engage in extensive product quality programs and processes, our warranty obligation is affected by product failure rates, user error, variability in physiology and anatomy of customers' patients, material usage and delivery costs. Should actual product failure and user error rates, material usage or delivery costs differ from our estimates, the amount of actual warranty costs could materially differ from our estimates. Warranty costs are based on the cost of repairing or replacing monitors and docking stations.



### *Inventory*

The realizable value of inventories is based upon the types and levels of inventory 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.

### *Accounting for 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. SFAS No. 109 "*Accounting for Income Taxes*," requires the Company 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.

In June 2006, the FASB issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" which is an interpretation of FASB Statement 109, "Accounting for Income Taxes." FIN 48 requires management to perform 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. The adoption of FIN 48 in 2007 did not have a material impact on the Company's financial position, results of operations or cash flows.

### *Accounting for Stock-Based Compensation*

Effective January 1, 2006, we adopted SFAS No. 123(R), "*Share Based Payment*" ("SFAS No. 123(R)") using the modified prospective method and began reflecting the stock-based compensation expense determined under fair value based methods in our statement of operations rather than as pro forma disclosure in our notes to the financial statements. Under this transition method, the compensation cost recognized beginning January 1, 2006 includes compensation cost for (i) all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123, and (ii) all share based payments granted subsequent to January 1, 2006 based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123(R). Compensation cost is generally recognized ratably over the requisite service period. Prior period amounts have not been restated. We use the Black-Scholes option pricing model for determining the fair value of our stock options and amortize our 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 annual dividend yield, expected life of options, and risk-free interest rate. (See Note 3 to the Financial Statements for additional information related to share-based compensation.) An increase in the volatility of the Company's stock will increase the amount of compensation expense on new awards. An increase in the holding period of options will also cause an increase in compensation expense. Dividend yields and risk-free interest rates are less difficult to estimate, but an increase in the dividend yield will cause a decrease in expense and an increase in the risk-free interest rate will increase compensation expense.

#### *Goodwill and Other Intangible Assets*

As result of our acquisition of EyeTel on December 26, 2007, there was approximately \$5.8 million of goodwill.

SFAS No. 142, "*Goodwill and Other Intangible Assets*", ("SFAS No. 142") requires us to assess the realizability of goodwill annually, as well as whenever events or changes in circumstances suggest that the carrying amount may not be recoverable. For all of our acquisitions, various analyses, assumptions and estimates were made at the time of each acquisition specifically regarding product development, market conditions and expected cash flows that were used to determine the valuation of goodwill and intangibles. The Company's ability to realize the value of goodwill depends on the future cash flows of the business.

We are required to perform impairment tests under SFAS No. 142 annually and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. As of December 31, 2008, the goodwill balance was zero.

#### *Other Long-Lived Assets*

We periodically evaluate long-lived assets for potential impairment under SFAS No. 144, "*Accounting for the Impairment or Disposal of Long-Lived Assets*" ("SFAS No. 144".) We plan to perform these evaluations whenever events or changes in circumstances suggest that the carrying value of an asset or group of assets is not recoverable. If we believe an indicator of potential impairment exists, we test to determine whether the impairment recognition criteria in SFAS No. 144 have been met. In evaluating long-lived assets for potential impairment, we will make several significant estimates and judgments, including:

- determining the appropriate grouping of assets at the lowest level for which cash flows are available;
- estimating future cash flows associated with the asset or group of assets; and
- determining an appropriate discount rate to use in the analysis.

If different estimates and judgments are used, the amount and timing of impairments could be affected.

#### **Recently Issued Accounting Pronouncements**

In September 2006, the FASB issued SFAS No. 157, "*Fair Value Measurements*" ("SFAS No. 157"). SFAS No. 157 defines fair value in numerous accounting pronouncements, establishes a framework for measuring fair value in GAAP and expands disclosures related to the use of fair value measures in financial statements. SFAS No. 157 does not expand the use of fair value measures in financial statements, but standardizes its definition and guidance in GAAP. SFAS No. 157 emphasizes that fair value is a market-based measurement and not an entity-specific measurement based on an exchange transaction in which the entity sells an asset or transfers a liability (exit price). SFAS No. 157

establishes a fair value hierarchy from observable market data as the highest level to fair value based on an entity's own fair value assumptions as the lowest level. SFAS No. 157 is effective for assets and liabilities as of January 1, 2008. In February 2008, the FASB issued FASB Statement of Position, ("FSP") No. 157-2 "*Partial Deferral of the Effective Date of Statement 157*," ("FSP No. 157-2"), which delays the effective date of SFAS No. 157 for all non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually) to fiscal years beginning after November 15, 2008. The adoption of SFAS No. 157 did not have a material effect on the Company's financial position, results of operations or its cash flows (refer Note 13).

In December 2007, the FASB issued SFAS 141 (Revised 2007), "Business Combinations." SFAS No. 141R retains the underlying concepts of SFAS No. 141 in that business combinations are still accounted for at fair value. However, the accounting for certain other aspects of business combinations will be affected. Acquisition costs will generally be expensed as incurred. Restructuring costs associated with a business combination will generally be expensed subsequent to the acquisition date. In-process research and development will be recorded at fair value as an indefinite-lived intangible at the acquisition date until it is completed or abandoned and its useful life can be determined. Changes in deferred tax asset valuation allowances and uncertain tax positions after the acquisition date will generally impact income tax expense. SFAS No. 141R also expands required disclosures surrounding the nature and financial effects of business combinations. SFAS No. 141R is effective, on a prospective basis, for the Company in the first quarter of fiscal 2010, only if we complete a business combination.

In April 2008, the FASB issued Staff Position ("FSP") No. 142-3, "Determination of the Useful Life of Intangible Assets". FSP No. 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, "Goodwill and Other Intangible Assets". FSP No. 142-3 is effective for the Company in the first quarter of 2010. The Company is currently assessing the impact of FSP No. 142-3 on its results of operations, financial position or cash flows.

In May 2008, the FASB issued Statement of Financial Accounting Standards ("SFAS") No. 162, "The Hierarchy of Generally Accepted Accounting Principles" (SFAS No. 162). SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements. SFAS No. 162 is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, "The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles". The Company has adopted this accounting standard which did not have material impact on its results of operations, financial position or cash flows.

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

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, including, without limitation, statements regarding our or our management’s expectations, hopes, beliefs, intentions or strategies regarding the future. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “plan” and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. The forward-looking statements contained in this annual report are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in the section titled “Risk Factors.” Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects 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.

### **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, cash equivalents, short-term investments, accounts receivable, accounts payable and accrued expenses. 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-33 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, 2008					
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Revenues . . . . .	\$ 8,735,691	\$ 8,127,800	\$ 7,077,238	\$ 7,180,071	\$ 31,120,800
Cost of revenue . . . . .	\$ 2,315,920	\$ 2,302,647	\$ 2,082,805	\$ 2,310,569	\$ 9,011,941
Loss from continuing operations . . . . .	\$(10,078,778)	\$(4,245,889)	\$(2,310,161)	\$(4,494,548)	\$(21,129,376)
Income (loss) from discontinued operations . .	\$ (728,739)	\$ (682,048)	\$(5,541,986)	\$ 352,100	\$ (6,600,673)
Net loss . . . . .	\$(10,807,517)	\$(4,927,937)	\$(7,852,147)	\$(4,142,448)	\$(27,730,049)
Basic earnings per share:					
Loss from continued operations . . . . .	\$ (0.74)	\$ (0.31)	\$ (0.17)	\$ (0.33)	\$ (1.54)
Income (loss) from discontinued operations . .	\$ (0.05)	\$ (0.05)	\$ (0.40)	\$ 0.03	\$ (0.48)
Net loss . . . . .	\$ (0.79)	\$ (0.36)	\$ (0.57)	\$ (0.30)	\$ (2.02)
Diluted earnings per share:					
Loss from continued operations . . . . .	\$ (0.74)	\$ (0.31)	\$ (0.17)	\$ (0.33)	\$ (1.54)
Income (loss) from discontinued operations . .	\$ (0.05)	\$ (0.05)	\$ (0.40)	\$ 0.03	\$ (0.48)
Net loss . . . . .	\$ (0.79)	\$ (0.36)	\$ (0.57)	\$ (0.30)	\$ (2.02)

Year Ended December 31, 2007					
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Revenues . . . . .	\$11,551,981	11,271,509	11,019,628	\$ 9,824,158	\$43,667,276
Cost of revenue . . . . .	\$ 2,926,233	2,905,059	2,845,354	\$ 2,661,176	\$11,337,822
Loss from continuing operations . . . . .	\$(1,387,337)	(1,305,289)	(3,602,691)	\$(2,187,143)	\$(8,482,460)
Income from discontinued operations . . . . .	\$ 10,055	\$ 14,298	\$ 31,766	\$ 47,867	\$ 103,986
Net loss . . . . .	\$(1,377,282)	\$(1,290,991)	\$(3,570,925)	\$(2,139,276)	\$(8,378,474)
Basic earnings per share:					
Loss from continued operations . . . . .	\$ (0.11)	\$ (0.10)	\$ (0.28)	\$ (0.18)	\$ (0.67)
Income from discontinued operations . . . . .	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.01	\$ 0.01
Net loss . . . . .	\$ (0.11)	\$ (0.10)	\$ (0.28)	\$ (0.17)	\$ (0.66)
Diluted earnings per share:					
Loss from continued operations . . . . .	\$ (0.11)	\$ (0.10)	\$ (0.28)	\$ (0.18)	\$ (0.67)
Income from discontinued operations . . . . .	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.01	\$ 0.01
Net loss . . . . .	\$ (0.11)	\$ (0.10)	\$ (0.28)	\$ (0.17)	\$ (0.66)

## **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 management carried out an evaluation, with the participation of our Chief Executive Officer and our Principal Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of December 31, 2008. Our disclosure controls and procedures are designed to provide reasonable assurance 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 that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, to allow timely decisions regarding required disclosures.

Based upon the evaluation described above, our Chief Executive Officer and Acting Chief Financial Officer have concluded that they believe that our disclosure controls and procedures are effective, as of the end of the period covered by this report, in providing reasonable assurance that information required to be disclosed by us in 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 the issuer's management, including its principal executive and financial officers, as appropriate to allow timely decisions regarding required disclosures. We continue to review and document our disclosure controls and procedures, including our internal controls over financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

#### **(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 Acting Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2008 based on the criteria in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on our evaluation under the framework in *Internal Control—Integrated Framework* issued by the COSO, our management concluded that our internal control over financial reporting was effective as of December 31, 2008.

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



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

There have been no changes to the Company's internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the quarter ended December 31, 2008 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

**ITEM 9B. Other Information**

None.

### **PART III**

#### **ITEM 10. Directors, Executive Officers and Corporate Governance**

The response to this item is contained in our Proxy Statement relating to our 2009 Annual Meeting of Stockholders (the “Proxy Statement”) and is incorporated herein by reference.

#### **ITEM 11. Executive Compensation**

The response to this item is incorporated herein by reference from the discussion responsive thereto in the Proxy Statement.

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

The response to this item is incorporated herein by reference from the discussion responsive thereto in the Proxy Statement.

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

The response to this item is incorporated herein by reference from the discussion responsive thereto in the Proxy Statement.

#### **ITEM 14. Principal Accountant Fees and Services**

The response to this item is incorporated herein by reference from the discussion responsive thereto in the Proxy Statement.

## PART IV

### ITEM 15. Exhibits and Financial Statement Schedules

#### (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.

#### 3. *Exhibit Index:*

Exhibit Number	Description
2.1	Asset Purchase Agreement by and among NeuroMetrix, Inc., EyeTel Imaging, Inc. and EyeTel Reading Center, LLC, dated as of December 26, 200 (8)
2.2	Asset Purchase Agreement dated November 7, 2008 by and between NeuroMetrix, Inc. and Advanced Diagnostics, LLC (11)
3.1	Third Amended and Restated Certificate of Incorporation of NeuroMetrix, Inc. (9)
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. (9)
3.4	Amendment No. 1 to Second Amended and Restated Bylaws of NeuroMetrix, Inc. (7)
4.1	Specimen certificate for shares of common stock (1)
4.2	Shareholder Rights Agreement, dated as of March 7, 2007, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent (6)
10.1	Lease Agreement dated October 18, 2000 between Fourth Avenue LLC and NeuroMetrix, Inc. (1)
10.2	Amendment Number One to Lease between Fourth Avenue LLC and NeuroMetrix, Inc. dated February 22, 2008 (12)
10.3+	Amended and Restated 1996 Stock Option/Restricted Stock Plan (1)
10.4+	Amended and Restated 1998 Equity Incentive Plan (1)
10.5+	First Amendment to Amended and Restated 1998 Equity Incentive Plan (1)
10.6+	Second Amendment to Amended and Restated 1998 Equity Incentive Plan (1)
10.7+	2004 Employee Stock Purchase Plan (1)
10.8+	Second Amended and Restated 2004 Stock Option and Incentive Plan (12)
10.9+	Form of Indemnification Agreement between NeuroMetrix, Inc. and each of its directors (1)
10.10+	Employment Agreement, dated June 21, 2004, by and between NeuroMetrix, Inc. and Shai N. Gozani, M.D., Ph.D. (1)
*10.11+	First Amendment to Employment Agreement dated December 31, 2008, by and between NeuroMetrix, Inc. and Shai N. Gozani, M.D., Ph.D.
10.12+	NeuroMetrix, Inc. Confidentiality and Non-Compete Agreement dated as of June 21, 2004, by and between Shai N. Gozani, M.D., Ph.D. and NeuroMetrix, Inc. (1)
10.13+	Indemnification Agreement dated June 21, 2004, by and between Shai N. Gozani, M.D., Ph.D., and NeuroMetrix, Inc. (1)
10.14+	Letter Agreement, dated June 19, 2002, by and between NeuroMetrix, Inc. and Gary L. Gregory (1)
10.15+	NeuroMetrix, Inc. Stock Option Agreements (1998 Plan) dated as of July 1, 2002 and April 8, 2004 by and between NeuroMetrix, Inc. and Gary L. Gregory (1)
10.16+	NeuroMetrix, Inc. Confidentiality and Non-Compete Agreement, dated as of June 28, 2002, by and between Gary L. Gregory and NeuroMetrix, Inc. (1)

Exhibit Number	Description
10.17+	NeuroMetrix, Inc. Non-Statutory Stock Option Agreement (1998 Plan) dated as of June 21, 2004, by and between Shai N. Gozani M.D., Ph.D., and NeuroMetrix, Inc. (1)
10.18+	NeuroMetrix, Inc. Non-Statutory Stock Option Agreement (1998 Plan) dated as of June 21, 2004 by and between Gary Gregory and NeuroMetrix, Inc. (1)
10.19+	NeuroMetrix, Inc. Confidentiality and Non-Compete Agreement, dated as of May 1, 2000, by and between Michael Williams, Ph.D. and NeuroMetrix, Inc. (1)
10.20+	Letter Agreement between NeuroMetrix, Inc. and Michael Williams, Ph.D. dated February 5, 2008 (11)
*10.21+	First Amendment to Letter Agreement between NeuroMetrix, Inc. and Michael Williams, Ph.D. dated December 31, 2008
10.22+	NeuroMetrix, Inc. Confidentiality and Non-Compete Agreement, dated as of October 13, 1998, by and between Guy Daniello and NeuroMetrix, Inc. (1)
10.23+	Letter Agreement between NeuroMetrix, Inc. and Guy Daniello dated February 5, 2008 (11)
*10.24+	First Amendment to Letter Agreement between NeuroMetrix, Inc. and Guy Daniello dated December 31, 2008
10.25	Manufacturing and Supply Agreement, dated as of August 2, 2006, by and etween Parlex Polymer Flexible Circuits, Inc. and NeuroMetrix, Inc. (2)
10.26	Deferred Prosecution Agreement dated February 5, 2009 by and between NeuroMetrix, Inc. and the United States Attorney's Office for the District of Massachusetts (7)
10.27	Settlement Agreement and Release dated February 9, 2009 by and among NeuroMetrix, Inc. and the United States of America acting through the 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)
10.28+	Separation Agreement between NeuroMetrix, Inc. and Gary L. Gregory dated May 1, 2008 (10)
10.29+	Consulting Agreement, dated July 22, 2008, by and between NeuroMetrix, Inc. and Joseph A. Calo (13)
10.30+	Indemnification Agreement, dated July 22, 2008, by and between NeuroMetrix, Inc. and Joseph A. Calo (13)
*23.1	Consent of PricewaterhouseCoopers LLP
*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.

# Portions of this exhibit have been omitted pursuant to a request for confidential treatment.

+ Indicates management contract or any compensatory plan, contract or arrangement.

(1) Incorporated herein by reference to NeuroMetrix, Inc.'s Registration Statement on Form S-1 (Registration No. 333-115440).

(2) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on August 2, 2006 (File No. 000-50856).

(3) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on March 8, 2007 (File No. 001-33351).

- (4) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on September 17, 2007 (File No. 001-33351).
- (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 Registration Statement on Form S-8 (Registration No. 333-118059).
- (7) Incorporated hereby by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on February 9, 2009 (File No. 001-33351).
- (8) Incorporated hereby by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on November 26, 2008 (File No. 001-33351).
- (9) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on February 22, 2008 (File No. 001-33351).
- (10) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on May 2, 2008 (File No. 001-33351).
- (11) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on February 6, 2008 (File No. 001-33351).
- (12) 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).
- (13) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on July 24, 2008 (File No. 001-33351).

## 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. Gozani, M.D. Ph.D.  
*Chairman, President and Chief Executive Officer*

Date: March 20, 2009

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 20, 2009 in the capacities indicated below.

<u>Name</u>	<u>Title</u>
<u>/s/ SHAI N. GOZANI, M.D., PH.D.</u> Shai N. Gozani, M.D., Ph. D.	Chairman, President and Chief Executive Officer (Principal Executive Officer)
<u>/s/ JOSEPH A. CALO</u> Joseph A. Calo	Acting Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)
<u>/s/ DAVID E. GOODMAN, M.D.</u> David E. Goodman, M.D.	Director
<u>/s/ ALLEN J. HINKLE M.D.</u> Allen J. Hinkle M.D.	Director
<u>/s/ CHARLES R. LAMANTIA</u> Charles R. LaMantia	Director
<u>/s/ W. MARK LORTZ</u> W. Mark Lortz	Director



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**INDEX TO FINANCIAL STATEMENTS**  
**NeuroMetrix, Inc.**  
**Years ended December 31, 2008, 2007 and 2006**

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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 income (loss), of stockholders' equity, and of cash flows present fairly, in all material respects, the financial position of NeuroMetrix, Inc. at December 31, 2008 and December 31, 2007, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2008 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/ Pricewaterhouse Coopers LLP

Boston, Massachusetts  
March 20, 2009

**NeuroMetrix, Inc.**  
**Balance Sheets**

	December 31,	
	2008	2007
<b>Assets</b>		
Current assets:		
Cash and cash equivalents . . . . .	\$ 12,302,284	\$ 7,097,239
Short-term held-to-maturity investments . . . . .	7,495,000	22,621,741
Restricted cash . . . . .	—	45,000
Accounts receivable, net of allowance for doubtful accounts of \$650,000 and \$906,000 at December 31, 2008 and 2007, respectively . . . . .	3,660,848	5,731,697
Inventories . . . . .	5,606,807	5,354,338
Prepaid expenses and other current assets . . . . .	313,795	710,159
Current portion of deferred costs . . . . .	263,755	464,061
Total current assets . . . . .	29,642,489	42,024,235
Restricted cash . . . . .	408,000	1,458,598
Fixed assets, net . . . . .	1,073,176	2,973,718
Long-term available-for-sale investment . . . . .	—	1,058,255
Goodwill . . . . .	—	5,833,464
Other intangible assets . . . . .	—	2,800,000
Deferred costs . . . . .	116,972	226,304
Other long-term assets . . . . .	137,705	—
Total assets . . . . .	<u>\$ 31,378,342</u>	<u>\$ 56,374,574</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable . . . . .	\$ 201,275	\$ 2,627,889
Accrued compensation . . . . .	1,335,430	2,127,546
Accrued expenses . . . . .	5,386,699	2,308,563
Current portion of deferred revenue . . . . .	1,057,215	1,643,026
Current portion of capital lease obligation . . . . .	29,748	12,900
Total current liabilities . . . . .	8,010,367	8,719,924
Deferred revenue . . . . .	483,365	891,958
Other long-term liabilities and capital lease obligation . . . . .	52,059	32,821
Total liabilities . . . . .	8,545,791	9,644,703
Commitments and contingencies (Note 12)		
Stockholders' equity		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized, none outstanding . . . . .	—	—
Common stock, \$0.0001 par value; 50,000,000 authorized; 13,858,797 and 13,690,134 shares issued and outstanding at December 31, 2008 and 2007, respectively . . . . .	1,386	1,369
Additional paid-in capital . . . . .	112,626,802	110,235,835
Accumulated deficit . . . . .	(89,795,637)	(62,065,588)
Accumulated other comprehensive loss . . . . .	—	(1,441,745)
Total stockholders' equity . . . . .	22,832,551	46,729,871
Total liabilities and stockholders' equity . . . . .	<u>\$ 31,378,342</u>	<u>\$ 56,374,574</u>

The accompanying notes are an integral part of these financial statements.

**NeuroMetrix, Inc.**  
**Statements of Operations and Comprehensive Income (Loss)**

	Years Ended December 31,		
	2008	2007	2006
Revenues:			
Medical equipment . . . . .	\$ 2,709,104	\$ 4,254,011	\$ 7,538,320
Consumables . . . . .	28,411,696	39,413,265	47,711,396
Total revenues . . . . .	31,120,800	43,667,276	55,249,716
Costs and expenses:			
Cost of revenues, excluding amortization . . . . .	9,011,941	11,337,822	13,558,054
Research and development . . . . .	5,256,721	4,891,937	5,010,513
Sales and marketing . . . . .	14,646,958	22,836,867	22,013,682
General and administrative . . . . .	12,016,158	14,834,073	11,805,062
Goodwill impairment . . . . .	5,833,464	—	—
Charge for legal settlement . . . . .	3,705,866	—	—
Intangible asset impairment . . . . .	1,767,500	—	—
Gain from deconsolidation of joint venture . . . . .	(2,100,000)	—	—
Amortization of intangible assets . . . . .	332,500	—	—
Total costs and expenses . . . . .	50,471,108	53,900,699	52,387,311
Income (loss) from continuing operations . . . . .	(19,350,308)	(10,233,423)	2,862,405
Loss on available-for-sale investment . . . . .	(2,500,000)	—	—
Interest income . . . . .	720,932	1,750,963	1,598,401
Income (loss) from continuing operations before provision for income taxes . . . . .	(21,129,376)	(8,482,460)	4,460,806
Provision for income taxes . . . . .	—	—	193,000
Income (loss) from continuing operations . . . . .	(21,129,376)	(8,482,460)	4,267,806
Income (loss) from discontinued operations . . . . .	(6,600,673)	103,986	—
Net income (loss) . . . . .	<u>\$(27,730,049)</u>	<u>\$ (8,378,474)</u>	<u>\$ 4,267,806</u>
Net income (loss) per common share from continuing operations:			
Basic . . . . .	\$ (1.54)	\$ (0.67)	\$ 0.34
Diluted . . . . .	\$ (1.54)	\$ (0.67)	\$ 0.33
Net income (loss) per common share from discontinued operations:			
Basic . . . . .	\$ (0.48)	\$ 0.01	\$ 0.00
Diluted . . . . .	\$ (0.48)	\$ 0.01	\$ 0.00
Net income (loss) per common share:			
Basic . . . . .	\$ (2.02)	\$ (0.66)	\$ 0.34
Diluted . . . . .	\$ (2.02)	\$ (0.66)	\$ 0.33
Weighted average shares used to compute net income (loss) per common share:			
Basic . . . . .	13,733,733	12,628,310	12,501,742
Diluted . . . . .	13,733,733	12,628,310	13,097,891
Comprehensive income (loss):			
Net income (loss) . . . . .	<u>\$(27,730,049)</u>	<u>\$ (8,378,474)</u>	<u>\$ 4,267,806</u>
Unrealized loss on available-for-sale investment . . . . .	—	(1,441,745)	—
Realized loss on available-for-sale investment . . . . .	1,441,745	—	—
Comprehensive income (loss) . . . . .	<u>\$(26,288,304)</u>	<u>\$ (9,820,219)</u>	<u>\$ 4,267,806</u>

The accompanying notes are an integral part of these financial statements.

**NeuroMetrix, Inc.**  
**Statements of Changes in Stockholders' Equity**

	Common Stock		Additional Paid-In Capital	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Items	Total
	Number of Shares	Amount					
Balance at December 31, 2005 . . . . .	12,375,276	\$1,238	\$ 93,212,368	\$(425,623)	\$(57,954,920)	\$ —	\$ 34,833,063
Issuance of stock upon exercise of stock options and warrants . . . . .	202,808	20	1,180,637	—	—	—	1,180,657
Compensation expense associated with stock options . . . . .	—	—	2,403,222	—	—	—	2,403,222
Adjustment to deferred compensation associated with terminated employees . . . . .	—	—	(65,503)	65,503	—	—	—
Amortization of deferred compensation . . . . .	—	—	—	249,415	—	—	249,415
Issuance of common stock under employee stock purchase plan . . . .	23,140	2	394,621	—	—	—	394,623
Income tax effect of the exercise of stock options . . . . .	—	—	79,800	—	—	—	79,800
Net income . . . . .	—	—	—	—	4,267,806	—	4,267,806
Balance at December 31, 2006 . . . . .	12,601,224	1,260	97,205,145	(110,705)	(53,687,114)	—	43,408,586
Issuance of stock upon exercise of stock options . . . . .	5,957	1	24,099	—	—	—	24,100
Stock-based compensation expense . .	—	—	2,976,059	—	—	—	2,976,059
Adjustment to deferred compensation associated with terminated employees . . . . .	—	—	(15,674)	15,674	—	—	—
Amortization of deferred compensation . . . . .	—	—	—	95,031	—	—	95,031
Issuance of common stock under employee stock purchase plan . . . .	32,656	3	261,763	—	—	—	261,766
Issuance of common stock to complete the acquisition of Eyetel . . . . .	1,050,297	105	9,784,443	—	—	—	9,784,548
Unrealized loss on available-for-sale investment . . . . .	—	—	—	—	—	(1,441,745)	(1,441,745)
Net income . . . . .	—	—	—	—	(8,378,474)	—	(8,378,474)
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 upon exercise of stock options . . . . .	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 . . . . .	<u>13,858,797</u>	<u>\$1,386</u>	<u>\$112,626,802</u>	<u>\$ —</u>	<u>\$(89,795,637)</u>	<u>\$ —</u>	<u>\$ 22,832,551</u>

The accompanying notes are an integral part of these financial statements.



**NeuroMetrix, Inc.**  
**Statements of Cash Flows**

	Years Ended December 31,		
	2008	2007	2006
<b>Cash flows for operating activities:</b>			
Net income (loss) . . . . .	\$(27,730,049)	\$ (8,378,474)	\$ 4,267,806
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization . . . . .	1,593,467	422,938	380,655
Compensation expense associated with stock options . . . . .	2,228,839	3,071,090	2,652,637
Provision for doubtful accounts . . . . .	355,774	358,141	946,850
Amortization of premium on investments . . . . .	(38,158)	(41,811)	184,163
Income tax effect of the exercise of stock options . . . . .	—	—	79,800
Goodwill impairment . . . . .	5,833,464	—	—
Intangible assets impairment . . . . .	4,147,500	—	—
Assets impairment relating to discontinued operations . . . . .	2,227,104	—	—
Charge for legal settlement . . . . .	3,705,866	—	—
Loss on available-for-sale investment . . . . .	2,500,000	—	—
Gain from deconsolidation of joint venture . . . . .	(2,100,000)	—	—
Gain on disposal of fixed assets . . . . .	(20,000)	—	—
Changes in operating assets and liabilities; net of effect of acquisition:			
Accounts receivable . . . . .	1,715,075	1,643,712	(4,102,061)
Inventories . . . . .	(252,469)	(1,720,949)	(949,980)
Prepaid expenses and other current assets . . . . .	(171,400)	267,241	(147,231)
Other long-term asset . . . . .	(137,705)	—	—
Accounts payable . . . . .	(2,426,614)	(7,340)	1,068,067
Accrued expenses and compensation . . . . .	(1,419,846)	(3,386,539)	2,147,762
Other long-term liabilities . . . . .	(14,545)	(58,181)	(58,182)
Deferred revenue and deferred costs . . . . .	(684,766)	(158,943)	827,617
Net cash provided by (used in) operating activities . . . . .	(10,688,463)	(7,989,115)	7,297,903
<b>Cash flows for investing activities:</b>			
Purchases of fixed assets . . . . .	(529,872)	(257,520)	(620,540)
Purchases of investments . . . . .	(8,545,598)	(27,959,957)	(42,141,626)
Maturities of investments . . . . .	23,710,497	37,790,712	33,628,724
Purchase of Cyberkinetics common stock . . . . .	—	(2,500,000)	—
Proceeds from sale of assets related to discontinued operations . . . . .	20,000	—	—
Acquisition of EyeTel . . . . .	—	(175,000)	—
Release of restricted cash . . . . .	1,095,598	—	—
Net cash provided by (used in) investing activities . . . . .	15,750,625	6,898,235	(9,133,442)
<b>Cash flows from financing activities:</b>			
Proceeds from exercise of stock options . . . . .	5,404	24,100	1,180,657
Proceeds from issuance of common stock under employee stock purchase plan . . . . .	156,741	261,766	394,623
Payments under capital leases . . . . .	(19,262)	(7,525)	—
Net cash provided by financing activities . . . . .	142,883	278,341	1,575,280
Net increase (decrease) in cash and cash equivalents . . . . .	5,205,045	(812,539)	(260,259)
Cash and cash equivalents, beginning of year . . . . .	7,097,239	7,909,778	8,170,037
Cash and cash equivalents, end of year . . . . .	<u>\$ 12,302,284</u>	<u>\$ 7,097,239</u>	<u>\$ 7,909,778</u>
<b>Supplemental disclosure of cash flow information:</b>			
Equipment acquired under capital lease . . . . .	\$ 89,244	\$ 38,700	\$ —

The accompanying notes are an integral part of these financial statements.

**NeuroMetrix, Inc.**  
**Notes to Financial Statements**

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

NeuroMetrix, Inc. (the “Company”), a Delaware corporation, was founded in June 1996. We are a science-based medical device company advancing patient care through the development and commercialization of innovative products that aid physicians in the assessment, treatment, and repair of peripheral nerve and spinal cord injuries and disorders, and that provide regional anesthesia and pain control. To date, our focus has been on products that help physicians with the diagnosis or detection of neuropathies and neurovascular disorders. 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 have two medical devices cleared by the United States Food and Drug Administration (FDA) that are used for the assessment of neuropathies. We market the ADVANCE™ NCS/EMG System a comprehensive platform for the performance of traditional nerve conduction studies and invasive electromyography procedures. The system is used primarily by neurologists, PM&R physicians, hand surgeons, and other specialists. We also market the NC-stat System, a sophisticated, automated system for the performance of nerve conduction studies. The system is used in over five thousand physician offices. Over one and a half million patients have been tested with the Company’s neurodiagnostic equipment since 1999.

In November 2007, we entered into a strategic alliance with Cyberkinetics, a medical device company focused on neurological conditions. We made an investment of \$2.5 million in shares of Cyberkinetics common stock, which has been fully written off during 2008, and agreed to negotiate the terms of a joint venture with Cyberkinetics. In February 2008, we formed PNIR (Peripheral Nerve Injury Repair) LLC, a joint venture with initial ownership of 50% by NeuroMetrix and 50% by Cyberkinetics, and entered into a Collaboration Agreement and Operating Agreement with them. The joint venture was included in our consolidated financial statements until the entity was deconsolidated in the fourth quarter of 2008 at which time the joint venture with Cyberkinetics was dissolved (refer Note 5).

In December 2007, we acquired substantially all of the assets of EyeTel Imaging, Inc., or EyeTel. EyeTel was engaged in the design, development, and commercialization of proprietary medical devices, including the DigiScope, a device that helps physicians detect eye disorders such as diabetic retinopathy, the leading cause of blindness in patients with diabetes. The Company had previously entered into an exclusive licensing agreement with EyeTel pursuant to which the Company had sales and marketing rights to the DigiScope in the primary diabetes care physician market. On September 30, 2008, as part of our ongoing focus on cost-efficiencies in all areas of our business, and our refocused efforts towards our core business, we approved a plan for the closure of our facility in Columbia, Maryland and 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 the DigiScope business to Advanced Diagnostics, LLC. The financial results for 2008 and 2007 related to the DigiScope operations have been presented as discontinued operations in the statement of operations and comprehensive loss (refer Note 4).

The Company expects that existing cash, cash equivalents and short term investments will be sufficient to finance our ongoing operations into 2010. 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 estimated future revenues; (b) changes the Company makes to its ongoing operating expenses; (c) future changes in the Company’s business strategy; (d) decisions the Company makes regarding the size of its sales force and

**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

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

the magnitude of its sales and marketing programs; (e) research and development spending plans; (f) the outcome of the class action lawsuits that the Company is currently subject to; and (g) other items affecting the Company's forecasted level of expenditures and use of existing cash and cash equivalents and short term investments. 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 our operations. However, there are no assurances that the Company will 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 operations and potentially delay product development efforts 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.

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*

The Company's investment portfolio is 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, 2008, the Company invested only in bank certificates of deposits.

*Long-Term Available-for-Sale Investment*

In accordance with the provisions of Statement of Financial Accounting Standards ("SFAS") No. 115, "Accounting for Certain Investments in Debt and Equity Securities", ("SFAS No. 115"), the Company's investment in Cyberkinetics is classified as available-for-sale and is carried at fair value, with

**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

any unrealized gains and losses, net of taxes, reported in accumulated other comprehensive income, a separate component of stockholders' equity. We marked this investment to market as of December 31, 2008 and have recorded year to date loss of \$2.5 million because we believe the decline in the value of this investment is other-than-temporary.

***Restricted Cash***

The Company maintained long-term restricted cash in the amount of \$408,000 and \$1,458,598 at December 31, 2008 and 2007, respectively, associated with a facility lease (refer Note 12).

At December 31, 2007, the Company held short-term restricted cash in the amount of \$45,000 in connection with certain liabilities assumed with the acquisition of EyeTel on December 26, 2007.

***Concentration 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 or short-term investments and does not believe it is exposed to any significant credit risks relating to its cash and cash equivalents and short-term investments.

The Company distributes its products through its own regional sales managers who manage independent sales agencies. At December 31, 2008 and 2007 and for the years ended December 31, 2008, 2007 and 2006, no single customer accounted for more than 10% of accounts receivable or revenue.

The Company relies on two third-party manufacturers to manufacture all 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 of Financial Instruments***

The carrying amounts of the Company's financial instruments, which include cash equivalents, short-term held to maturity investments, long-term available for sale investment, accounts receivable, accounts payable and accrued expenses approximate their fair value at December 31, 2008 and 2007.

***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. The Company records revenue on a

**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

net basis for product sales made to independent sales agencies or distributors, based upon the amount billed to the distributors, when the distributor accepts the responsibility for invoicing the customer and the responsibility for the risk of collections and product returns from the customer.

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 consists of the NC-stat devices, NC-stat docking stations and ADVANCE devices and related modules. Revenues associated with the sale of the NC-stat and ADVANCE monitors are recognized upon shipment provided that the fee is fixed or determinable, evidence of a 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 a NC-stat docking station as well as the ADVANCE communication hub together with access to the onCall Information System 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 onCall Information System, which is the shorter of the estimated customer relationship period or the estimated useful life of the docking station, currently three years. The resulting deferred revenue and deferred costs are presented as separate line items on the accompanying balance sheet.

Consumables revenues consisting of single use nerve specific electrodes, which are used with our NC-stat System and our ADVANCE System and disposable universal electrodes, and EMG concentric needles, which are used with our ADVANCE System, 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.

The Company recognizes revenues associated with installation and training services related to NC-stat and ADVANCE Systems sales upon completion of the service. The fair value of the installation and training is based on hourly service billing rates.

Certain product sales are made with a 30-day right of return. Since 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 by the amount of estimated returns under the provisions of Statement of Financial Accounting Standards ("SFAS") No. 48, *"Revenue Recognition When Right of Return Exists"*.

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

***Accounts Receivable and Allowance for Doubtful Accounts***

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. 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 over 90 days,

**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

are reviewed individually for collectibility. Account balances are charged 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.

***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. SFAS No. 109 "*Accounting for Income Taxes*," requires the Company 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.

In June 2006, the FASB issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" which is an interpretation of FASB Statement 109, "Accounting for Income Taxes." FIN 48 requires management to perform 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. The adoption of FIN 48 in 2007 did not have a material impact on the Company's financial position, results of operations or cash flows.

***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



**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

historical information such as past experience, product failure rate, number of units repaired and estimated cost of material and labor.

The following is a rollforward of the Company's accrued warranty liability for the years ended December 31, 2008, 2007 and 2006:

	<b>Years Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
Balance at beginning of period . . . . .	\$ 251,948	\$ 231,725	\$ 124,852
Accrual for warranties . . . . .	504,105	749,078	688,234
Settlements made . . . . .	(619,883)	(728,855)	(581,361)
Balance at end of period . . . . .	<u>\$ 136,170</u>	<u>\$ 251,948</u>	<u>\$ 231,725</u>

***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, when circumstances indicate that an event of impairment may have occurred in accordance with the provisions of SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets". 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. During the year ended December 31, 2008, we recorded a charge of approximately \$2.2 million relating to fixed asset impairments and \$2.4 million related to intangible asset impairment in connection with our discontinued business. No impairments were identified in the years ended December 31, 2007 and 2006.

***Goodwill and Other Intangible Assets***

As a result of the acquisition of EyeTel on December 26, 2007, the Company recorded approximately \$5.8 million of goodwill and \$2.8 million of other intangible assets on its balance sheet at December 31, 2007 (refer Note 4). The Company was amortizing the intangible assets using the straight-line method over their estimated economic lives. Determining the economic lives of acquired intangible assets required us to make significant judgment and estimates, and could have materially impacted the Company's operating results.

**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

We perform impairment tests related to our goodwill under Statement of Financial Accounting Standards, or SFAS, No. 142, “*Goodwill and Other Intangible Assets*,” or SFAS No. 142, annually and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable, such as the decline in the market capitalization of our common stock that occurred during the first quarter of 2008. Subsequent to the AMA CPT Panel meeting in February 2008, our common stock price declined significantly such that as of March 31, 2008, our publicly traded market value was below our net book value. EyeTel’s operations were incorporated into our one segment and we determined that we are comprised of a single reporting unit for goodwill impairment testing. We determined that an interim goodwill impairment test was required. As the net book value of our assets exceeded the enterprise value, we performed step two of the SFAS No. 142 impairment test in which we assessed the fair value of all recorded and unrecorded tangible and intangible assets and liabilities, including our recently acquired EyeTel and PNIR intangibles. We determined that there was no residual value of goodwill. Accordingly, we recorded a charge of \$5.8 million to write off the goodwill resulting from the EyeTel acquisition during the first quarter of 2008. Further, we recorded a charge for impairment of intangibles of approximately \$1.8 million on deconsolidation of PNIR (refer Note 5) and approximately \$2.4 million on the decision to discontinue operations of EyeTel (refer Note 4).

***Accounting for Stock-Based Compensation***

Beginning January 1, 2006, the Company adopted SFAS No. 123(R) using the modified prospective method and has begun reflecting the stock-based compensation expense determined under fair value based methods in the statement of operations rather than as pro forma disclosure in the notes to the financial statements. Under this transition method, the compensation cost recognized beginning January 1, 2006 includes compensation cost for (i) all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123, and (ii) all share based payments granted or modified subsequent to January 1, 2006 based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123(R). Compensation cost is generally recognized ratably over the requisite service period. Prior period amounts have not been restated. 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 annual dividend yield, expected life of options, and risk-free interest rate. (See Note 3 to the Financial Statements for additional information related to share-based compensation.) An increase in the volatility of the Company’s stock will increase the amount of compensation expense on new awards. An increase in the holding period of options will also cause an increase in compensation expense. Dividend yields and risk-free interest rates are less difficult to estimate, but an increase in the dividend yield will cause a decrease in expense and an increase in the risk-free interest rate will increase compensation expense.

***Net Income (Loss) Per Common Share***

The Company accounts for and discloses net income (loss) per common share in accordance with SFAS No. 128, “*Earnings Per Share*”. Basic net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares outstanding. Diluted net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares and dilutive potential common share equivalents then outstanding. Potential

**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

common shares consist of shares issuable upon the exercise of stock options (using the treasury stock method).

	<u>Year Ended December 31, 2006</u>
Basic:	
Net income . . . . .	\$ 4,267,806
Weighted average shares . . . . .	12,501,742
Basic income per common share . . . . .	\$ 0.34
Diluted:	
Net income . . . . .	\$ 4,267,806
Weighted average shares . . . . .	12,501,742
Effect of stock options . . . . .	596,149
Weighted average shares, as adjusted . . . . .	<u>13,097,891</u>
Diluted income per common share . . . . .	<u>\$ 0.33</u>

In the years ended December 31, 2008 and 2007, common share equivalents relating to stock options were anti-dilutive.

The following potentially dilutive common shares were excluded from the calculation of diluted net income (loss) per common share because their effect was anti-dilutive for each of the periods presented:

	<u>Years Ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
Options . . . . .	<u>2,248,929</u>	<u>1,661,427</u>	<u>366,618</u>

***Advertising and Promotional Costs***

Advertising and promotional costs are expensed as incurred. Advertising and promotion expense was \$475,212, \$718,650 and \$547,441 in the years ended December 31, 2008, 2007 and 2006, respectively.

***Accumulated Other Comprehensive Items***

SFAS No. 130, “Reporting Comprehensive Income” establishes standards for reporting and displaying comprehensive income and its components in a full set of general-purpose financial statements. 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 this investment as an available-for-sale security and followed the provisions of SFAS No. 115, “Accounting for Certain Investments in Debt and Equity Securities” (“SFAS No. 115”). During the year of 2008 the Company recorded a loss of \$2.5 million on the investment in Cyberkinetics in the statement of operations as a result of the change in fair market value and the determination that the loss was other-than-temporary. For the year ended December 31, 2007, the Company recorded a \$1.4 million decrease in fair value in

**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

investment within the other comprehensive loss as the decrease in fair value was considered temporary. For the year ended December 31, 2006, the Company had no components of other comprehensive income or loss other than net income (loss).

***Segments***

Substantially all of our assets, revenues and expenses for the years ended December 31, 2008, 2007 and 2006 were located at or derived from operations in the United States. We operate in one segment for the sale of medical equipments and consumables. As a result of the launch of the NC-stat and ADVANCE Systems in the United Kingdom and various countries in Latin America, we had initial revenues from sales outside the United States which accounted for less than 1% of total revenues for the years ending December 31, 2008 and 2007, respectively.

***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.

***Reclassification***

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

***Recently Issued Accounting Pronouncements***

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" ("SFAS No. 157"). SFAS No. 157 defines fair value in numerous accounting pronouncements, establishes a framework for measuring fair value in GAAP and expands disclosures related to the use of fair value measures in financial statements. SFAS No. 157 does not expand the use of fair value measures in financial statements, but standardizes its definition and guidance in GAAP. SFAS No. 157 emphasizes that fair value is a market-based measurement and not an entity-specific measurement based on an exchange transaction in which the entity sells an asset or transfers a liability (exit price). SFAS No. 157 establishes a fair value hierarchy from observable market data as the highest level to fair value based on an entity's own fair value assumptions as the lowest level. SFAS No. 157 is effective for assets and liabilities as of January 1, 2008. In February 2008, the FASB issued FASB Statement of Position, ("FSP") No. 157-2 "Partial Deferral of the Effective Date of Statement 157," ("FSP No. 157-2"), which delays the effective date of SFAS No. 157 for all non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in the financials statements on a recurring basis (at least annually) to fiscal years beginning after November 15, 2008. The adoption of SFAS No. 157 did not have a material effect on the Company's financial position, results of operations or its cash flows (refer Note 13).

In December 2007, the FASB issued SFAS 141 (Revised 2007), "Business Combinations." SFAS No. 141R retains the underlying concepts of SFAS No. 141 in that business combinations are still accounted for at fair value. However, the accounting for certain other aspects of business combinations will be affected. Acquisition costs will generally be expensed as incurred. Restructuring costs associated with a business combination will generally be expensed subsequent to the acquisition date. In-process

**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

research and development will be recorded at fair value as an indefinite-lived intangible at the acquisition date until it is completed or abandoned and its useful life can be determined. Changes in deferred tax asset valuation allowances and uncertain tax positions after the acquisition date will generally impact income tax expense. SFAS No. 141R also expands required disclosures surrounding the nature and financial effects of business combinations. SFAS No. 141R is effective, on a prospective basis, for the Company in the first quarter of fiscal 2010, only if we complete a business combination.

In April 2008, the FASB issued Staff Position (“FSP”) No. 142-3, “Determination of the Useful Life of Intangible Assets”. FSP No. 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, “Goodwill and Other Intangible Assets”. FSP No. 142-3 is effective for the Company in the first quarter of 2010. The Company is currently assessing the impact of FSP No. 142-3 on its results of operations, financial position or cash flows.

In May 2008, the FASB issued Statement of Financial Accounting Standards (“SFAS”) No. 162, “The Hierarchy of Generally Accepted Accounting Principles” (SFAS No. 162). SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements. SFAS No. 162 is effective 60 days following the SEC’s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, “The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles”. The Company has adopted this accounting standard which did not have material impact on its results of operations, financial position or cash flows.

**3. Stock Option Plans, Stock-Based Compensation and Common Stock**

***Stock Option Plans***

During 1996, the Company adopted the 1996 Stock Option/Restricted Stock Plan (the “1996 Stock Plan”). The 1996 Stock Plan provides for the granting of incentive and non-qualified stock options and stock bonus awards to officers, directors and employees of the Company. The maximum number of shares that may be issued pursuant to the 1996 Stock Plan is 156,250. All of the outstanding options under the 1996 Stock Plan are fully vested 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, 2006, all shares had been issued under the 1996 Stock Plan.

During 1998, the Company adopted the 1998 Equity Incentive Plan (the “1998 Stock Plan”). The 1998 Stock Plan also provides for granting of incentive and nonqualified stock option and stock bonus awards to officers, employees and outside consultants. Outstanding options under the 1998 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, 2008, 1,250,000 shares of common stock were authorized for issuance under the 1998 Stock Plan, of which 550,851 shares had been issued and 590,001 shares were subject to outstanding options at a weighted average exercise price of \$7.33 per share. The 1998 Stock Plan was closed to any future grants at the time of the Company’s IPO and therefore the Company will not make any additional grants under the 1998 Stock Plan.

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

**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**3. Stock Option Plans, Stock-Based Compensation and Common Stock (Continued)**

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, 2008, 2,946,022 shares of common stock were authorized for issuance under the 2004 Stock Plan, of which 92,963 shares had been issued, 1,743,101 shares were subject to outstanding options at a weighted average exercise price of \$6.95 per share and 1,109,958 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.

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 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.

Certain stock options granted prior to January 1, 2006 covering a total of 15,480 shares were modified during 2006 to increase the exercise price to the estimated fair market value as of the original date of grant. These stock options were originally issued at a discount to fair market value in the first half of 2004 prior to the Company's IPO. The grants have been revalued using the Black Scholes option pricing model and the sum of the difference between fair value immediately before and after the modifications and the remaining original intrinsic value is being amortized to expense over the remaining vesting period.

In June 2004, the Company adopted the 2004 Employee Stock Purchase Plan ("ESPP"). All of our employees who have 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 are eligible to participate and any employee who owns 5% or more of the voting power or value of our stock is not eligible to participate. An employee may purchase no more than \$25,000 worth of common stock, valued at the start of the purchase period, in any calendar year. The ESPP authorizes the issuance of up to a total of 375,000 shares of our common stock to participating employees.

Under the 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 ESPP is regarded as a compensatory plan according to the provisions of SFAS No. 123(R). Under this plan, the Company has issued 164,550, 32,656 and 23,140 shares of its common stock during the years ended December 31, 2008, 2007 and 2006, respectively.



**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**3. Stock Option Plans, Stock-Based Compensation and Common Stock (Continued)**

A summary of activity under the Company's 1996, 1998 and 2004 Stock Plans for the year ended December 31, 2008 is presented below:

	<u>Number of Shares</u>	<u>Exercise Price Range</u>	<u>Weighted Average Exercise Price</u>
Stock Option Awards			
Outstanding at December 31, 2007 . . . . .	1,848,892	0.40–38.96	11.92
Granted at fair value . . . . .	1,352,750	0.61–10.92	1.99
Exercised . . . . .	(4,113)	0.90– 2.52	1.31
Forfeited . . . . .	(864,427)	0.40–38.96	9.59
Outstanding at December 31, 2008 . . . . .	<u>2,333,102</u>	\$0.61–37.23	\$ 7.05

The aggregate intrinsic value of options exercised during the years ended December 31, 2008, 2007 and 2006 was \$4,961, \$99,034 and \$5,304,033, respectively.

The following table summarizes information about stock options outstanding at December 31, 2008:

<u>Exercise Price</u>	<u>Number of Options Outstanding</u>	<u>Weighted Average Remaining Contractual Life (Years)</u>	<u>Weighted Average Exercise Price</u>
\$0.61–1.45 . . . . .	210,223	9.7	\$ 1.07
\$1.46–2.02 . . . . .	381,499	8.8	1.99
\$2.13–2.13 . . . . .	498,000	9.4	2.13
\$2.17–7.98 . . . . .	79,153	5.1	3.22
\$8.00–8.00 . . . . .	511,250	5.5	8.00
\$8.13–37.23 . . . . .	652,977	7.6	15.40
	<u>2,333,102</u>	7.8	\$ 7.05

The following table summarizes information about stock options exercisable at December 31, 2008:

<u>Exercise Price</u>	<u>Number of Options Exercisable</u>	<u>Weighted Average Exercise Price</u>
\$0.61–1.45 . . . . .	4,723	\$ 1.33
\$1.46–2.02 . . . . .	17,499	1.99
\$2.13–2.13 . . . . .	—	—
\$2.17–7.98 . . . . .	70,371	2.95
\$8.00–8.00 . . . . .	511,250	8.00
\$8.13–37.23 . . . . .	367,238	16.79
	<u>971,081</u>	\$10.82

**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**3. Stock Option Plans, Stock-Based Compensation and Common Stock (Continued)**

The weighted average remaining contractual life for stock options exercisable at December 31, 2008 was 6.0 years. The aggregate intrinsic value for stock options outstanding and exercisable at December 31, 2008 was \$9,160 and \$0.00 respectively.

***Stock-Based Compensation***

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, 2008, 2007 and 2006 is calculated using the Black-Scholes option pricing model with the following weighted average assumptions:

	Years Ended December 31,		
	2008	2007	2006
Risk-free interest rate . . . . .	1.3%–3.5%	3.3%–5.1%	4.3%–5.2%
Expected dividend yield . . . . .	—	—	—
Expected option term . . . . .	5 years	5 years	5 years
Volatility . . . . .	85.0%–120.0%	60.0%–70.0%	50.0%–75.0%
Weighted average fair value of options granted at fair value . . . . .	\$1.44	\$5.76	\$14.76
Weighted average fair value of options granted below fair value . . . . .	\$—	\$—	\$—

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 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 using four classifications of employees.

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 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. In 2008, 2007 and 2006, the Company used a risk-free interest rate assumption that ranged from 0.3% to 2.2%, 3.5% to 5.1% and 5.1%-5.2%, respectively. 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. In 2008, 2007 and 2006, the expected future stock price volatility ranged from 90.0% to 120.0%, 60.0% to 70.0% and 50%-90%, respectively.

The Company recorded stock-based compensation expense of \$2,228,839, \$3,071,090 and \$2,652,637 for the years ended December 31, 2008, 2007 and 2006, respectively. Included in the stock-

**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**3. Stock Option Plans, Stock-Based Compensation and Common Stock (Continued)**

based compensation expense recorded by the Company for the years ended December 31, 2008, 2007 and 2006 is (a) \$2,176,825, \$2,902,662 and \$2,265,556, respectively, in compensation expense relating to stock options granted to employees subsequent to the Company's July 2004 IPO that are accounted for according to the provisions of SFAS No. 123(R); (b) \$9,574, \$37,752 and \$53,471, respectively, in reductions of compensation expense related to stock options granted to non-employees that are accounted for according to the provisions of Emerging Issues Task Force ("EITF") Issue No. 96-18 *"Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services"* ("EITF No. 96-18"); (c) \$79,401, \$94,325 and \$159,450, respectively, in compensation expense related to the ESPP and accounted for under the provisions of SFAS No. 123(R); (d) \$0, \$95,031 and \$249,415, respectively in compensation expense relating to stock options granted to employees prior to the Company's IPO that are being accounted for using the intrinsic value method according to the provisions of SFAS No. 123(R) and (e) \$(17,813) reduction, \$16,824 and \$31,657, respectively in modifications to pre-IPO option grants.

Stock options granted to non-employees are recorded at fair value and adjusted to market over the vesting period according to the provisions of EITF No. 96-18. 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 120% and a dividend yield of zero.

Total unrecognized stock-based compensation costs related to non-vested stock options was approximately \$6,088,301 which related to approximately 1,362,021 shares with a per share weighted fair value of \$4.47 as of December 31, 2008. This unrecognized cost is expected to be recognized over a weighted average period of approximately 2.2 years.

As of December 31, 2008, there were 2,056,092 stock options vested and expected to vest with a weighted average exercise price of \$7.28 per share, a weighted average contractual remaining life of 7.6 years and an aggregate intrinsic value of \$7,457. 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, 2008, 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, 2008.

***Common Stock***

As of December 31, 2008, the Company had 50,000,000 shares of common stock authorized and 13,858,797 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.

**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**3. Stock Option Plans, Stock-Based Compensation and Common Stock (Continued)**

At December 31, 2008, the Company has reserved authorized shares of common stock for future issuance as follows:

Outstanding stock options . . . . .	2,333,102
Possible future issuance under stock option plans . . . . .	1,109,958
Possible future issuance under employee stock purchase plan . . . . .	<u>121,857</u>
Total . . . . .	<u><u>3,564,917</u></u>

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.

**4. Acquisition of EyeTel**

On December 26, 2007, the Company acquired substantially all of the assets of EyeTel for an aggregate purchase price 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 engaged in the design, development, and commercialization of proprietary medical devices, including the DigiScope, a device that helps physicians detect eye disorders such as diabetic retinopathy, the leading cause of blindness in patients with diabetes. The Company had previously entered into an exclusive licensing agreement with EyeTel pursuant to which the Company had sales and marketing rights to the DigiScope in the primary diabetes care physician market.

In accordance with the provisions of SFAS No. 141, "*Business Combinations*" the assets acquired and liabilities assumed have been 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. The fair value of the intangible assets was determined primarily through assessments by the Company's management and the fair value of the tangible assets acquired and liabilities assumed approximated their carrying values.

**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**4. Acquisition of EyeTel (Continued)**

The purchase price was allocated to the acquired tangible, intangible and assumed liabilities based on their estimated fair values at the date of acquisition as follows:

Cash . . . . .	\$ 175,000
Issuance of 1,050,297 shares of NeuroMetrix Stock . . . . .	9,784,548
Acquisition costs . . . . .	150,000
Total consideration . . . . .	<u>\$10,109,548</u>
Net tangible assets:	
Restricted cash . . . . .	\$ 45,000
Accounts receivable . . . . .	35,000
Fixed assets . . . . .	1,985,000
Other current assets . . . . .	216,000
Accounts payable and accrued expenses . . . . .	<u>(804,916)</u>
Net tangible assets . . . . .	1,476,084
Other intangible assets . . . . .	2,800,000
Goodwill . . . . .	5,833,464
Total . . . . .	<u><u>\$10,109,548</u></u>

***Pro Forma Financial Summary (Unaudited)***

The following pro forma financial summary is presented as if the acquisition of EyeTel was completed as of the beginning of 2007. The pro forma combined results are not necessarily indicative of the actual results that would have occurred had the acquisitions been consummated on those dates, or of the future operations of the combined entities.

	<b>December 31, 2007</b>
Total revenues . . . . .	<u>\$ 44,814,865</u>
Net loss . . . . .	<u><u>\$(19,760,624)</u></u>
Loss per common share:	
Basic and diluted loss per common share . . . . .	<u><u>\$ (1.44)</u></u>
Weighted average shares used to compute net loss per common share:	
Basic and diluted weighted average shares used to compute net loss per common share: . . . . .	13,678,607

On September 30, 2008, the Company approved a plan for the closure of our facility in Columbia, Maryland and discontinuance of sales and support of DigiScopes and DigiScope related services, effective November 1, 2008. On November 7, 2008, the Company signed an Asset Purchase Agreement with Advanced Diagnostics, LLC relating to the sale of substantially all of our EyeTel/DigiScope assets in exchange for assuming 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 ours who continued to receive payments under a separation agreement with us through February 2009.

**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**4. Acquisition of EyeTel (Continued)**

The Company incurred a net loss of approximately \$4.6 million on sale of discontinued operations to the related party which has been included in “(Loss) on sale of discontinued operations” in the Statements of Operations. As of December 31, 2008, there is a receivable balance of \$30,000 outstanding under this agreement.

In 2007, the Company had been marketing the DigiScope to the primary diabetes care physician office market through an exclusive sales and marketing license with EyeTel. All revenues and associated costs related to the sale of the DigiScope have been recast to discontinued operations for 2008 and 2007. Loss from discontinued operations includes loss on operations and sale of assets relating to our discontinued operation.

**5. Joint Venture with Cyberkinetics**

In February 2008, the Company and Cyberkinetics formed PNIR and entered into a Collaboration Agreement and Operating Agreement to develop and commercialize products for the treatment of peripheral nerve injury. The joint venture was initially 50% owned by the Company and 50% owned by Cyberkinetics. Under the terms of the joint venture, the Company had agreed to fund the initial \$2.0 million in product development costs and the Company and Cyberkinetics were to share equally in all costs in excess of the initial \$2.0 million. Cyberkinetics had contributed technology, know-how and intellectual property, primarily relating to their Andara OFS technology, to the joint venture.

The Company obtained sales and marketing rights and Cyberkinetics obtained commercial manufacturing rights to any products commercialized under the joint venture. Each party was to charge the joint venture at cost for all expenses incurred in connection with their respective commercialization activities. Profits and losses realized from the joint venture were to split equally between the Company and Cyberkinetics based on the initial ownership percentage.

The joint venture was considered to be a variable interest entity under the provisions of FIN 46(R). The Company had determined that it is 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 had consolidated the joint venture and recorded the \$2.1 million contribution of technology and intellectual property by Cyberkinetics to intangible assets and a minority interest of \$2.1 million at the formation date of the joint venture. The fair value of the intangible assets was determined primarily by an assessment made by the Company’s management applying the income approach and a relief from royalty approach.

Cyberkinetics, in its Form 8-K filed on November 3, 2008, disclosed that its existing cash and cash equivalents are only sufficient to meet their projected operating requirements for approximately 30 days. As Cyberkinetics was in the process of winding down its operations, the value of the Company’s investment in Cyberkinetics was adversely affected (refer Note 8).

The Company re-evaluated the value of the joint venture intangible assets and determined them to be fully impaired as a result of (i) the Cyberkinetics announcement in November and (ii) a strategic change in direction with the development of the intangible assets. The Company recorded an impairment charge of \$1.8 million within the Statement of Operations. The joint venture was legally dissolved in January 2009, effective as of December 31, 2008, and was deconsolidated from the Company’s books, resulting in a gain on deconsolidation to the Statement of Operations of \$2.1 million recognized within continuing operations in the fourth quarter of the year ended December 31, 2008.



**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**6. Goodwill and Intangible Assets**

*Goodwill*

As result of the acquisition of EyeTel on December 26, 2007, the Company identified approximately \$5.8 million of goodwill on its balance sheet at December 31, 2007 (refer Note 4). The operations of EyeTel were incorporated into the Company's one segment and the Company determined that it is comprised of a single reporting unit for goodwill impairment testing. Subsequent to the AMA CPT Panel meeting in February 2008, the Company's common stock price declined significantly.

In March 2008, the Company determined that an interim goodwill impairment test was required. As the net book value of the Company's assets significantly exceeded the enterprise value, the Company performed step two of its SFAS No. 142 impairment test in which it assessed the fair value of all recorded and unrecorded tangible and intangible assets and liabilities, including its recently acquired EyeTel and PNIR intangible assets and determined that there was no residual value of goodwill. Accordingly, the Company recorded a charge of \$5.8 million to write off the goodwill during the first quarter of 2008.

*Intangible Assets*

As a result of the acquisition of substantially all of the assets of EyeTel on December 26, 2007, the Company recorded \$2.8 million of gross intangibles assets representing the fair value of technology and intellectual property. The Company amortizes intangible assets using the straight-line method over their estimated economic lives and performs impairment tests under SFAS No. 144. On September 30, 2008, as part of our ongoing focus on cost-efficiencies in all areas of our business, and our refocused efforts towards our core business, we approved a plan for the closure of our facility in Columbia, Maryland and to discontinue 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.

The Company recorded an intangible asset of \$2.1 million, representing the value of the contribution of technology and intellectual property by Cyberkinetics upon the formation of PNIR. 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 (i) the Cyberkinetics announcement in November and (ii) a strategic change in direction with the development of the intangible assets. The Company recorded an impairment charge of \$1.8 million within the Statement of Operations.

Changes in intangible assets for the years ended 31 December 2008 and 2007 were as follows:

	December 31, 2008				December 31, 2007		
	Gross Intangibles	Accumulated Amortization	Asset Impairment	Net Intangibles	Gross Intangibles	Accumulated Amortization	Net Intangibles
Technology . . . . .	\$2,800,000	\$(420,000)	\$(2,380,000)	\$—	\$2,800,000	\$—	\$2,800,000
Contribution of technology . . . . .	2,100,000	(332,500)	(1,767,500)	—	—	—	—
Total . . . . .	\$4,900,000	\$(752,500)	\$(4,147,500)	\$—	\$2,800,000	\$—	\$2,800,000

Amortization expense for the year ended December 31, 2008 was \$752,000. There was no amortization expense for the same period in 2007.

**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**7. Inventories**

At December 31, 2008 and 2007, inventories consist of the following:

	December 31,	
	2008	2007
Purchased components . . . . .	\$1,640,967	\$1,216,758
Finished goods . . . . .	3,965,840	4,137,580
	<u>\$5,606,807</u>	<u>\$5,354,338</u>

**8. Investments**

***Short-Term Held-to-Maturity***

Held-to-maturity investments as of December 31, 2008 and 2007 are as follows:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
<b>2008</b>				
Certificate of deposits . . . . .	\$ 7,495,000	\$ —	\$ —	\$ 7,495,000
	<u>\$ 7,495,000</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 7,495,000</u>
<b>2007</b>				
Commercial paper and bank notes . . . . .	\$ 964,900	\$ 9,960	\$ —	\$ 974,860
Corporate bonds . . . . .	21,656,841	5,049	(25,807)	21,636,083
	<u>\$22,621,741</u>	<u>\$15,009</u>	<u>\$(25,807)</u>	<u>\$22,610,943</u>

The following table shows the gross unrealized losses and fair value of the Company's held-to-maturity investments with unrealized losses that are not deemed to be other-than-temporarily impaired, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position, at December 31, 2008 and 2007:

	12 Months or less		Greater than 12 Months		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
<b>2008</b>						
Certificate of deposits . . . . .	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
<b>2007</b>						
Corporate bonds . . . . .	<u>\$15,701,223</u>	<u>\$(25,807)</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$15,701,223</u>	<u>\$(25,807)</u>

Corporate bonds—At December 31, 2007, the Company held 13 corporate bonds in an unrealized loss position which was primarily the result of higher market interest rates since the date of purchase, rather than a decline in credit quality of these investments. The contractual terms of these investments do not permit the issuers to settle the securities at a price less than the face value of the investment.

**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**8. Investments (Continued)**

Each of the bonds maintains a Standard & Poor's rating of A or higher and has made each of their scheduled interest payments. The Company held these investments until maturity.

The amortized cost and fair value of fixed maturity securities at December 31, 2008 and 2007, by contractual maturity, are shown below:

	December 31,			
	2008		2007	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Due in one year or less . . . . .	\$7,495,000	\$7,495,000	\$22,621,741	\$22,610,943

***Long-Term Available-for-Sale Investment***

In November 2007, the Company purchased approximately 5.4 million shares of common stock of Cyberkinetics, representing approximately 13% of the Cyberkinetics' issued and outstanding shares at the time of the investment, at a price of \$0.46 per share for an aggregate purchase price of \$2.5 million. The Company also received a warrant to purchase up to approximately 2.7 million shares of Cyberkinetics common stock. The warrant is exercisable at \$0.46 per share and has a term of five years. We would have been required to exercise the warrant if Cyberkinetics received FDA approval of an HDE filing for the Andara OFS device for acute spinal cord injuries by December 31, 2008, which they did not. In addition, Cyberkinetics agreed to nominate and recommend to their stockholders for election to their board of directors a representative designated by the Company. Dr. Shai Gozani M.D. Ph.D., our Chief Executive Officer and President, had been named as our initial designee.

We reviewed the carrying value of this investment periodically to determine whether an other-than-temporary decline in market value existed. The Company considered factors such as the length of time the value of the investment has been below its original purchase price, the financial condition of the investee and near-term prospects for the investee's recovery to original purchase price and our intent with regard to the underlying investment. Cyberkinetics, in its Form 8-K filed on November 3, 2008, disclosed that its existing cash and cash equivalents were only sufficient to meet their projected operating requirements for approximately 30 days. As Cyberkinetics was in the process of winding down operations, the value of the Company's investment in Cyberkinetics was adversely affected. The Company marked this investment to market as of December 31, 2008 and, taking into account the factors noted above, have recorded year-to-date charges of \$2.5 million because it is believed that the decline in the value of this investment is other-than-temporary. Accordingly, as of December 31, 2008 this investment has been written down to zero.

**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**9. Fixed Assets**

Fixed assets consist of the following:

	Estimated Useful Life	December 31,	
	(Years)	2008	2007
Computer and laboratory equipment .	3	\$ 2,156,195	\$ 1,908,750
Furniture and equipment . . . . .	3	594,415	411,116
DigiScope equipment . . . . .	5	—	1,985,000
Production equipment . . . . .	7	1,022,987	665,267
Construction in progress . . . . .	—	11,606	288,829
Leasehold improvements . . . . .	*	158,172	150,097
		3,943,375	5,409,059
Less—accumulated depreciation . . . .		(2,870,199)	(2,435,341)
		<u>\$ 1,073,176</u>	<u>\$ 2,973,718</u>

\* Lesser of life of lease or estimated useful life

Depreciation expense was \$840,967, \$422,938 and \$380,655 for the years ended December 31, 2008, 2007 and 2006, respectively.

A capital lease is included as a component of furniture and equipment at December 31, 2008 and 2007. Amortization of assets under this capital lease amounting to \$7,437 and \$7,525 is included in depreciation expense for the years ended December 31, 2008 and 2007 respectively.

**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**10. Accrued Expenses**

Accrued expenses consist of the following for the years ended December 31, 2008 and 2007:

	December 31,	
	2008	2007
Professional services . . . . .	\$ 470,857	\$ 706,952
Sales taxes . . . . .	325,847	489,555
Legal settlements . . . . .	3,705,866	—
Other . . . . .	884,129	1,112,056
	<u>\$5,386,699</u>	<u>\$2,308,563</u>

**11. Income Taxes**

The Company's effective income tax rate differs from the statutory federal income tax rate as follows for the years ended December 31, 2008, 2007 and 2006.

	Years Ended December 31,		
	2008	2007	2006
Federal tax provision (benefit) rate . . . . .	34.0%	34.0%	34.0%
State tax provision (benefit), net of federal provision (benefits) . .	2.1	4.6	7.4
Permanent items . . . . .	(19.2)	(1.1)	11.1
Federal research and development credits . . . . .	0.3	0.5	(4.2)
Alternative minimum tax . . . . .	—	—	4.3
Alternative minimum tax credit . . . . .	—	—	(2.7)
Valuation allowance . . . . .	(17.2)	(38.0)	(45.8)
Effective income tax rate . . . . .	<u>—%</u>	<u>—%</u>	<u>4.3%</u>

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

	December 31,	
	2008	2007
Deferred tax assets:		
Net operating loss carryforwards . . . . .	\$ 16,249,932	\$ 11,797,528
Research and development credit carryforwards . . . .	1,056,590	957,221
Alternative minimum tax credit . . . . .	120,490	120,490
Accrued expenses . . . . .	1,122,066	1,713,220
Other . . . . .	2,642,634	1,650,107
Total gross deferred tax assets . . . . .	21,191,712	16,238,566
Valuation allowance . . . . .	(21,191,712)	(16,238,566)
Net deferred tax assets . . . . .	<u>\$ —</u>	<u>\$ —</u>

At December 31, 2008, the Company has federal and state net operating loss carry-forwards ("NOL") of approximately \$49.3 million and \$28.2 million, respectively, as well as federal and state tax credits of approximately \$651,000 and \$575,000, respectively, which may be available to reduce future

**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**11. Income Taxes (Continued)**

taxable income and the related taxes thereon. This amount includes tax benefits of \$3.8 million and \$71,000 attributable to NOL and tax credit carry-forwards, 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 begin to expire in 2009.

As required by SFAS 109, 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 loss. 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 \$16.2 million and \$21.2 million has been established at December 31, 2007 and 2008, respectively.

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 their ability to utilize the affected loss carry-forwards in future years. Subsequent ownership changes could further impact the limitation in future years.

In June 2006, the FASB issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" which is an interpretation of FASB Statement 109, "Accounting for Income Taxes." FIN 48 requires management to perform 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. The adoption of FIN 48 did not have a material impact on the Company's financial position, results of operations or cash flows.

Management reviewed the tax position of the R&D credit carry-forward in 2007 and determined that a \$100,000 reserve against the carry-forward balance should be made. The 2007 R&D credit balance of \$698,000 was reduced by this \$100,000 reserve, prior to the recording of 2008 activity. The Company charges interest and penalties related to income taxes to general and administrative expense. The amounts charged for the 12 months ended December 31, 2008, 2007 and 2006 were \$9,838, \$13,439, and \$1,292, respectively.

**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 April 2009 through March 2013 will be reduced from \$930,000 annually to a range of \$675,000 to \$765,000 annually.



**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**12. Commitments and Contingencies (Continued)**

Future minimum lease payments under noncancelable operating leases as of December 31, 2008 are as follows:

2009 .....	\$ 738,750
2010 .....	697,500
2011 .....	727,500
2012 .....	757,500
2013 .....	<u>191,250</u>
Total minimum lease payments .....	<u>\$3,112,500</u>

Total recorded rent expense was \$719,568 for the year ended December 31, 2008, and \$871,819 for each of the years ended December 31, 2007 and 2006. The Company records rent expense on its facility lease on a straight line basis over the term.

***Capital Lease***

In September 2008, the Company entered into a non-cancelable capital lease for copiers located at our corporate headquarters valued at \$89,244, expiring in August 2011.

Future minimum lease payments under the capital lease as of December 31, 2008, are as follows:

2009 .....	45,600
2010 .....	45,600
2011 .....	<u>34,200</u>
Total capital lease payments .....	<u>\$125,400</u>

***Other Commitments***

At December 31, 2008, other commitments, mainly comprising of purchase orders, totaled approximately \$1.7 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, 2008 and 2007, the Company has recorded \$408,000 and \$1,458,598, respectively as restricted cash associated with this lease on the accompanying balance sheet.

***Legal Matters***

As previously disclosed in our filings with the Securities and Exchange Commission, or SEC, pursuant to Section 13 or 15(d) under the Securities Act, 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

**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**12. Commitments and Contingencies (Continued)**

subsequently consolidated, and the court appointed a lead plaintiff. On November 10, 2008, a consolidated amended class action complaint was filed, which alleges, among other things, that between October 27, 2005 and February 12, 2008, 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 are seeking 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. In March 2009, the parties mutually agreed to participate in mediation to attempt to resolve the litigation, and the court entered an order staying the proceedings until the mediation is complete. A mediation is currently scheduled for June 2009.

As previously disclosed in our filings with the SEC pursuant to Section 13 or 15(d) under the Securities Act, 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. The complaint alleges, among other things, that, between August 2004 and the date the action was filed, the defendants engaged in the same conduct alleged in the putative securities class actions, causing us to make false and misleading statements, to fail to disclose material information to the public and to engage in improper business practices. The plaintiffs are seeking various forms of monetary and non-monetary relief. In March 2009, the parties agreed to participate in mediation to attempt to resolve the litigation, currently scheduled for June 2009.

The litigation process is inherently uncertain, and we cannot guarantee that the outcomes of the above lawsuits will be favorable for us or that they will not be material to our business, results of operations or financial position.

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. We have been cooperating with the investigation since it began in 2006.

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, or the Settlement Agreement, dated February 9, 2009, with the DOJ and OIG. 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 do 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.

**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**12. Commitments and Contingencies (Continued)**

As of December 31, 2008, we have accrued \$3.7 million for this settlement which is included in “Accrued expenses” on our Balance Sheet at that date and was subsequently paid in the first quarter of 2009.

**13. Fair Value Measurements**

The Company adopted SFAS No. 157 effective January 1, 2008 for its financial assets and liabilities that are re-measured and reported at fair value at each reporting period. In accordance with the provisions of FSP No. 157-2, the Company elected to defer implementation of SFAS No. 157 as it related to its non-financial assets and liabilities that are recognized and disclosed at fair value in the financial statements on a non-recurring basis until January 1, 2009. The Company is evaluating the impact, if any, that SFAS No. 157 will have on its non-financial assets and liabilities.

The adoption of SFAS No. 157 with respect to financial assets and liabilities and non-financial assets and liabilities that are re-measured and reported at fair value at least annually was not material to the Company’s financial position, results of operations or its cash flows for the year ended December 31, 2008. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in applying generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS No. 157 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, SFAS No. 157 requires companies to prioritize the inputs used to measure fair value into one of three broad levels. Fair values determined by Level 1 inputs utilized 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 table provides fair value measurement information for the Company’s major categories of financial assets and liabilities measured on a recurring basis:

		<b>Fair value measurements at reporting date using</b>		
	<b>December 31, 2008</b>	<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
Cash Equivalents . . . . .	\$8,992,107	\$8,992,107	\$—	\$—
Total . . . . .	<u>8,992,107</u>	<u>8,992,107</u>	<u>—</u>	<u>—</u>

**NeuroMetrix, Inc.**  
**Notes to Financial Statements (Continued)**

**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, 2008, 2007 and 2006 the Company made no contributions to the plan.

**NeuroMetrix, Inc.**  
**Schedule II—Valuation and Qualifying Accounts**

<u>Description</u>	<u>Balance at Beginning of Period</u>	<u>Charged to costs and expenses</u>	<u>Deductions (Describe)</u>	<u>Balance at End of Period</u>
<b>December 31, 2008</b>				
Allowance for Doubtful Accounts . . . . .	\$ 906,000	\$ 355,774	\$ (611,774) <sup>(1)</sup>	\$ 650,000
Deferred Tax Asset Valuation Allowance .	16,238,566	5,155,327	(202,181) <sup>(2)</sup>	21,191,712
<b>December 31, 2007</b>				
Allowance for Doubtful Accounts . . . . .	900,000	358,141	(352,141) <sup>(1)</sup>	906,000
Deferred Tax Asset Valuation Allowance .	13,803,416	2,642,021	(206,871) <sup>(2)</sup>	16,238,566
<b>December 31, 2006</b>				
Allowance for Doubtful Accounts . . . . .	400,000	946,850	(446,850) <sup>(1)</sup>	900,000
Deferred Tax Asset Valuation Allowance .	16,081,539	2,226,513	(4,504,636) <sup>(2)</sup>	13,803,416

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(1) Write-offs

(2) Utilization and expiration of Federal and State Net Operating Loss Carryforwards

**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 and 333-151195) and on Form S-3 (No. 333-150087) of NeuroMetrix, Inc. of our report dated March 20, 2009 relating to the financial statements and financial statement schedule, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts

March 20, 2009



**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
  - d) 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 20, 2009

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

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Shai N. Gozani, M.D., Ph. D.  
*Chief Executive Officer and President*

**CERTIFICATION**

I, Joseph A. Calo, 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
  - d) 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 20, 2009

/s/ JOSEPH A. CALO

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Joseph A. Calo  
*Acting Chief Financial Officer and  
Treasurer (Principal Financial Officer)*

**CERTIFICATION**

Each of the undersigned officers of NeuroMetrix, Inc. (the “Company”) hereby certifies that, to his knowledge, the Company’s Annual Report on Form 10-K to which this certification is attached (the “Report”), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 20, 2009

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

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Shai N. Gozani, M.D., Ph. D.  
*Chief Executive Officer and President*

/s/ JOSEPH A. CALO

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Joseph A. Calo  
*Acting Chief Financial Officer and  
Treasurer (Principal Financial Officer)*

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.

# Corporate Information

## Corporate Officers

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**Shai N. Gozani, M.D., Ph.D.** – Chairman, President and CEO

**Joseph A. Calo** – Acting Chief Financial Officer and Treasurer

**Guy Daniello** – Senior Vice President of Information Technology

**Michael Williams, Ph.D.** – Senior Vice President of Engineering

## Board of Directors

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**Shai N. Gozani, M.D., Ph.D.** – Chairman, President and CEO, NeuroMetrix, Inc.

**David E. Goodman, M.D.** – Executive Vice President of Business Development, Masimo Corporation

**Charles R. LaMantia** – Former President and CEO, Arthur D. Little

**W. Mark Lortz** – Independent Consultant; Former President and CEO, TheraSense

**Allen J. Hinkle, M.D.** – Chief Medical Officer, Tufts Health Plan

**Timothy R. Surgenor** – Partner, Red Sky Partners, LLC;

Former President and CEO, Cyberkinetics Neurotechnology Systems, Inc.

## Corporate Directory

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### Corporate Headquarters

NeuroMetrix, Inc., 62 Fourth Avenue, Waltham, Massachusetts 02451

### Registrar and Transfer Agent

American Stock Transfer & Trust Company

40 Wall Street, New York, New York 10005

### Legal Counsel

Goodwin Procter LLP, Boston, Massachusetts

### Independent Registered Public Accounting Firm

PricewaterhouseCoopers LLP, Boston, Massachusetts

### Common Stock

The company's common stock is traded on the NASDAQ Global Market under the symbol NURO.

### Form 10-K

Additional copies of the company's Form 10-K may be obtained without charge through our website at [www.neurometrix.com/investors](http://www.neurometrix.com/investors) or by writing to Investor Relations.

### Annual Meeting of Shareholders

The annual meeting of shareholders will be held on Thursday, May 21, 2009, at 8:30 am at the offices of Goodwin Procter LLP, Exchange Place, 53 State Street, Boston, Massachusetts.

# NEUROMetrix

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62 Fourth Avenue  
Waltham, Massachusetts 02451

Phone: 781.890.9989

Fax: 781.890.1556

[www.neurometrix.com](http://www.neurometrix.com)

NASDAQ Ticker Symbol: NURO