

NEUROMETRIX, INC.

FORM 10-K (Annual Report)

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

FORM 10-K

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

For the Year Ended December 31, 2005

Commission File Number 000-50856

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 02451
(Address, Including Zip Code, of Principal Executive Offices)

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

Securities Registered Pursuant To Section 12(b) of the Act: None
Securities Registered Pursuant to Section 12(g) of the Act:
Common Stock, \$0.0001 par value per share
(Title of Class)

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 or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act (check one): Large accelerated filer Accelerated filer Non-accelerated filer

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, 2005 the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately \$163,134,000, based on the closing sale price of the common stock as reported on the NASDAQ National Market on June 30, 2005. 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 10, 2006, there were 12,457,108 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the registrant's 2006 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, 2005, are incorporated by reference into Part III of this Annual Report on Form 10-K.

NEUROMETRIX, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2005

TABLE OF CONTENTS

	<u>Page</u>
PART I	
Item 1: Business	1
Item 1A: Risk Factors	26
Item 1B: Unresolved Staff Comments	40
Item 2: Properties	40
Item 3: Legal Proceedings	40
Item 4: Submission of Matters to a Vote of Security Holders	40
PART II	
Item 5: Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	41
Item 6: Selected Financial Data	42
Item 7: Management's Discussion and Analysis of Financial Condition and Results of Operations	43
Item 7A: Quantitative and Qualitative Disclosures About Market Risk	61
Item 8: Financial Statements and Supplementary Data	62
Item 9: Disagreements with Accountants on Accounting and Financial Disclosure	62
Item 9A: Controls and Procedures	62
Item 9B: Other Information	63
PART III	
Item 10: Directors and Executive Officers of the Registrant	64
Item 11: Executive Compensation	64
Item 12: Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	64
Item 13: Certain Relationships and Related Transactions	64
Item 14: Principal Accountant Fees and Services	64
PART IV	
Item 15: Exhibits and Financial Statement Schedule	64
Signatures	67

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, 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

We design, develop and sell proprietary medical devices used to diagnose neuropathies. Neuropathies are diseases of the peripheral nerves and parts of the spine that frequently are caused by or associated with diabetes, low back pain and carpal tunnel syndrome, as well as other clinical disorders. We believe that our neuropathy diagnostic system, the NC-stat System, improves the quality and efficiency of patient care by offering all physicians the ability to diagnose 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.

Neuropathies traditionally have been evaluated by simple clinical examination by the primary care physician, and, in some cases, subsequently diagnosed by a nerve conduction study and needle electromyography, or NCS/nEMG, procedure performed by a neurologist or physician in a related specialty. We estimate that there are approximately 2.0 million traditional NCS/nEMG procedures currently performed each year in the United States. We believe that use of traditional NCS/nEMG procedures is limited by: (1) the need to obtain a referral to a neurologist for the procedure and the resulting delay in availability of diagnostic information; (2) the inconvenience and discomfort of these procedures for the patient; and (3) the expense to the patient and third-party payer. We anticipate that the advantages and increased availability of the NC-stat System will significantly increase the number of nerve conduction studies performed. Based on our analysis of current data, we estimate that the potential market size for point-of-service nerve conduction studies in the diabetes, low back pain and carpal tunnel syndrome markets in the aggregate could be greater than 9.5 million annual patient tests, estimated to be more than \$1.0 billion annually for our disposable biosensors, in the United States.

Our goal is to become the leading provider of innovative, proprietary, high margin medical devices that provide comprehensive solutions for the diagnosis and treatment of patients with neuropathies. To date, our primary focus has been on the diagnosis of neuropathies. We also believe that our core technology can be adapted and extended to provide minimally invasive approaches to treating neuropathies. We are in the early stages of designing a drug delivery system for the minimally invasive treatment of neuropathies by both primary care and specialist physicians.

All of our current products have received 510(k) clearance by the United States Food and Drug Administration, or FDA. The NC-stat System has been on the market since May 1999 and is presently used in nearly 3,300 physician's offices, clinics and other health care facilities. We hold issued utility patents covering a number of important aspects of our NC-stat System. In 2005, we increased our revenues from the prior year by 91%, generating \$34.3 million in revenues, compared with \$17.9 million in 2004. Our gross margin percentage in 2005 was 74.2%, and 88% of our revenues were attributable to sales of the disposable biosensors that physicians use to perform tests with our NC-stat System. We recorded net income of approximately \$938,000 in 2005 and incurred net losses of approximately \$4.3 million in 2004 and \$3.7 million in 2003. Since our inception, more than 500,000 patients have been tested with the NC-stat System.

Disorders of the Peripheral Nerves and Spine

The Nervous System

The nervous system is a collection of interconnected specialized cells called neurons, supported by other complementary cells. The basic function of the nervous system is to convert physical stimuli into neural signals, to process these neural signals, and to generate an appropriate motor response. The classic reflex obtained by tapping on the knee and eliciting a mild kick is a simple example of this function.

The nervous system is divided into the central nervous system, or CNS, and the peripheral nervous system, or PNS. The CNS is comprised of the neurons in the brain and spine, while the PNS consists of neurons and related elements outside the spine and within the extremities, such as the hands or feet. Neurons, which are the primary components of the nervous system, typically have three elements: (1) the dendrites, or input region; (2) the cell body, where the cell nucleus resides; and (3) the axon, or output region. The dendrites and the cell body of most neurons reside within the CNS (e.g., in the spine), while the axons may reside within the CNS, the PNS or both. The axon carries information from one neuron to another or to a muscle. Axons can exceed one meter in length yet represent the same cell. The term "nerve" generally refers to a collection of axons encased within a common sheath. Axons combine into nerves in the extremities that are considered part of the PNS.

All neurons, and particularly their axons, are highly susceptible to metabolic or mechanical damage and have limited regenerative ability. Disorders of the nervous system lead to symptoms, which can range from numbness and weakness in the extremities if confined to the PNS, to changes in cognition, speech and personality if the CNS is involved.

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 currently 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. Clinical studies have demonstrated that nerve conduction studies can detect DPN in cases where symptoms are not present. 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 American Diabetes Association that over 75% of all foot amputations are in patients with diabetic peripheral neuropathy. Other neuropathies may be present in as many as 30% of patients with diabetes, including carpal tunnel syndrome, radiculopathy and chronic inflammatory demyelinating polyneuropathy, or CIDP.

- *Low back pain.* Low back pain can have many causes. When low back pain has a neurological source, it is often focal in nature and associated with pain that radiates from the lower back region into the leg, called sciatica. In some cases, the patient may also experience loss of sensation and weakness in the lower leg. In advanced cases, these symptoms can become disabling. The symptoms result from pressure on the nerve roots, the precursors of the nerve, as they exit the spine. The source of the pressure is usually part of an intervertebral disc that is displaced from its normal location between the vertebral bodies. These disorders are often called herniated or ruptured discs.
- *Carpal tunnel syndrome.* Carpal tunnel syndrome, or 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.

Market Opportunity

The sensitivity of the nervous system to metabolic and mechanical damage, compounded by its limited regenerative ability, creates a market opportunity for a medical device that can assist in point-of-service diagnoses of neuropathies in a manner that is cost-effective for the patient and third-party payer. We believe the ease of use, accuracy and convenience provided by the NC-stat System position it to become a standard of care for the assessment of neuropathies at the point-of-service. We believe that the availability of point-of-service nerve conduction studies, through the NC-stat System, will result in earlier detection of neuropathies, leading to earlier therapeutic intervention and, in many cases, improved clinical and economic outcomes. We believe that use of traditional NCS/nEMG procedures is limited by the referral process and the resulting delay in availability of diagnostic information, the inconvenience and discomfort of these methods for the patient, and the expense to the patient and third-party payer. Our policy is to promote and support the utilization of nerve conduction studies in a manner strictly consistent with prevailing guidelines on the medically appropriate use of this diagnostic procedure. We estimate that there are approximately 2.0 million traditional NCS/nEMG procedures currently performed each year in the United States. Although the most common indication for which the NC-stat System has been used historically is carpal tunnel syndrome, we have since expanded our marketing efforts to include DPN and low back pain, as well as other indications. We anticipate that our future growth will be generated mainly from this expanded focus. Based on our analysis of current patient data, we estimate that the potential for point-of-service nerve conduction studies in the diabetes, low back pain and carpal tunnel syndrome markets in the aggregate could be greater than 9.5 million annual patient tests, estimated to be more than

\$1.0 billion annually for our disposable biosensors, in the United States. However, market size is difficult to predict, and we cannot assure you that our estimates will prove to be correct. We believe that additional applications of a point-of-service product offering such as the NC-stat System, including the clinical assessment of patients with neuropathies caused by or associated with other clinical disorders, could further increase this potential market size. Additionally, although we have not yet quantified the size of the market, we believe a potential international market opportunity exists for the NC-stat System.

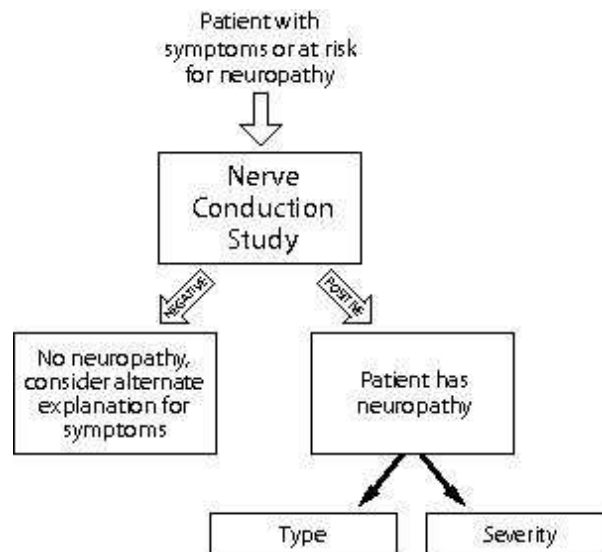
Assessment and Treatment Methods for Neuropathies

Traditional Methods for Detecting Neuropathies

Neuropathies traditionally have been evaluated using clinical and diagnostic methods. The clinical examination of a patient with a potential neuropathy focuses on the nature, location and duration of the symptoms. The physician will also perform a physical examination of the patient to corroborate and qualify the patient's symptoms. In many cases, the physician will use simple instruments such as a reflex hammer or a tuning fork. Although the clinical examination is essential to the evaluation of the patient with a potential neuropathy, it has a number of important disadvantages, including the following:

- *It is qualitative.* A clinical examination provides qualitative rather than quantitative information, and results can vary greatly depending on the physician performing the examination. In this respect, it has limited use as an objective and repeatable measure of disease.
- *It is subjective.* Much of the clinical examination relies on the patient experiencing and reporting symptoms or perceptions. As a result, it depends greatly on the investigative efforts of the physician in interviewing the patient, is highly variable because of individual differences in recollection and discomfort thresholds, and requires an alert, cooperative patient. Because of the subjective nature of the clinical examination, the results must be interpreted cautiously.
- *It often does not detect pre-clinical or early stage disease.* Because the clinical examination relies on the patient reporting symptoms or physical signs of disease, the physician typically cannot detect early stage disease with this evaluation. The progressive nature of neurological damage is such that pre-clinical or early detection creates the optimal opportunity for intervention and successful clinical outcomes.

The limitations of the clinical examination in detecting and monitoring neuropathies suggest that an objective and quantitative diagnostic procedure would be of value for many patients. The role of an objective diagnostic procedure in a patient at risk for a neuropathy or experiencing common symptoms of a neuropathy, such as numbness, unusual sensations, pain and weakness, is shown in the diagram below.



The cause of symptoms in many of these patients will not be disorders of the nervous system, but rather arthritic pain, musculo-skeletal disturbances, inflammatory conditions, psychiatric disorders and others. The importance of an objective diagnostic procedure in this type of patient is to determine if the patient does in fact have a neuropathy, and if so, of what type and severity. Only with this information can appropriate therapy be determined.

The principal diagnostic method used today to assess patients with or at risk for neuropathies is a traditional nerve conduction study and a needle electromyography, or nEMG. Traditional nerve conduction studies and nEMGs are distinct studies and can be performed independently, but are collectively described as traditional NCS/nEMG procedures. In a traditional nerve conduction study, electrodes are placed on the patient's skin surface and the physician performing the study electrically stimulates the nerve, evoking a neural impulse that travels along the nerve, thereby enabling the physician to measure a series of nerve conduction parameters. In an nEMG, recording needles are inserted through the skin's surface into a muscle and the physician performing the study reviews the electrical activity of those muscles. From these data, the physician can determine whether or not the patient has a neuropathy, and if so, its characteristics and severity. The traditional nerve conduction study, in some cases combined with an nEMG, is considered by most physicians to be the "gold standard" in terms of diagnostic accuracy for most neuropathies.

Limitations of Traditional Diagnostic Methods

Traditional NCS/nEMG procedures have a number of limitations, which have frequently resulted in these procedures not being performed until late in the patients' care episodes. These limitations include the following:

- *Referral process.* Traditional NCS/nEMG procedures typically are performed under a referral from a primary care physician or orthopedic surgeon to a neurologist. This process may lead to loss of control of the patient's care by the referring physician, higher expense for the patient and third-party payer, and the likely delay and inconvenience for the patient associated with a separate office visit to a new physician.

- *Expense.* When the patient visits a new physician under a referral for the purpose of a traditional NCS/nEMG procedure, that physician is less familiar with the patient’s medical history and condition than the primary care physician. Therefore, these physicians may need to perform more extensive testing incorporating multiple nerves and muscles. Because of the breadth of these studies, the cost per study can exceed \$1,000 per patient, which leads to greater expense for the patient and third-party payer.
- *Equipment.* The equipment used to perform a traditional NCS/nEMG procedure is expensive and typically ranges in cost from \$15,000 to \$40,000. For this reason, it is generally only purchased by neurologists and physicians in related specialties, who expect high utilization to offset this cost.
- *Complexity.* Traditional procedures require familiarity with equipment and engineering principles that most physicians do not acquire during their medical training. This fact, combined with high equipment cost, has meant that only a small number of physicians, such as neurologists and physicians in related specialties, perform testing under traditional methods, making this type of testing not generally widely available.
- *Discomfort.* The traditional NCS/nEMG procedure is considered uncomfortable or painful by most patients. In particular, the nEMG component can be very painful because it involves a physician inserting needles into specific muscles of the patient, often in close proximity to the site of pain. Patients are sometimes therefore reluctant to undergo these procedures, and neuropathies may go undiagnosed.

Current Methods for Treating Neuropathies

Addressing the limitations of traditional methods for detecting neuropathies is important because of the expanding number of treatments for common neuropathies currently in use and under development. We believe earlier and more accurate detection of neuropathies would allow more patients to benefit from these treatments, which include the following:

- *Diabetic Peripheral Neuropathy.* Optimal clinical management of DPN is based on earliest possible detection so as to limit the degree of nerve damage. At the present time, most people with diabetes are evaluated for DPN with simple clinical procedures that generally do not identify the disease in its early stages. Although treatment options for DPN are presently limited, there are interventions designed to slow down the progression of nerve degeneration and to minimize the complications of the nerve disease. Current interventions consist primarily of increased attention to the individual’s blood glucose through monitoring and administration of insulin and other medications, as well as increased compliance with proper diet and exercise programs. In addition, greater attention to the existence and progression of foot ulcers that are often triggered by nerve disease has been shown to be valuable in preventing amputation. A number of pharmaceutical companies and researchers are investigating and developing drugs specifically designed to treat DPN. The following table summarizes the leading drug development programs in DPN known to us, as described, for each company, in current publicly available information released by that company.

<u>Company Name</u>	<u>Drug Name</u>	<u>Status</u>
Eli Lilly and Company	ruboxistaurin mesylate (Arxxant)	U.S. Phase III clinical trial
Sanwa Kagaku Kenkyusho Co., Ltd., Sankyo Co., Ltd., and NK Curex	Fidarestat	U.S. Phase II clinical trial

Dainippon Pharmaceutical Co., Ltd.	AS-3201	U.S. Phase III clinical trial
Johnson & Johnson	Topiramate	Approved in the United States as anticonvulsant; Phase II clinical trials being conducted to determine efficacy in the treatment of DPN
Vitaris GmbH	α -lipoic acid	Approved in Germany; studies being conducted to determine efficacy in the treatment of DPN

- *Sciatica*. The widespread incidence of low back pain and intense discomfort associated with the condition makes the detection of true sciatica difficult. However, treatment decisions require a clear delineation between those patients that have non-neuropathic back pain, such as muscle strains or spasms, and those that have underlying neuropathies. Mild sciatica may be treated with non-steroidal anti-inflammatory drugs, or NSAIDs, rest and physical therapy. More advanced sciatica is often treated with steroid injections and eventually a minimally invasive or more involved surgical procedure may be required.
- *Carpal Tunnel Syndrome*. Mild CTS is treated conservatively using wrist splints, NSAIDs, and physical and occupational therapy. Moderate to severe CTS is treated by injecting steroids into the carpal tunnel in the immediate vicinity of the median nerve, or ultimately by a surgical procedure called a carpal tunnel release, or CTR. Most physicians and third-party payers require confirmation of median nerve damage by a nerve conduction study, like that performed using the NC-stat System, prior to performing CTR. According to the Centers for Disease Control and Prevention, or CDC, over 350,000 CTR procedures were performed in 1997.

NEUROMetrix Solution

Recognizing the opportunity created by the limitations of traditional diagnostic methods coupled with the availability of current and potential new treatments for certain neuropathies, NEUROMetrix has developed the NC-stat System for the performance of non-invasive nerve conduction studies at the point-of-service. Our proprietary technology provides physicians with an in-office diagnostic system that enables physicians to make rapid and accurate diagnoses that are cost-effective for the patient and third-party payer. We believe that the NC-stat System represents a significant advance in neurological diagnostics and offers an improvement over traditional diagnostic procedures with the following benefits:

- *Facilitates performance of nerve conduction studies at the point-of-service*. The complexity and high capital cost of traditional diagnostic methods generally has limited their use to neurologists and physicians in related specialties. We believe the features of the NC-stat System facilitate the performance of nerve conduction studies within the offices of a wide range of physicians. By allowing nerve conduction studies to be performed in the primary care physician's office, the patient can avoid the expense and inconvenience of a referral visit to a neurologist. Additionally, the NC-stat System enables primary care physicians to retain greater control over their patients by eliminating the need to refer them out for a traditional NCS/nEMG procedure.

- *Provides a cost-effective diagnostic tool.* We believe that the NC-stat System should reduce the cost to the patient and third-party payer of many nerve conduction studies. This belief is based on our observation that when these procedures are performed by the physician with primary clinical responsibility for the patient, the study is more directed so that generally fewer nerves are tested without compromising the accuracy of the diagnosis. As the cost to third-party payers for nerve conduction studies is typically based on the number of nerves tested, use of the NC-stat System can result in lower costs to patients and third-party payers. For example, a nerve conduction study for DPN using the NC-stat System would typically be performed by testing four nerves, whereas a nerve conduction study for the same indication performed by a neurologist using traditional NCS/nEMG equipment upon referral could involve the testing of six nerves or more.
- *Requires minimal capital investment.* We sell the NC-stat System, with equivalent technical specifications to the more expensive traditional instruments, for under \$5,000, compared with \$15,000 to \$40,000 for the cost of traditional NCS/nEMG equipment. We believe the lower capital cost of the NC-stat System will aid in the expansion of nerve conduction studies beyond neurologist offices.
- *Simple to operate.* The NC-stat biosensors are designed for ease in placement, which allows a wide range of physician office personnel to administer the technical parts of the study under supervision of a physician. The NC-stat monitor utilizes software algorithms that perform each step of a nerve conduction study in a reliable manner, with embedded automation technology that addresses and minimizes the technical training requirements for performing nerve conduction studies, while also ensuring that the end diagnostic result is accurate and reliable. We believe that, in combination, these features allow accurate and reliable nerve conduction studies to be performed in 15 to 30 minutes on average.
- *Patient-friendly, non-invasive procedure.* The NC-stat System allows for reduced patient discomfort during the nerve conduction study by minimizing the magnitude of the electrical stimulus to the nerve via a proprietary patient-specific calibration procedure. In most cases, the sophisticated signal processing and automation capabilities of the NC-stat System provide sufficient diagnostic information to eliminate the need for an nEMG procedure. This saves the patient the discomfort, stress and risk of this invasive procedure.

We believe point-of-service testing will expand the use of nerve conduction studies to include at-risk individuals who may have early-stage neuropathies, a population that would be unlikely to be tested under the current inconvenient, expensive referral system. Because traditional NCS/nEMG procedures are typically not performed until late in patients' care episodes, permanent nerve damage may have already occurred, which can limit treatment options. We believe that more widespread use of nerve conduction studies would lead to earlier detection of neuropathies. Clinical studies published in peer-reviewed medical journals have demonstrated that nerve conduction studies performed with the NC-stat System result in comparable accuracy to traditional NCS/nEMG procedures, as described below in "—Clinical Studies." By incorporating nerve conduction studies early in patients' care episodes through the use of the NC-stat System, we expect better long-term clinical and economic outcomes will emerge because of the ability to implement available preventive care based on accurate early diagnostic results.

The NC-stat System

The NC-stat System is comprised of: (1) disposable single use NC-stat biosensors that are placed on the patient's body; (2) the NC-stat monitor 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 onCall Information System formulates the data it receives for each test into a detailed report that is sent to the physician via facsimile or e-mail in three to four minutes on average and aids in the physician's

diagnosis. The NC-stat System enables the physician to make rapid and accurate diagnoses that are cost-effective for the patient and third-party payer.

- *NC-stat biosensors.* The NC-stat biosensors are single use, self-adhesive, nerve-specific, patch-like devices that are placed on the body and connected to the NC-stat monitor. Through the use of a specialized gel and a temperature sensor, both of which are contained within the biosensor, NC-stat biosensors convert nerve signals to electronic data that can be received and displayed by the NC-stat monitor. Currently we sell eight different types of biosensors:

- Median motor;
- Median motor/sensory;
- Ulnar motor at wrist;
- Ulnar motor/sensory;
- Combination ulnar motor/sensory at wrist and ulnar at elbow;
- Peroneal;
- Tibial; and
- Sural.

The biosensors are designed to be positioned according to common anatomical landmarks with a configuration that facilitates correct placement. We designed the sensors so that they could be easily and quickly applied with minimal training by members of a physician’s office staff. The biosensors are encoded with a unique electronic serial number, which allows us to track each biosensor throughout the manufacturing, shipping and end-use stages. The biosensors also are electronically inactivated after use, thus preventing re-use. This inactivation is essential since prior use of the biosensor adhesive and specialized gel would significantly degrade the quality of the measurements. In a typical nerve conduction study, multiple nerves are evaluated and multiple biosensors are used according to general guidelines established by the Center for Medicaid and Medicare Services, or CMS, and physician associations.

The table below provides sample testing protocols for several common clinical indications.

<u>Clinical Indication</u>	<u>Specific Biosensors Utilized</u>	<u>Total Number of Biosensors Utilized</u>	<u>Aggregate Price of Biosensors Utilized</u>
Diabetic peripheral neuropathy	Peroneal (2) Median Motor/Sensory (1) Sural (1)	4	\$134
Low back pain with bilateral sciatica	Peroneal (2) Tibial (2) Sural (1)	5	\$145
Bilateral carpal tunnel syndrome	Median Motor/Sensory (2) Ulnar Motor/Sensory (2)	4	\$180

- *NC-stat monitor.* The NC-stat monitor is designed for efficient and easy use by the physician or a member of the physician’s clinical staff. The NC-stat monitor can only be operated with our NC-stat

biosensors. This instrument, which is lightweight and slightly larger than a cordless telephone, customizes and calibrates the test for each patient, analyzes neurophysiological signals collected from the biosensor and displays the pertinent results on an LCD screen immediately at the conclusion of each nerve conduction study. It also stores data from multiple patients for optional transmission to the onCall Information System. We also sell optional related components that allow for the testing of long nerve segments, such as those between the elbow and wrist or the knee and foot. The monitor is powered for several months by two AA batteries. The NC-stat monitor contains software that performs all the control and analysis algorithms necessary to carry out a nerve conduction study. A complete nerve conduction study may be performed with just the monitor and the biosensors. A third generation neurodiagnostic system is currently in development and is expected to be introduced during 2006.

- *NC-stat docking station and onCall Information System.* The NC-stat docking station is an optional device that automatically transmits data from the NC-stat monitor via any available telephone line, such as those used by facsimile machines, to the onCall Information System that we maintain. The docking station has its own data storage so it does not lose data if the telephonic connection to the onCall Information System cannot be established for some time or is disrupted during transmission. The data is automatically processed by the onCall Information System and stored in a central database, and a detailed computer generated report is created for each patient that is then sent to the physician via facsimile or e-mail in three to four minutes on average. The report includes the raw waveform data, comparisons to an age- and height-adjusted normal range population, study reference table and text summaries of the study, which facilitate rapid and accurate diagnosis by the physician examining the patient. Although the study data presented in the onCall report can be generated manually by the physician using the numerical measurements displayed by the NC-stat monitor, the report is a convenient and fast adjunct. Whether using the information from the onCall report or the NC-stat monitor display, the actual clinical interpretation of the NC-stat results is always performed by the physician ordering the study. The onCall Information System can also provide daily, monthly and quarterly reports to customers. These reports provide assistance in correct submission for third-party reimbursement and assist in tracking overall clinical utilization. The onCall Information System generally is available 24 hours per day, seven days per week. Although purchase of the NC-stat docking station and utilization of the onCall Information System are entirely optional, we believe substantially all of our customers use this system in all studies they conduct with the NC-stat System. We currently have a record of over 1.5 million individual nerve tests within the onCall information system database. We believe that this information provides us with the ability to continually improve our products and provide our customers with a very high level of customer service and value.

Strategy

Our goal is to become the leading provider of innovative, proprietary, high margin medical devices that provide comprehensive solutions for the diagnosis and treatment of patients with neuropathies. To achieve this objective, we are pursuing the following business strategies:

- *Establish the NC-stat System as a Standard of Care.* Our primary objective is to establish the NC-stat System as the standard of care for point-of-service assessment of neuropathies. To accomplish this goal, we dedicate significant efforts to the development of marketing and educational materials that encourage the medically appropriate use of the NC-stat System by a broad range of physicians. We also support clinical studies that are designed to demonstrate the clinical accuracy and cost-effectiveness of the NC-stat System.
- *Expand Sales and Marketing Efforts.* We currently sell our products through 37 regional managers, three sales representatives and three district sales directors who are our direct employees. We

invest significant amounts of time and money in technical, clinical and business practices training for our regional managers. We also have established a sales network with more than 75 independent regional sales agencies employing a total of more than 500 sales representatives. Our regional managers utilize sales agencies to identify selling opportunities and to assist in the ongoing servicing of our customers, in order to enhance and leverage their selling efforts. We intend to hire more direct regional managers and potentially expand the number of independent sales agencies and representatives generating sales leads for our products, in order to increase the market penetration of our products.

- *Focus on Primary Care Market.* We intend to capitalize on the trend towards the utilization of more sophisticated diagnostic and therapeutic procedures by primary care physicians. To achieve this goal, we have expended and are continuing to expend significant resources to establish a physician office distribution channel. This channel focuses on primary care physicians, comprising general internists, family practice physicians, rheumatologists, endocrinologists and diabetologists. By offering our system to primary care physicians, we are also capitalizing on the trend towards convenient and efficient medical care created by having multiple clinical services provided within one facility.
- *Strengthen Our Presence within Selected Specialty Markets.* We intend to continue to strengthen our presence within specific physician specialty markets that are complementary to our major focus on the primary care market. These markets provide both revenue opportunities and additional product validation within the marketplace. We believe that the orthopedic, neurology, pain medicine and occupational medicine markets represent the most suitable specialty markets for expansion.
- *Continue to Introduce New Products.* We believe that one of our strengths is our ability to develop and commercialize innovative products for neurological applications. We have an ongoing program of making enhancements and improvements to the NC-stat System, including the introduction of new biosensors. We are also developing a third generation neurodiagnostic system. In addition, we are in the early stages of designing a drug delivery system for the minimally invasive treatment of neuropathies by both primary care and specialist physicians. We are also engaged in the development of products for the diagnosis of additional neuropathies. These potential new products build upon our mission of enhancing the clinical and business practices of our customers. We believe that these potential new products will improve patient care, allowing us to generate more revenues at attractive margins from our existing customer base, as well as to attract new customers.

Market Size

We estimate that there are approximately 2.0 million traditional NCS/nEMG procedures currently performed each year in the United States. This estimate is based on (1) data from a CDC report in 1996 regarding NCS/nEMG procedures ordered or performed during ambulatory patient visits and (2) data from a 2001 CMS report regarding Medicare reimbursement under Current Procedural Terminology, or CPT, codes for nerve conduction studies and assumptions that Medicare represents 30% of the total existing nerve conduction study market and that the average number of CPT codes used per nerve conduction study is eight. We anticipate that the advantages and increased availability of the NC-stat System will significantly increase the number of nerve conduction studies performed.

- *We estimate the potential DPN market for a point-of-service product offering such as the NC-stat System could be over six million annual patient tests.* The number of individuals with diabetes in the United States was estimated to be 21.0 million, or 7.0% of the population. Among this group, approximately 6.0 million were undiagnosed. According to the CDC, there are about 26 million annual patient visits to office-based physicians for diabetes. We anticipate that the increasing focus on early detection and prevention of the chronic complications of diabetes will lead to increased

nerve conduction studies for DPN. We believe that the estimated 50% rate of annual foot examinations in patients known to have diabetes is a reasonable estimate for the addressable testing market in diabetes. If these examinations were replaced by a nerve conduction study, or a nerve conduction study were added to the examination, the diabetes arena would represent an opportunity for over six million annual NC-stat patient tests. The number of Americans with diabetes is projected to more than double over the next 40 to 50 years. At the present time, there are no currently marketed pharmaceuticals targeted specifically at DPN, and therefore nerve conduction studies are performed on a selective basis in order to address specific clinical issues. If a targeted therapy for DPN were successfully developed and marketed, we believe the rate of testing would further increase. Based on current clinical trial activity, we anticipate that drugs for the treatment of DPN will eventually become available in the marketplace, accelerating the need to detect DPN at its earliest stages to allow for earlier therapeutic intervention and a decrease in the adverse clinical and economic outcomes associated with DPN.

- *We estimate the potential low back pain market for a point-of-service product offering such as the NC-stat System could be as great as three million annual patient tests.* Low back pain is one of the most common medical conditions in the United States. Over 63 million people report experiencing at least one day of serious low back pain in the prior year. Furthermore, back disorders account for over one-quarter of all nonfatal occupational injuries and illnesses that result in days away from work. According to the CDC, there are about nine million annual patient visits to office-based physicians specifically for low back symptoms. The CDC further estimates that about one-third of office visits are initial visits, at which time we believe utilization of the NC-stat System is most likely. We thus anticipate that there may be as many as approximately three million testing opportunities for nerve conduction testing related to low back pain for a point-of-service product offering such as the NC-stat System. We believe that the number of testing opportunities may be even higher, as there are many patients that visit physicians for symptoms and medical conditions that must be differentiated from sciatica, such as leg and foot symptoms, rheumatoid arthritis and diabetes.
- *We estimate the potential carpal tunnel syndrome market for a point-of-service product offering such as the NC-stat System could be as great as 650,000 annual patient tests.* CTS is a significant occupational issue, as the disorder results in the most days away from work among all major disabling workplace injuries and illnesses. In a recent health care survey published in the Journal of the American Medical Association, approximately 14% of adults reported symptoms characteristic of CTS. It was further estimated that 2.5% of adults have true CTS, which could be confirmed by clinical examination and nerve conduction studies. This is equivalent to approximately five million individuals in the United States. Over 350,000 surgeries are performed annually for CTS. The surgical procedure is called a carpal tunnel release, or CTR. Most third-party payers require a nerve conduction study prior to authorizing CTR surgery. According to the CDC, there are more than two million annual visits to office-based physicians for which CTS is the primary diagnosis. The CDC estimates that about one third of CTS-related office visits are initial visits, at which time we believe utilization of the NC-stat System is most likely. As a result, we estimate that there may be as many as 650,000 testing opportunities for the NC-stat System related to CTS. We further believe that this estimate is conservative, as there are many patients that visit physicians for hand and wrist pain, or medical conditions with a high association with CTS such as rheumatoid arthritis, diabetes and obesity. We also anticipate that the high costs of CTS-related workers' compensation claims could motivate employers to increasingly use a point-of-service product offering such as the NC-stat System to pre-screen and monitor employees for CTS.

Based on the data outlined above, we estimate that the potential market size for a point-of-service product offering such as the NC-stat System for nerve conduction studies in the diabetes, low back pain and CTS markets in the aggregate could be greater than 9.5 million annual patient tests in the United States. We

estimate that the potential market for NC-stat System could be more than \$1.0 billion annually in the United States. However, market size is difficult to predict, and we cannot assure you that our estimates will prove to be correct. We believe that additional applications of a point-of-service product offering such as the NC-stat System, including the clinical assessment of patients with neuropathies caused by or associated with other clinical disorders, could further increase this market size. Additionally, although we have not yet quantified the size of the market, we believe a potential international market opportunity exists for the NC-stat System.

Clinical Studies

The performance of the NC-stat System has been substantiated in clinical studies that we have supported, the results of which have been published in peer-reviewed medical journals or presented at major medical conferences.

- In studies published in the April 2000 issue of the *Journal of Occupational & Environmental Medicine*, the September 2000 issue of *Neurology and Clinical Neurophysiology*, and the May 2004 issue of the *Journal of Hand Surgery*, the correlation between the results generated by the NC-stat System and traditional nerve conduction studies in measuring nerve function of 198 patients was examined. The correlation was equivalent to that found between different neurologists performing traditional nerve conduction studies.
- Two abstracts presented at the American Diabetes Association Meeting in June 2004 outline the results of a study of 1,000 patients with diabetes. In this study, the NC-stat System was found to detect DPN at the same level and stage as would have been expected from traditional NCS/nEMG procedures.
- A study published in the December 2002 issue of *Spine* evaluated the ability of the NC-stat System to detect neurological impairment in 25 patients with sciatica, confirmed by MRI and clinical examination. The diagnostic accuracy of the NC-stat System was equivalent to traditional NCS/nEMG procedures as documented in several other published studies.
- In a study published in the August 2005 American Journal of Orthopedics, the clinical utility of the NC-stat System was assessed in 72 patients with carpal tunnel syndrome. The NC-stat was found to have a high correlation with traditional laboratory testing. The NC-stat also measured statistically significant improvement in median nerve function six months following carpal tunnel release surgery.

We continue to support well-designed clinical research studies utilizing the NC-stat System that are designed to demonstrate its clinical accuracy and cost-effectiveness. In addition, several clinical studies and trials have been performed, and others are underway, in which the NC-stat System is used to measure changes in nerve function. The NC-stat System was utilized by Eli Lilly in a clinical trial of Cymbalta for the treatment of pain associated with diabetic peripheral neuropathy. Cymbalta received FDA approval in the second half of 2004.

Customers

We market our products directly to physicians. The NC-stat System provides primary care physicians, who previously were not performing a nerve conduction study at the point-of-service or were referring these patients to a neurologist for a traditional NCS/nEMG procedure, with a potential new source of revenues. As of December 31, 2005, we had nearly 3,300 active customers. No single customer accounted for more than 10% of our revenues in 2005, 2004 or 2003.

Geographic Information

All of our assets, revenues and expenses for the years ended December 31, 2005, 2004 and 2003 were located at or derived from operations in the United States.

Sales, Marketing and Distribution

Our sales team is led by our Chief Operating Officer. We presently employ 37 regional sales managers, three sales representatives and three district sales directors who lead more than 75 independent regional sales agencies employing a total of more than 500 independent sales representatives. We plan to increase the number of regional sales managers to a total of 46 by the end of the first quarter of 2006. At present, our products are marketed and distributed solely within the United States. We select our sales agencies and representatives based on their expertise and experience calling on primary care or specialty physicians, their reputation within the targeted physician community and their sales coverage. Each sales agency is assigned a sales territory for the NC-stat System and is subject to periodic performance reviews. Our current operating practice is to limit coverage overlap within most regions. Through this, we believe we gain a more focused sales approach and more dedicated sales agency organization. Typically, our independent sales representatives identify potential customers for us and assist in monitoring our existing customer accounts, and our regional sales managers complete sales to these customers. Our independent sales agencies do not act as distributors of our products.

We invest significant efforts in technical, clinical and business practices training for our regional managers. We work closely with our sales agencies and their sales representatives in order to provide them with the information and assistance that they need in order to successfully generate qualified sales leads for our products. We also require each sales representative to attend periodic sales and product training programs. The efforts of our regional sales managers and independent sales representatives are enhanced by proprietary software tools that are accessed via a secure website, which we refer to as the sales and sales partner portals, respectively. These portals give 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 portals also provide customer relationship management functions. Our corporate management and reimbursement team have access to the same information, as well as portal usage information by all sales personnel.

We market our products directly to physicians. The NC-stat System provides primary care physicians, who previously were not performing a nerve conduction study at the point-of-service or were referring these patients to a neurologist for a traditional NCS/nEMG procedure, with a potential new source of revenues. We believe that this potential revenue stream is an essential marketing advantage of the NC-stat System. We also market our products at various industry conferences in order to accelerate the market awareness of our products, our customer accrual efforts and market adoption for our products.

We generally invoice products directly to physician offices and other customers, typically at list prices. We currently have a relationship with one distributor that directly invoices the physician practice and we invoice the distributor at list price less a negotiated discount. We ship all products directly to the customer even in cases where we are selling through a distributor. The independent regional sales agencies and their sales representatives are compensated by commissions. Our regional managers are compensated by a combination of base salary, commissions and goal-based bonus compensation.

As we launch new products and increase our marketing efforts with respect to existing products, we intend to expand the reach of our marketing and sales force. We plan to accomplish this by increasing the number of direct regional managers and maintaining a broad-based network of independent sales agencies and representatives. The establishment and development of a larger sales force will be expensive and time consuming. Because of the intense competition for their services, we may be unable to enter into agreements with additional qualified independent sales agencies and representatives on commercially

reasonable terms or at all. Even if we are able to enter into agreements with additional independent sales agencies, 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 are subject to federal and state fraud and abuse enforcement activities.

In March 2005, we entered into an education and development program agreement with Eli Lilly and Company, an Indiana corporation, pursuant to which the parties agreed to work together to conduct and present up to eighty-four educational and development programs regarding DPN across the United States. During the second quarter of 2005, the first series of approximately 20 programs were conducted as originally planned. In August 2005, Eli Lilly announced that a Phase III clinical trial evaluating the use of ruboxistaurin, Eli Lilly's drug candidate, for the treatment of DPN did not meet its primary endpoints, but Eli Lilly also announced that it was continuing an ongoing, three-year Phase III clinical trial evaluating the use of ruboxistaurin for the treatment of DPN that was scheduled to complete in 2007. Since Eli Lilly's announcement we have not conducted, or made any plans to conduct, any further programs with Eli Lilly. The agreement with Eli Lilly is scheduled to terminate in September 2006 unless we agree to extend it and we may, or may not, conduct additional programs prior to the termination of this agreement.

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 NC-stat monitor, docking station or biosensors 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 2005. We occasionally experience transient inventory shortages, typically lasting less than one month, on new products during the initial production ramp-up phase. We are currently working with our third-party manufacturers to increase manufacturing capabilities to meet the demand we expect as we increase our sales efforts. Manufacturers often experience difficulties in scaling-up production, including problems with production yields and quality control and assurance. If our third-party manufacturers are unable to manufacture our products to keep up with demand, we would not meet expectations for growth of our business.

Parlex Polymer Flexible Circuits, Inc., which was previously known as PolyFlex Circuits, Inc., a wholly owned subsidiary of the Parlex Corporation, or Parlex, has been manufacturing NC-stat biosensors under general purchase orders since early 1999. While our relationship with Parlex is good, we do not have a formal supply agreement in place with them, although we are negotiating such an agreement, and it could cease manufacturing NC-stat biosensors at any time. If we are forced to engage an alternative supplier, we may incur additional expense, higher cost per unit, delays in delivery and quality control problems. We cannot assure you that a supply agreement will be successfully negotiated, or if negotiated, that it will be on reasonable terms. Parlex was acquired by Johnson Electric, a Hong Kong based manufacturing company,

in November 2005. While we do not expect any material changes in Parlex's operations as a result of the acquisition, we cannot assure you that Johnson Electric will not implement changes that may be adverse to our company or remain committed to the manufacturing of our NC-stat biosensors.

Sunburst EMS, Inc., or Sunburst, has been manufacturing our NC-stat monitors and docking stations since November 2005. Previously, Advanced Electronics, Inc., or AEI, had been manufacturing our monitors and docking stations since 2002. Sunburst could cease manufacturing NC-stat monitors and docking stations for us at any time. We are currently negotiating a supply agreement with Sunburst but we cannot assure you that we will be able to successfully negotiate a supply agreement, or if negotiated, that the supply agreement will be on reasonable terms.

We have identified alternative suppliers capable of manufacturing the NC-stat monitors and docking stations should this become necessary. However, if we are forced to engage an alternative supplier, we may incur additional expense, higher cost per unit, delays in delivery and quality control problems.

We and our third-party manufacturers are registered with the FDA and subject to compliance with FDA quality system regulations. We are also ISO registered and undergo frequent quality system audits by European agencies. Our products are cleared for market within the United States and Canada, and are also approved for distribution in the European Union, although to date we have sales only in the United States. Our facility and the facilities of our manufacturers are subject to periodic unannounced inspections by regulatory authorities, and may undergo compliance inspections conducted by the FDA and corresponding state agencies. We experienced an FDA inspection in May 2003. During its inspection, the FDA issued a Form 483, which is a notice of inspection observations. Two minor items were identified and the corrective actions for both were initiated prior to the completion of the audit. The responses provided to the FDA were deemed adequate and no further action has been requested. 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.

Information Technology Infrastructure

Our information technology infrastructure is designed to support the requirements of our onCall Information System. The onCall Information System employs a high performance, scalable platform consisting of standard hardware, proprietary and off-the-shelf system software components, database servers, proprietary application servers, a modem bank and desktop applications. The in-bound infrastructure consists of telephone lines and proprietary communications gateway software to collect data from the remote NC-stat Systems. The gateway assembles the data sent from each remote NC-stat docking station, stores it and queues it for processing by our proprietary software. The processing infrastructure consists of proprietary software to process each nerve conduction study. The out-bound infrastructure consists of a proprietary report server application and a fax and email server that is an off-the-shelf product.

The onCall Information System utilizes sophisticated expert system technology to provide real-time quality control monitoring and reporting of nerve conduction study results. The onCall applications include:

- a communications gateway for receiving test files and updating the software of remote NC-stat Systems;
- a relational database server to store and retrieve nerve conduction studies;
- an application server to analyze and maintain the nerve conduction study data;
- an application server to format and produce nerve conduction reports;
- a fax and email server to send reports to remote users; and
- a client application that is designed to monitor quality and service customer requests.

The application servers and client applications use a common set of software components that form the onCall class library.

The onCall Information System is physically secured in our restricted-access computer room at our facilities in Waltham, Massachusetts. Our computer facility's electrical power is backed up with auxiliary power in the event of a power outage. Automated backups of the databases and computer files are maintained both on- and off-site. We also maintain a lock box at an off-site location that contains copies of the business continuity plan and application server software vital to the operation of the onCall Information System that would be needed in a disaster recovery situation.

Products Under Development and Research and Development

Our research and development efforts are focused in the near term on further enhancing our existing products and developing the third generation neurodiagnostic system and new NC-stat biosensors, as well as designing a drug delivery system for the minimally invasive treatment of neuropathies by both primary care and specialist physicians. Our research and development staff consists of 20 people, including five who hold Ph.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), our scientific advisors and our customers to design products that are intended to improve clinical and economic outcomes.

Devices for the Treatment of Neuropathy

In pursuit of our objective to develop medical devices that provide comprehensive solutions for the diagnosis and treatment of patients with neuropathies, we are seeking to expand our product base beyond the diagnostic and into the treatment arena. We believe that our core technology can be adapted and extended to provide minimally invasive approaches to treating neuropathies. In particular, we believe that neuropathies that are focal, or localized, 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 product development program includes the design of a product that we believe will reduce the risk involved in providing these treatments. We are in the early stages of designing this product to enable a broad base of physicians to provide this type of minimally invasive neuropathy therapy at the point-of-service.

NC-stat System

We have an ongoing program of making enhancements and improvements to the NC-stat System. We are developing new NC-stat biosensors and associated software for the medically appropriate testing of additional nerves. We also are developing our third generation neurodiagnostic system with an improved user interface, along with new features for the onCall Information System, that will allow our customers to perform more complex analyses of diagnostic data. In addition, we continually seek ways to reduce the manufacturing costs and improve the performance of the NC-stat biosensors.

NEUROMetrix[®], NC-stat[®] and onCall[™] are trademarks of ours.

During 2005, 2004 and 2003, we spent \$3.8 million, \$3.3 million and \$2.4 million, respectively, on research and development.

Customer Service and Clinical Support

Our customer service group consists of six representatives. These representatives are available by telephone 12 hours per day, five days per week (plus limited coverage on Saturday) to address a wide range of technical questions from customers on the use of the NC-stat System, respond to customer requests for product and clinical materials that have been released by our marketing department, take orders, and provide customers with order status information. Our customer service representatives receive specialized ongoing product and clinical training. We also maintain a clinical support group consisting of four individuals. Our clinical support group is available to address questions from our customers relating to test results and use of our products. This group is led by a board-certified neurologist, who is a full-time employee.

Competition

We consider the primary competition for our products to be traditional NCS/nEMG procedures. Our success depends in large part on convincing physicians to adopt the NC-stat System in order to perform nerve conduction studies at the point-of-service.

There are a number of companies that sell traditional NCS/nEMG equipment, typically to neurologists. These companies include Viasys Healthcare Inc., Cadwell Laboratories, Inc and Xltec, Inc. Viasys Healthcare has substantially greater financial resources than we do, and they have established reputations as worldwide distribution channels for medical instruments to neurologists and other physicians. We do not know if these companies are engaged in research and development efforts to develop products to perform point-of-service nerve conduction studies that would be competitive with the NC-stat System. We are aware of one company, Neumed Inc., that markets a nerve conduction study system to the point-of-service market.

We believe that among systems marketed for performance of nerve conduction studies today, only the NC-stat System provides both the level of diagnostic accuracy, the level of automation and the ease of use required for successful penetration of the point-of-service market. We also believe that the reporting and data repository functions provided by the onCall Information System, although entirely optional, provide our customers who use this service with significant added clinical and economic value that is not matched by other currently marketed products. We further believe that the expanding database of nerve conduction study data captured by the onCall Information System facilitates our ability to improve the performance of the NC-stat System. We believe that the size of our database and ongoing improvements provide us with a significant competitive advantage.

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 System. We believe that in order to have a competitive advantage, we must develop and maintain the proprietary aspects of our technologies. Currently, we require our employees, consultants and advisors to execute confidentiality agreements in connection with their employment, consulting or advisory relationships with us, where appropriate. 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, 2005, we had 12 issued U.S. patents, three issued foreign patents and 23 pending patent applications, including 16 U.S. applications, one international (PCT application and six foreign national applications. We also hold an exclusive license to two issued U.S. patents, one issued foreign patent (Europe) and one pending foreign national patent application. The issued and pending patents that we own and license cover, among other things:

- Nerve conduction biosensors and related methods;
- Nerve conduction hardware;
- Algorithms for performing and analyzing nerve conduction studies; and
- NC-stat System industrial design.

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 general terms, a utility patent protects the way an article is used or works, while a design patent protects the way an article looks. More particularly, utility patents are provided for a new, nonobvious and useful process, machine, article of manufacture, composition of matter or improvement of any of the foregoing. Design patents are provided for a new, nonobvious and useful ornamental design of an article of manufacture. In a design patent application, the subject matter which is claimed is the design embodied in or applied to an article of manufacture, or a portion thereof, and not the article itself. Both design and utility patents may be obtained on an article if invention resides both in its utility and ornamental appearance.

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 and certain foreign trademark registrations for the marks NEUROMETRIX and NC-STAT. The U.S. registration for NEUROMETRIX is on the Supplemental Register. In addition, we also have two other pending U.S. trademark applications for the mark NEUROMETRIX. We also have a U.S. trademark application pending for the mark onCall.

Third-Party Reimbursement

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 the NC-stat System if they determine that the diagnostic test or product was not medically appropriate or necessary. The third-party payers may also 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 CPT 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.

A key component in the reimbursement decision by most private insurers and CMS, which administers Medicare, is the assignment of a CPT code. This code is used in the submission of claims to insurers for reimbursement for medical services. CPT codes are assigned, maintained and revised by the CPT Editorial Panel administered by the American Medical Association, or AMA. According to present Medicare guidelines, nerve conduction studies may be performed by medical doctors, or M.D.s, and doctors of osteopathic medicine, or D.O.s, and are reimbursable under the three CPT codes: 95900, 95903, and 95904. We believe that the nerve conduction measurements performed by the NC-stat System meet the requirements stipulated in the code descriptions published by the AMA and that these codes are currently used by physicians performing nerve conduction studies with the NC-stat System. If the CPT codes that apply to the procedures performed using our products are changed, reimbursement for performances of these procedures may be adversely affected.

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 there may be pressure applied on payer organizations by specialists, such as neurologists, who perform traditional nerve conduction studies and view the NC-stat System as competitive with their business.

FDA and Other Governmental Regulation

FDA Regulation

Our products are medical devices subject to extensive regulation by the FDA under the U.S. Food, Drug, and Cosmetic Act, as well as other regulatory bodies. FDA regulations govern, among other things, the following activities that we or our contract manufacturers perform and will continue to perform to ensure that medical devices distributed domestically or exported internationally are safe and effective for their intended use:

- product design and development;
- product testing;
- product manufacturing;
- product labeling;
- product safety;
- product storage;
- pre-market clearance or approval;
- recordkeeping;
- advertising and promotion;
- production
- postmarket surveillance and reporting; and
- product sales and distribution.

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.

Before being introduced into the market, our products must obtain market clearance through either the 510(k) pre-market notification process, the *de novo* review process or the pre-market approval 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 pre-market approval application. In some cases, we may be required to perform clinical trials to support a claim of substantial equivalence. It generally takes from three to twelve months from the date of submission to obtain 510(k) clearance, but it may take longer.

After a medical device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a significant change in its intended use, requires a new 510(k) clearance or could require *de novo* classification or pre-market approval. 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 retroactively require the company to seek 510(k) clearance, *de novo* classification or pre-market approval. 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 pre-market approval 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 pre-market approval 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 approve or deny the *de novo* classification request. 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.

Pre-Market Approval 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 pre-market approval application. The pre-market approval 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 pre-market approval process can take one to three years or longer. The pre-market approval process requires the company to prove 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 pre-market approval, 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. After any pre-market approval, a new pre-market approval application or application supplement may be required in the event of modifications to the device, its labeling, intended use or indication, or its manufacturing process.

Clinical Studies

A clinical study is almost always required to support a pre-market approval application and is sometimes required to obtain 510(k) clearance. Before conducting clinical trials, a manufacturer generally must submit to the FDA an application for an investigational device exemption, or IDE. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. If a medical device is considered a “non-significant” risk, an IDE application to the FDA is not required. Instead, only approval from the Institutional Review Board overseeing the clinical trial is required. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for more abbreviated investigational device exemption requirements. Clinical trials for a significant risk device may begin once the investigational device exemption application is approved by the FDA and the appropriate institutional review boards at the clinical study sites. All clinical studies must be conducted in accordance with FDA regulations and federal regulations concerning human subject protection and healthcare privacy. Failure to comply with these requirements can prevent the clinical trial sponsor from using the study data, and could result in regulatory enforcement or liability. Even if all regulatory standards are met, the results of our clinical testing may not support or may not be sufficient to obtain clearance or approval for our product.

NC-stat System

The NC-stat System has received five 510(k) clearances as a Class II medical device, the first of which was received in 1998, and the most recent (K041320) in August 2004. The NC-stat System has the following intended use:

The NEUROMetrix NC-stat is intended to 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. Since we received our most recent 510(k) clearance for the NC-stat System in August 2004, we have enhanced the NC-stat System by making changes to the software it employs. We do not believe that these changes require new 510(k) clearances. We further believe that the addition of new indications and enhancements to the NC-stat System in the future either will not require new FDA authorization or will be able to be cleared using the 510(k) pre-market notification process. However, the FDA could disagree, and could require us to halt selling and/or recall the product until we obtain 510(k) clearance or pre-market approval.

Post-Market Regulation

After a device is placed on the market, numerous regulatory requirements apply. These include:

- quality system regulations, which require manufacturers to follow design, testing, control, documentation and other quality assurance procedures during the manufacturing process;
- labeling regulations, which prohibit the promotion of products for unapproved or “off-label” uses and impose other restrictions on labeling; and
- medical device reporting regulations, which require that manufacturers, which term includes companies such as us that create the specifications for the regulated products, report to the 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 it were to recur.

Also, we are subject to unannounced inspections by the FDA, and these inspections may include the manufacturing facilities of our contractor manufacturers.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refund, recall or seizure of our products;
- operating restrictions, suspension or shutdown of production;
- refusing our request for 510(k) clearance or pre-market approval of new products, new intended uses, or modifications to existing products;
- withdrawing 510(k) clearance or pre-market approvals that already have been granted; and
- criminal prosecution.

International Regulations

International sales of medical devices are subject to foreign governmental regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ.

The primary regulatory environment in Europe is that of the European Union, which consists of 25 countries encompassing most of the major countries in Europe. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive are entitled to bear CE conformity marking, indicating that the device conforms with the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout Europe. The method of assessing conformity varies depending on the class of the product, but may involve self-assessment by the manufacturer, a third-party assessment by a Notified Body, which is a third-party organization appointed by a member of the European Union, or some combination thereof. This third-party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's product. An assessment by a Notified Body in one country within the European Union generally is required in order for a manufacturer to distribute the product commercially throughout the European Union. In 2000, we were certified by TUV Product Service, a Notified Body, under the European Union Medical Device Directive allowing the CE conformity marking to be applied to the NC-stat System. We had a successful renewal audit in 2005.

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 intended, among other things, to induce the purchase or recommendation of healthcare products and services. 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 authorized "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. Although we believe we have and will continue to structure our business relationships with purchasers of our products to comply with these and other applicable laws, it is possible

that some of our business practices could be subject to scrutiny and challenge by federal or state enforcement officials or others under these laws. This type of challenge could have a material adverse effect on our business, financial condition and results of operations.

Health Insurance Portability and Accountability Act of 1996 and Related Laws

Federal and state laws protect the confidentiality of certain patient health information, including patient records, and restrict the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services promulgated patient privacy rules under 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 protected health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. We believe that, as a medical device manufacturer, we are not directly subject to the HIPAA privacy rules. In addition, we only receive patient data in our onCall Information System on an anonymous basis, with all patient specific information de-identified. Nevertheless, we seek to comply with a number of the HIPAA privacy rules. We believe that we are not in violation of federal or state health information privacy or confidentiality statutes or regulations. However, if we are found to have violated any of these laws, we could be subject to civil or criminal penalties. Additionally, changes in these laws could adversely affect our business.

Employees

As of December 31, 2005, we had a total of 100 employees. Of the total employees, 21 were in research and development, 53 in sales and marketing and 26 in general and administrative services. Two employees hold both M.D. and Ph.D. degrees, five 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

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

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 sustain profitability.

Since our inception in 1996, we have incurred losses every quarter with the exception of the third and fourth quarters of 2005. We began commercial sales of our products in May 1999 and we have yet to demonstrate that we can consistently generate sufficient sales of our products to sustain profitability. The extent of our future operating income or losses is highly uncertain, and we may not be able to sustain profitability. We have incurred significant net losses since our inception, including net losses of approximately \$8.7 million in 2001, \$4.8 million in 2002, \$3.7 million in 2003 and \$4.3 million for in 2004. In 2005 we recorded net income of \$938,200. At December 31, 2005, we had an accumulated deficit of approximately \$56.5 million. We cannot assure you that we will be able to sustain the profitability achieved in 2005.

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

Widespread adoption of the NC-stat System by the medical community is unlikely to occur if physicians do not receive sufficient reimbursement from third-party payers for performing nerve conduction studies using the NC-stat System or if certain changes are imposed on the professional requirements for performing nerve conduction studies and we may be required to expend substantial resources to address potential reimbursement issues with third-party payers. If physicians are unable to obtain adequate reimbursement for procedures performed using the NC-stat System, we may be unable to sell the NC-stat System 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 the NC-stat System. Third-party payers include those governmental programs such as Medicare and Medicaid, workers' compensation programs, private health insurers and other organizations. These third-party payers 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 the NC-stat System. Medicaid reimbursement differs from state to state, and some state Medicaid programs may not reimburse physicians for performing procedures using the NC-stat System 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. Additionally, we may be required to expend substantial resources to address potential reimbursement issues with third party payers.

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

We believe that the drawbacks of traditional nerve conduction studies, including those related to the referral process, and the limited treatment options for DPN, have limited the number of nerve conduction studies that are performed. 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 System, 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 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 System, our ability to increase our revenues will be limited and our business prospects will be adversely affected.

We may not be able to accurately predict the size of the market for our NC-stat System.

We may not be able to accurately predict the size of the market for products used to diagnose neuropathies, such as our NC-stat System. Neuropathies traditionally have been diagnosed by an NCS/nEMG procedure, performed by a neurologist or physician in a related specialty. We estimate that there are approximately 2.0 million traditional NCS/nEMG procedures performed each year in the United States; however, we anticipate that the advantages and increased availability of the NC-stat System will significantly increase the number of nerve conduction studies performed. Based on our analysis of current data, we estimate that the potential market size for the NC-stat System in the diabetes, low back pain and carpal tunnel syndrome markets in the aggregate could be greater than 9.5 million annual patient tests. This represents a significant increase in the size of the market for nerve conduction studies and is based upon a number of assumptions and estimates, which themselves may not be accurate. For example, we have assumed that all initial office visits for low back pain may represent an opportunity for use of the NC-stat System, and we have estimated that an annual testing rate of 50% for all individuals diagnosed with diabetes represents the potential addressable market in diabetes. Market size is difficult to predict, and we cannot assure you that our assumptions or estimates will prove to be correct. The industry and market data in this annual report on Form 10-K on which we have based our assumptions and estimates of future market size, may be inaccurate or incomplete, and we have not independently verified those data. If our estimate of the size of the market for our NC-stat System is incorrect, our potential revenue growth may be limited.

If we are unable to successfully sell the NC-stat System to primary care physicians, 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. As these physicians traditionally have not been targeted by companies selling equipment used to perform nerve conduction studies, we may face difficulties in selling our products to them. Particularly, we may be unable to convince these physicians that the NC-stat System provides an effective alternative or useful supplement to existing testing methods. In addition, these physicians may be reluctant to make the capital investment to purchase the NC-stat System and alter their existing practices. If we are unable to successfully sell the NC-stat System to primary care physicians, our ability to increase our revenues will be severely limited.

We are dependent on two single source manufacturers to produce all of our current products, and any change in our relationship with either of 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 two third-party manufacturers to manufacture all of our current products. In the event that either of our manufacturers ceases to manufacture sufficient quantities of our products in a timely manner and on terms acceptable to us, we would be forced to locate an alternate manufacturer. Additionally, if either of our manufacturers experiences a failure in its production process, is unable to obtain sufficient quantities of the components necessary to manufacture our products or otherwise fails 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 NC-stat biosensors, for which the manufacturing process is relatively specialized, on terms acceptable to us, or at all. Currently, we rely on a single manufacturer, Parlex, for the manufacture of the NC-stat biosensors, and a single manufacturer, Sunburst, for the manufacture of our NC-stat monitors and docking stations. We order all of our products from Parlex on a purchase order basis. Because we do not have a supply agreement in place with Parlex, Parlex may cease manufacturing our products or increase the price it charges us for our products at any time. Johnson Electric, a Hong Kong based manufacturing company, acquired Parlex, in November 2005. We cannot assure you that the acquisition will not have a material adverse impact on our relationship with Parlex or that Johnson Electric will remain committed to the manufacturing of our biosensors. The manufacturing of the NC-stat monitors and devices was transitioned from AEI to Sunburst in November 2005 as a result of a decision by AEI to shut down its operations. We cannot assure you that the transition will proceed smoothly or that Sunburst will be able to manufacture NC-stat monitors and docking stations with the same level of quality and on the same delivery schedule as AEI. We do occasionally experience transient inventory shortages, typically lasting less than one month, 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 growth could be limited and our business could be harmed.

In order for us successfully to expand our business within the United States and internationally, our contract manufacturers must be able to provide us with the products that comprise the NC-stat System in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable cost and on a timely basis. Our anticipated growth may strain the ability of our manufacturers to deliver an increasingly large supply of 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 System to generate 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. We derive all of our revenues from sales of the products that comprise the NC-stat System, and we expect that sales of these products will continue to constitute the substantial majority of our sales for the foreseeable future. Accordingly, our ability to generate revenues is entirely reliant on our ability to market and sell the products that comprise the NC-stat System, particularly the disposable biosensors, sales of which accounted for approximately 87.7%, 87.6% and 85.8% of our total revenues in 2005, 2004 and 2003, respectively. 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;
- 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, and 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 U.S. Food and Drug Administration, which could restrict the sales and marketing of the NC-stat System and could cause us to incur significant costs.

We sell medical devices that are subject to extensive regulation in the United States by the FDA 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 either 510(k) clearance, grant of a *de novo* classification or pre-marketing approval from the FDA, unless an exemption applies. We may be required to obtain a new 510(k) clearance or *de novo* classification or pre-market approval for significant post-market modifications to our products. Each of these processes can be expensive and lengthy. The FDA's process for obtaining 510(k) clearance usually takes from three to twelve months, but it can last longer. The process for obtaining *de novo* classification involves a level of scrutiny similar to the 510(k) clearance process. The process for obtaining pre-market approval 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.

Medical devices may be marketed only for the indications for which they are approved or cleared. We have obtained 510(k) clearance for the current clinical applications for which we market our products. However, our clearances can be revoked if safety or effectiveness problems develop. Further, we may not be able to obtain additional 510(k) clearances or premarket 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 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. We also are subject to numerous post-marketing regulatory requirements, including quality system regulations, which relate to the manufacturing of our products, labeling regulations and medical device reporting regulations. Our failure or either contract manufacturer's failure 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, consent decrees and civil penalties;
- requiring repair, replacement, refunds, recall or seizure of our products;
- imposing operating restrictions, suspension or shutdown of production;

- refusing our requests for 510(k) clearance or pre-market approval of new products, new intended uses, or modifications to existing products;
- withdrawing 510(k) clearance or pre-market approvals that have already been granted; and
- criminal prosecution.

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

If we or our contract manufacturers 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 unannounced inspections. We cannot assure you that our facilities or our contract manufacturers’ facilities would pass any future quality system inspection. If our or any of our contract manufacturers’ facilities fails 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 force a suspension or shutdown of our packaging and labeling operations, the manufacturing operations of our contract manufacturers or a recall of our products. 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 are 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 cause or contribute to a death or serious injury, or malfunction in a way that would likely cause or contribute to a death or serious injury. The FDA and similar governmental bodies in other countries have the authority to require the recall of our products if we or our contract manufacturers fail to comply with relevant regulations pertaining to manufacturing practices, labeling, advertising or promotional activities, or if new information is obtained concerning the safety or efficacy of our products. 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 System would be particularly harmful to our business and financial results because the products that comprise the NC-stat System are currently our only products.

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 payments that are 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 our sales, marketing and other promotional activities by limiting the kinds of 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 from Medicare, Medicaid or other third-party payers that are false or fraudulent, or for items or services that were not provided as claimed. Because we may provide some coding and billing information to purchasers of our products, and because we cannot assure that the government will regard any billing errors that may be made as inadvertent, these laws are potentially applicable to us. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance, which can be substantial. 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.

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 certain 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 because we receive patient data in our onCall Information System on an anonymous basis, 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 the NC-stat System 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 System may be susceptible to claims of injury because it involves the electric stimulation of a patient's nerves. Although we maintain product liability insurance for our products, the coverage limits of these policies may not be adequate to cover future claims. As sales of our products increase, we may be unable to maintain sufficient product liability 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 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 NC-stat biosensors, require a significant degree of technical expertise to produce. If our 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 and President and Chief Executive Officer; Gary L. Gregory, our Chief Operating Officer; Guy Daniello, our Senior Vice President of Information Technology; Michael Williams, Ph.D., our Senior Vice President of Engineering; W. Bradford Smith, Chief Financial Officer; and our other key employees. We maintain a \$5.0 million key person life insurance policy on Dr. Gozani, for which the Company is the beneficiary, but do not maintain key person life insurance policies covering any of our other 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 100 employees as of December 31, 2005, 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. We will face challenges and risks in hiring, training, managing and retaining engineering and sales and marketing employees, as well as independent regional sales agencies and sales representatives, most of whom are geographically dispersed and must be trained in the use and benefits of our products. 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 growth, our business resources may become strained, we may not be able to deliver the NC-stat System in a timely manner and our results of operations may be adversely affected.

We have recently significantly increased our sales force and our total headcount. This growth, as well as any other growth that we may experience in the future, will 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 the NC-stat System 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 and maintain our independent sales agent network, our revenues may decline, our future revenue growth may be limited and our expenses may increase.

As of December 31, 2005, we employed 31 regional sales managers, three sales representatives and two district sales directors and utilize a network of over 500 independent sales agents. We are highly dependent on our regional sales managers and independent sales agents to generate our revenues. We have recently significantly increased our sales force and expect to add approximately 15 additional regional sales managers and several sales representative and sales directors during the first quarter of 2006. 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 sales agencies, 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 products other than the NC-stat System and enhance the NC-stat System could have an adverse effect on our business prospects.

All of our current revenues are derived from selling the NC-stat System. Our future business and financial success will depend, in part, on our ability to continue to introduce 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 NC-stat System or any future products. In addition, as we develop the market for point-of-service nerve conduction studies, 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 enjoy significant competitive advantages over us. Currently, in the point-of-service market, we indirectly compete with companies that sell traditional NCS/nEMG equipment. In this market, these companies are indirect competitors because the equipment they sell traditionally has been used by neurologists, who rely upon and seek to obtain referrals from primary care physicians to perform the same types of tests that may be performed by primary care physicians using the NC-stat System. Additionally, in

selling the NC-stat System to neurologists, which is not a market we historically have focused on, we compete directly with the companies that sell traditional NCS/nEMG equipment. There are a number of companies that sell traditional NCS/nEMG equipment including Viasys Healthcare Inc., Cadwell Laboratories, Inc. and Xltec, Inc. 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, Viasys Healthcare, in particular, enjoy significant competitive advantages, including:

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

As we develop the market for point-of-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 in selling the NC-stat System 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 the NC-stat System, 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 could endorse products or methods that compete with the NC-stat System or otherwise announce positions that are unfavorable to the NC-stat System. 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 and long-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 the NC-stat System and any other products that we develop;
- the costs associated with expanding 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;
- costs associated with any expansion;
- the costs associated with capital expenditures; 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. 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.

If we 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 the NC-stat System or other future 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 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.

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

We do not intend to pay cash dividends.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. In addition, the terms of 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.

ITEM 1B: UNRESOLVED STAFF COMMENTS

We have not received written comments from the Securities and Exchange Commission regarding our periodic or current reports under the Securities and Exchange Act of 1934, as amended, 180 days or more before December 31, 2005 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 2009. We believe that our existing facility is adequate for our current needs.

ITEM 3: LEGAL PROCEEDINGS

We are not currently party to any material legal proceedings. However, we may from time to time become a party to various legal proceedings arising in the ordinary course of our business.

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, 2005, 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 National 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. Our stock first started trading on July 22, 2004.

	Years ended December 31,			
	2005		2004	
	High	Low	High	Low
First quarter	\$ 11.65	\$ 9.28	N/A	N/A
Second quarter	\$ 20.03	\$ 9.05	N/A	N/A
Third quarter	\$ 30.20	\$ 19.57	\$ 11.05	\$ 7.39
Fourth quarter	\$ 37.23	\$ 26.91	\$ 11.75	\$ 8.20

On March 10, 2006, there were approximately 162 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 10, 2006, the last reported sale price per share of our common stock on the NASDAQ National Market was \$33.95.

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.

On July 21, 2004, the Securities and Exchange Commission declared effective our registration statement on Form S-1 (File No. 333-115440), relating to the initial public offering of our common stock. We expect to continue to use the net proceeds from the initial public offering for general corporate purposes, including to expand our selling and marketing and services organizations, develop new distribution channels, expand our research and development efforts, improve our operational and financial systems and for other working capital purposes. We may also use a portion of the net proceeds to acquire or invest in complementary businesses, products or technologies. We have no specific understandings, commitments or agreements with respect to any such acquisition or investment. Except as set forth below, we have not allocated any portion of the net proceeds for any specific purpose. The aggregate price of the offering amount registered on our behalf was \$27.6 million. In connection with the offering, we paid approximately \$1.9 million in underwriting discounts and commissions to the underwriters and incurred an estimated \$1.7 million in other offering expenses. None of the underwriting discounts and commissions or offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10 percent or more of our common stock or to any affiliates of ours. After deducting the underwriting discounts and commissions and offering expenses, we received net proceeds from the offering of approximately \$24.0 million. From July 21, 2004, the effective date of the registration statement, to December 31, 2005 we have used (i) \$3.1 million of the net proceeds to repay in full the outstanding balance under our secured line of credit with Lighthouse Capital Partners, (ii) an estimated \$4.4 million of the net proceeds to fund cash spending of our research and development activities, (iii) an estimated \$6.8 million of the net proceeds to fund the expansion of our sales and marketing efforts and (iv) an estimated \$517,100 for the purchase of capital equipment. The remainder of the net proceeds have been invested in marketable, investment grade, interest-bearing securities pending their use. Our use of the proceeds from our initial public offering does not represent a material change from the description provided in our prospectus.

See Part III, Item 12 for information regarding securities authorized for issuance under equity compensation plans.

ITEM 6: SELECTED FINANCIAL DATA

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

	Years Ended December 31,				
	2005	2004	2003	2002	2001
(In thousands, except share and per share data)					
Statement of Operations Data:					
Revenues	\$ 34,298	\$ 17,920	\$ 9,168	\$ 4,225	\$ 3,464
Cost of revenues	8,858	4,853	2,707	1,370	1,424
Gross margin	25,440	13,067	6,461	2,855	2,040
Operating expenses:					
Research and development(1)	3,821	3,268	2,397	2,146	2,561
Sales and marketing(1)	14,150	8,488	4,768	2,870	5,304
General and administrative(1)	7,333	4,844	2,850	2,673	3,228
Total operating expenses	25,304	16,601	10,015	7,689	11,093
Income (loss) from operations	136	(3,534)	(3,554)	(4,834)	(9,053)
Interest income (expense), net	837	(750)	(113)	41	336
Income (loss) before income taxes	973	(4,284)	(3,667)	(4,793)	(8,717)
Income tax provision	35	—	—	—	—
Net income (loss)	938	(4,284)	(3,667)	(4,793)	(8,717)
Accretion of dividend on redeemable convertible preferred stock	—	(1,386)	(2,009)	(1,893)	(1,757)
Deemed dividend on redeemable convertible preferred stock	—	(788)	—	(6,873)	—
Beneficial conversion feature associated with redeemable convertible preferred stock	—	(7,051)	—	—	—
Net income (loss) attributable to common stockholders	\$ 938	\$ (13,509)	\$ (5,676)	\$ (13,559)	\$ (10,474)
Net income (loss) per common share:					
Basic	\$ 0.08	\$ (2.35)	\$ (5.46)	\$ (13.17)	\$ (10.47)
Diluted	\$ 0.07	\$ (2.35)	\$ (5.46)	\$ (13.17)	\$ (10.47)
Weighted average common shares outstanding					
Basic	12,152,139	5,747,579	1,038,817	1,029,210	1,000,323
Diluted	12,986,365	5,747,579	1,038,817	1,029,210	1,000,323

(1) Non-cash stock-based compensation expense is included in these amounts as follows:

Research and development	\$ 77	\$ 249	\$ 35	\$ 7	\$ 8
Sales and marketing	168	356	37	6	15
General and administrative	161	423	25	37	33
Total non-cash stock-based compensation	\$ 406	\$ 1,029	\$ 96	\$ 50	\$ 56

	As of December 31,				
	2005	2004	2003	2002	2001 (unaudited)
	(in thousands)				
Balance Sheet Data:					
Cash and cash equivalents	\$ 8,170	\$ 1,936	\$ 1,623	\$ 2,701	\$ 5,396
Short-term investments	24,082	18,575	—	—	—
Working capital	34,683	22,500	2,754	3,724	6,380
Long-term investments	—	9,497	—	—	—
Total assets	42,897	37,953	7,218	7,053	9,899
Long-term debt and other long-term liabilities	131	189	2,232	124	331
Warrants for redeemable convertible preferred stock	—	—	450	—	—
Redeemable convertible preferred stock	—	—	47,694	45,684	34,995
Accumulated deficit	(56,540)	(57,478)	(44,901)	(39,860)	(26,321)
Total stockholders' equity/(deficit)	36,248	34,056	(45,502)	(39,928)	(26,431)

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 design, develop and sell proprietary medical devices used to diagnose neuropathies. Our proprietary technology provides physicians with an in-office diagnostic system, the NC-stat System, that enables physicians to make rapid and accurate diagnoses of neuropathies, including carpal tunnel syndrome, low back and leg pain and diabetic peripheral neuropathy. The NC-stat System is comprised of: (1) disposable single use NC-stat biosensors that are placed on the patient's body; (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. Each component of the NC-stat System is also sold separately. The sensitivity of the nervous system to metabolic and mechanical damage, compounded by its limited regenerative ability, creates a market opportunity for a medical device that can assist in point-of-service diagnoses of neuropathies in a manner that is cost-effective for the patient and third-party payer. We believe the ease of use, accuracy and convenience provided by the NC-stat System position it to become a standard of care for the assessment of neuropathies at the point-of-service.

From our inception until May 1999, we had devoted substantially all of our efforts to designing and developing the NC-stat System and other potential products, raising capital and recruiting personnel. We believe that one of our strengths is our ability to develop and commercialize innovative products for neurological applications. In May 1999, we shipped our first NC-stat System. At that time we sold one type of biosensor for the testing of the median motor nerve. In 2000, we introduced an additional biosensor for the testing of the ulnar motor nerve. In 2002, we introduced our second-generation NC-stat System, as well as two additional biosensors. In 2003, we added to our product line two biosensors with higher functionality that have the ability to test both motor and sensory nerves. In 2004, we introduced two new NC-stat biosensors as well as components for the NC-stat monitor to utilize these new biosensors. The first new biosensor is used to test the ulnar nerve at the elbow and the second to test the sural nerve. In 2005, our revenues grew 91.4% to \$34.3 million from \$17.9 million in 2004, of which 87.7% was attributable to sales of NC-stat biosensors in 2005. Our gross margin percentage in 2005 was 74.2%.

We derive our revenues from the sale of NC-stat biosensors, monitors and docking stations directly to end users, which are generally physician practice groups. Our NC-stat biosensors are disposable products that are used once and inactivated after use. The NC-stat monitor is an electronic instrument that is used with the NC-stat biosensors to perform nerve conduction studies for the purpose of diagnosing neuropathies. The NC-stat monitor displays the pertinent results of nerve conduction studies on an LCD screen immediately at the conclusion of each study. The NC-stat docking station is an optional device that is used to transmit to the onCall Information System data generated by the nerve conduction study performed with the NC-stat monitor. The onCall Information System formulates the data it receives for each test into a detailed report that is provided to the customer through facsimile or e-mail.

Diagnostic device revenues include revenues derived from the sale of our NC-stat monitors and NC-stat docking stations. Biosensor revenues include revenues derived from the sale of various types of disposable biosensors used to perform nerve conduction studies with the NC-stat monitor. Our revenue recognition policy is to recognize revenue from our monitors and biosensors upon shipment if the fee is fixed and determinable, persuasive evidence of an arrangement exists, collection of the resulting receivable is reasonably assured and product returns are reasonably estimable. Revenues from our docking station are deferred and recognized over the shorter of the estimated customer relationship period or the estimated useful life of the product, currently three years.

Reimbursement from third-party payers is an important element of success for medical products companies. Generally, we believe that the nerve conduction studies performed by our customers with the NC-stat System have been satisfactorily covered by third-party payers. As our presence in the market expands and the use of the NC-stat System increases, we have experienced and are likely to continue to experience an increased focus from third-party payers regarding the reimbursement of nerve conduction studies performed using the NC-stat System and an increased focus from third-party payers regarding the professional requirements for performing nerve conduction studies in general. 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. One of the primary challenges we face in our business is successfully expanding the market for nerve conduction studies. A successful market expansion will depend upon, in part, our targeting of primary care and specialty physicians who traditionally have not been targeted by companies selling equipment used to perform nerve conduction studies and our ability to alter physicians' practices relating to the diagnosis of neuropathies. In order to successfully implement this growth strategy, we have increased our sales force to 31 regional sales managers, three sales representatives and two district sales directors as of December 31, 2005 and plan to add approximately 15 additional regional sales managers and several additional sales representatives and sales directors during the first quarter of 2006. We also will participate in various industry conferences in order to accelerate the market awareness and adoption of our products. These efforts, as well as the overall expansion of our business, will provide challenges to our organization and

may increase the burden on our management and operations. We plan to monitor our business as it grows and appropriately acquire and allocate resources to address these issues, with a goal of sustaining profitable growth.

We incurred losses every year from the inception of the Company in 1996 through 2004 and recorded our first year of profitability in 2005. We incurred net losses of approximately \$8.7 million in 2001, \$4.8 million in 2002, \$3.7 million in 2003 and \$4.3 million in 2004 and recorded net income of \$938,000 in 2005. We do not know whether we will be able to sustain the profitability achieved in 2005. As of December 31, 2005, we had an accumulated deficit of approximately \$56.5 million. Historically, we have primarily financed our operations through the public and private placement of equity securities and through debt facilities. As of December 31, 2005, we had received net proceeds of \$43.5 million from the issuance of redeemable convertible preferred stock and \$24.0 million in net proceeds from our initial public offering (“IPO”). Upon completion of the IPO, all then outstanding shares of preferred stock converted into shares of our common stock.

Our financial objective is to grow our business through the sale of the NC-stat System and additional products that may be commercialized for the diagnosis and treatment of neuropathies and to achieve sustainable profitability. Our efforts in 2006 will continue to focus primarily on expanding our sales and marketing for the NC-stat System and continuing our ongoing program of making enhancements and improvements to the NC-stat System, with the goal of increasing our market penetration. During 2005 we continued efforts on improvements to our biosensors, on the development of new biosensors, on the development of products to diagnose additional neuropathies, and on the development of a third generation neurodiagnostic system. We are also in the early stages of designing a drug delivery system for the minimally invasive treatment of neuropathies by both primary care and specialist physicians. We believe that the accomplishment of these goals will have a positive impact on our progress toward the objective of growing the business and achieving sustainable profitability.

Results of Operations

The following table presents certain statement of operations information stated as a percentage of total revenues:

	<u>Years Ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Revenues:			
Diagnostic device	12.3%	12.4%	14.2%
Biosensor	<u>87.7</u>	<u>87.6</u>	<u>85.8</u>
Total revenues	100.0	100.0	100.0
Cost of revenues	25.8	27.1	29.5
Gross margin	74.2	72.9	70.5
Operating expenses:			
Research and development	11.1	18.2	26.1
Sales and marketing	41.3	47.4	52.0
General and administrative	<u>21.4</u>	<u>27.0</u>	<u>31.1</u>
Total operating expenses	73.8	92.6	109.2
Income (loss) from operations	0.4	(19.7)	(38.8)
Interest income (expense), net	<u>2.4</u>	<u>(4.2)</u>	<u>(1.2)</u>
Income (loss) before income taxes	2.8	(23.9)	(40.0)
Income tax provision	<u>0.1</u>	<u>—</u>	<u>—</u>
Net income (loss)	<u><u>2.7%</u></u>	<u><u>(23.9)%</u></u>	<u><u>(40.0)%</u></u>

Comparison of Years Ended December 31, 2005 and December 31, 2004

Revenues

The following tables present a breakdown of our customers, biosensor units used and revenues:

	Year Ended December 31,		Change	% Change
	2005	2004		
Customers	3,282	2,207	1,075	48.7%
Biosensor units used	704,800	357,400	347,400	97.2
(in thousands)				
Revenues:				
Diagnostic device	\$ 4,221.3	\$ 2,219.5	\$ 2,001.8	90.2
Biosensor	30,076.8	15,700.6	14,376.2	91.6
Total revenues	\$ 34,298.1	\$ 17,920.1	\$ 16,378.0	91.4

Diagnostic device revenues were \$4.2 million and \$2.2 million for the years ended December 31, 2005 and December 31, 2004, respectively, an increase of \$2.0 million, or 90.2%. Of this increase, approximately \$1.4 million is attributable to a greater number of units sold, primarily as a result of an increase in the number of regional sales managers and expanded clinical uses for the NC-stat System. In addition, approximately \$627,600 of this increase is attributable to an increase in the list price of our NC-stat monitors and docking stations from \$3,500 to \$4,000 effective January 1, 2005, which resulted in a higher average selling price during 2005 as compared to 2004. Diagnostic device revenues accounted for 12.3% and 12.4% of our total revenues for the years ended December 31, 2005 and December 31, 2004, respectively.

Biosensor revenues were \$30.1 million and \$15.7 million for the years ended December 31, 2005 and December 31, 2004, respectively, an increase of \$14.4 million, or 91.6%. The increase was primarily due to an increased customer base for our biosensors, increased frequency of testing by our customers and the introduction of new biosensors, including the sural biosensor in the fourth quarter of 2004. Biosensor revenues accounted for 87.7% and 87.6% of our total revenues for the years ended December 31, 2005 and December 31, 2004, respectively.

Our customers used 704,800 biosensor units in the year ended December 31, 2005, compared to 357,400 units for 2004, an increase of 347,400 units, or 97.2%. This increase in biosensor usage is primarily the result of the increase in the customer base, increased usage by customers and the introduction of new biosensors, including the sural biosensor in the fourth quarter of 2004. The sural biosensor is an important additional biosensor for our customers' use of the NC-stat System for low back pain and DPN and we believe that its introduction is contributing to the growth in biosensor usage for these clinical indications.

Our total revenues were \$34.3 million and \$17.9 million for the years ended December 31, 2005 and December 31, 2004, respectively, an increase of \$16.4 million, or 91.4%. During the 12-month period ending December 31, 2005, a total of 3,282 customers used our NC-stat System compared to 2,207 customers for the same period ending December 31, 2004. This represents a 48.7% year-over-year increase in the number of customers that used our NC-stat System.

We expect revenues to continue to increase in 2006 as a result of the recent expansion of our sales force, which grew from 22 regional sales managers as of December 31, 2004 to 31 regional sales managers, three sales representatives and two district sales directors at December 31, 2005, an increase in the number of active customer accounts and increased usage per customer account. However, our revenues could be negatively impacted by a variety of factors, including the level of demand for nerve conduction studies,

potential for changes in third-party reimbursement for nerve conduction studies, the overall economy and competitive factors.

Costs and expenses

The following table presents our costs and expenses and net loss:

	Years Ended December 31,		Change	% Change
	2005	2004		
	(in thousands)			
Cost of revenues:				
Diagnostic device	\$ 1,059.7	\$ 728.7	\$ 331.0	45.4%
Biosensor	7,798.4	4,124.6	3,673.7	89.1
Total cost of revenues	8,858.1	4,853.3	4,004.8	82.5
Gross margin:				
Diagnostic device	3,161.6	1,490.8	1,670.8	112.1
Biosensor	22,278.5	11,576.0	10,702.5	92.5
Total gross margin	25,440.0	13,066.8	12,373.3	94.7
Gross Margin %:				
Diagnostic device	74.9 %	67.2 %		
Biosensor	74.1	73.7		
Total gross margin	74.2	72.9		
Operating expenses:				
Research and development(1)	\$ 3,820.6	\$ 3,268.4	\$ 552.3	16.9
Sales and marketing(1)	14,150.2	8,488.0	5,662.1	66.7
General and administrative(1)	7,332.8	4,844.4	2,488.4	51.4
Total operating expenses	25,303.6	16,600.8	8,702.8	52.4
Income (loss) from operations	136.5	(3,534.0)	3,670.5	-103.9
Interest income	838.8	214.1	624.7	291.8
Interest expense	(2.0)	(964.1)	962.0	-99.8
Income (loss) before income taxes	973.3	(4,284.0)	5,257.2	-122.7
Income tax provision	35.0	—	35.0	N/A
Net income (loss)	938.3	(4,284.0)	5,222.2	-121.9
Accretion of dividend on preferred stock	—	(1,386.3)	1,386.3	-100.0
Deemed dividend and beneficial conversion feature on redeemable convertible preferred stock	—	(7,838.7)	7,838.7	-100.0
Net income (loss) available to common stockholders	<u>\$ 938.3</u>	<u>\$ (13,509.0)</u>	<u>\$ 14,447.2</u>	-106.9

(1) Includes non-cash stock-based compensation of:

Research and development	\$ 77.4	\$ 249.1
Sales and marketing	167.7	356.4
General and administrative	161.3	423.0
Total non-cash stock-based compensation	<u>\$ 406.3</u>	<u>\$ 1,028.6</u>

Gross Margin

Diagnostic device gross margin percentage was 74.9% and 67.2% for the years ended December 31, 2005 and December 31, 2004, respectively. The increase in the gross margin percentage in 2005 compared to 2004 is primarily attributable to an increase in the list price of our NC-stat System from \$3,500 to \$4,000 effective January 1, 2005.

Biosensor gross margin percentage increased slightly to 74.1% for the year ended December 31, 2005 from 73.7% for the year ended December 31, 2004. The increase in biosensor gross margin percentage is primarily due to manufacturing cost reductions realized for several of our biosensors, offset in part by a change in the mix of biosensors resulting from the introduction of new biosensors in the second half of 2004 which have modestly lower gross margins.

Our overall gross margin percentage was 74.2% for the year ended December 31, 2005 compared to 72.9% for 2004.

Our biosensors are manufactured by the Parlex Polymer Flexible Circuits division of Parlex Corporation. Johnson Electric, a Hong Kong based manufacturing company, acquired Parlex in November 2005. We expect to establish a second manufacturing line in an existing Parlex facility during 2006. We cannot assure you that this new manufacturing site will be capable of producing biosensors of the same quality or that they will be capable of delivering biosensors to us in a timely manner. Furthermore, we cannot assure you that the acquisition of Parlex by Johnson Electric will not result in adverse changes in our relationship with Parlex.

The manufacturing of NC-stat monitors and docking stations was transitioned from AEI to Sunburst in November 2005 as a result of a decision by AEI to shut down its operations. Several AEI employees who were involved in the manufacturing of our devices have been hired by Sunburst and we did not experience any interruptions during this transition. Sunburst has the required ISO certifications for manufacturing our monitors and docking stations and is qualified in the manufacturing of such devices based on our assessment of their operations. However, we cannot assure you that Sunburst will be able to manufacture the NC-stat monitors and docking stations with the same level of quality and on the same timely delivery schedule as AEI.

Research and Development

Our research and development, or R&D, expenses include expenses from the research, product development, clinical, regulatory and quality assurance departments.

R&D expenses increased \$552,300, or 16.9%, to \$3.8 million for the year ended December 31, 2005 from \$3.3 million for the year ended December 31, 2004. As a percentage of revenues, R&D expenses were 11.1% and 18.2% for the years ended December 31, 2005 and 2004, respectively. This increase was primarily due to a \$434,200 increase in employee compensation and benefit costs and a \$54,400 increase in recruiting costs. These increases resulted from the hiring of additional employees in our R&D department, particularly in product development to support our efforts on the development of a third generation neurodiagnostic system, new biosensors, improvements to existing biosensors, products to diagnose additional neuropathies and a drug delivery system for the minimally invasive treatment of neuropathies. Also contributing to the change was an increase of \$283,600 in outside consulting costs primarily related to efforts expended on the development of a third generation neurodiagnostic system and on new biosensors and improvements to existing biosensors. These increases were partially offset by a decrease in stock-based compensation expense of \$171,800 related to employee stock options.

We expect our spending on R&D will increase during 2006 due to additional consulting services and the hiring of several additional employees to support product development efforts as well as increased clinical study costs. In addition, we expect R&D expenses will also increase in 2006 due to the adoption of the provisions of Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment" ("SFAS No. 123(R)"). We expect R&D expenses, as a percentage of total revenues, to continue to decrease slightly due to an expected increase in revenue. This percentage may vary, however, depending primarily on our revenues for 2006.

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 \$5.7 million, or 66.7%, to \$14.2 million for year ended December 31, 2005 from \$8.5 million for the year ended December 31, 2004. As a percentage of revenues, sales and marketing expenses were 41.3% and 47.4% for the years ended December 31, 2005 and 2004, respectively. The change in expenses was primarily due to an increase of \$3.7 million in employee compensation and benefit costs, including sales commissions paid to our regional sales managers. This increase is due to the expansion of the sales force and higher revenues in 2005 as compared to 2004. Also contributing to the change in expenses was an increase of \$1.5 million in sales commissions paid to our independent sales agencies, which were related to our higher revenues in 2005, and increases of \$351,400 in travel expenses and \$73,300 in recruiting costs due to the expansion of the sales force. The change in expenses was also partially due to an increase of \$192,800 in costs for trade shows, advertising and promotional materials as we have increased our presence at tradeshow and developed new promotional materials. These increases were offset in part by a decrease in stock-based compensation expense of \$188,700 related to employee stock options.

We have increased our sales force to 31 regional sales managers, three sales representatives and two district sales directors as of the end of 2005 and expect to add approximately 15 additional regional sales managers and several sales representatives and sales directors during the first quarter of 2006. In addition, we expect sales and marketing expenses will also increase in 2006 due to the adoption of the provisions of SFAS No. 123(R). For 2006, we expect sales and marketing expenses, as a percentage of total revenues, to decrease slightly from the level experienced in 2005. This percentage may vary, however, depending primarily on our revenues for 2006.

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 \$2.5 million, or 51.4%, to \$7.3 million for year ended December 31, 2005 from \$4.8 million for the year ended December 31, 2004. As a percentage of revenues, general and administrative expenses were 21.4% and 27.0% for the years ended December 31, 2005 and 2004, respectively. The increase in expenses was primarily due to (a) an increase in employee compensation and benefit costs of \$885,500 due to the expansion of staff and increases in employee compensation; (b) an increase of \$663,700 in professional fees for legal services and for accounting and audit services primarily as a result of the increased regulatory requirements associated with being a publicly-traded company including the provisions of the Sarbanes-Oxley Act of 2002, and the rules promulgated thereunder, regarding internal control over financial reporting ("Sarbanes-Oxley 404") which began to apply to us as of December 31, 2005; (c) an increase of \$344,100 in our insurance costs, primarily relating to increases in director and officer insurance premiums as a result of the transition to a publicly-traded company; (d) an increase of \$177,600 in credit card and bank transaction fees related to customer sales; (e) an increase of \$148,000 in franchise taxes and other fees; and (f) an increase in recruiting costs of \$94,300 associated with new hires. The increases are offset in part by a decrease of \$261,800 in stock-based compensation expense related to employee stock options.

We expect our general and administrative expenses to increase during 2006 as a result of our expected growth and the expected hiring of additional general and administrative staff to support this growth. In addition, we expect general and administrative expenses will also increase in 2006 due to the adoption of the provisions of SFAS No. 123(R). Total general and administrative expenses, as a percentage of total revenues, are expected to decrease in 2006, in spite of the anticipated need to hire additional staff. This

percentage may vary, however, depending primarily on our revenues for 2006. We expect to be able to leverage certain existing resources such that the growth in general and administrative expenses is anticipated to be less than the growth in our revenues. Furthermore, while we experienced an increase in professional fees in 2005 largely due to the effect of the first year of compliance with Sarbanes-Oxley 404, we do not expect the costs associated with Sarbanes-Oxley 404 to increase in 2006.

Interest Income

Interest income was \$838,800 and \$214,100 during the years ended December 31, 2005 and 2004, respectively, representing an increase of \$624,700. Interest income was earned from investments in cash equivalents, short-term investments and long-term investments. Interest income increased during the year ended December 31, 2005 compared to the year ended December 31, 2004 due to the investment of the proceeds from the IPO, which was completed in the third quarter of 2004, the investment of the proceeds from the sale of preferred stock in March 2004 and increased yields on invested funds in 2005.

Interest Expense

Interest expense was \$2,000 and \$964,100 during the years ended December 31, 2005 and 2004, respectively, representing a decrease of \$962,000. The decrease in interest expense was due to the payment in the third quarter of 2004 of an outstanding debt balance of \$3.0 million under our line of credit with Lighthouse Capital Partners by using a portion of the proceeds received from the IPO.

Deemed Dividend and Beneficial Conversion Feature on Redeemable Convertible Preferred Stock

In 2004, we recorded a \$787,900 deemed dividend as a result of the March 2004 Series E-1 redeemable convertible preferred stock financing. The deemed dividend resulted from an adjustment to the conversion ratios pursuant to the anti-dilution protection provisions associated with the Series D redeemable convertible preferred stock. We also recorded a charge of \$7.1 million for a beneficial conversion feature associated with the Series E-1 redeemable convertible preferred stock issued in March 2004. There was no deemed dividend or beneficial conversion charge in 2005. All issued and outstanding shares of preferred stock were converted into shares of common stock in connection with the initial public offering.

Comparison of Years Ended December 31, 2004 and December 31, 2003

Revenues

The following table presents a breakdown of our customers, biosensor units used and revenues:

	Years Ended December 31,		Change	% Change
	2004	2003		
Customers	2,207	1,736	471	27.1 %
Biosensor units used	357,400	203,000	154,400	76.1
	(in thousands)			
Revenues:				
Diagnostic device	\$ 2,219.5	\$ 1,302.3	\$ 917.2	70.4
Biosensor	15,700.6	7,865.3	7,835.3	99.6
Total revenues	<u>\$ 17,920.1</u>	<u>\$ 9,167.6</u>	<u>\$ 8,752.5</u>	95.5

Diagnostic device revenues were \$2.2 million and \$1.3 million for the years ended December 31, 2004 and December 31, 2003, respectively, representing a year-over-year increase of \$917,200, or 70.4%. Of this increase, approximately \$518,600 is attributable to a greater number of units sold, primarily as a result of

an increase in the number of our regional sales managers and expanded clinical uses for the NC-stat System, and \$398,600 is attributable to an increase in the list price of our NC-stat monitors and docking stations. Diagnostic device revenues accounted for 12.4% and 14.2% of our total revenues for the years ended December 31, 2004 and December 31, 2003, respectively.

Biosensor revenues were \$15.7 million and \$7.9 million for the years ended December 31, 2004 and December 31, 2003, respectively, representing a year-over-year increase of \$7.8 million, or 99.6%. The increase was primarily due to an increased customer base for our biosensors, increased frequency of testing by our customers, and the introduction in May 2003 of higher functionality biosensors that test both motor and sensory nerve conduction. These higher functionality biosensors have an average selling price 60-80% higher than motor-only biosensors. Biosensor revenues accounted for 87.6% and 85.8% of our total revenues for the years ended December 31, 2004 and December 31, 2003, respectively.

Our customers used 357,400 biosensor units in the year ended December 31, 2004, compared to 203,000 units for the same period in 2003, an increase of 154,400 units, or 76.1%.

Our total revenues were \$17.9 million and \$9.2 million for the years ended December 31, 2004 and December 31, 2003 respectively, representing a year-over-year increase of \$8.8 million, or 95.5%. During the 12-month period ending December 31, 2004, a total of 2,207 customers used our NC-stat System compared to 1,736 customers for the same period ending December 31, 2003. This represents a 27.1% year-over-year increase in the number of customers that used our NC-stat System.

Costs and expenses

The following table presents our costs and expenses and net loss:

	<u>Years Ended December 31,</u>		<u>Change</u>	<u>% Change</u>
	<u>2004</u>	<u>2003</u>		
	(in thousands)			
Cost of revenues:				
Diagnostic device	\$ 728.7	\$ 658.1	\$ 70.6	10.7%
Biosensor	4,124.6	2,048.4	2,076.2	101.4
Total cost of revenues	4,853.3	2,706.5	2,146.8	79.3
Gross margin:				
Diagnostic device	1,490.8	644.2	846.6	131.4
Biosensor	11,576.0	5,816.8	5,759.2	99.0
Total gross margin	13,066.8	6,461.0	6,605.8	102.2
Gross margin %:				
Diagnostic device	67.2 %	49.5 %		
Biosensor	73.7	74.0		
Total gross margin %	72.9	70.5		
Operating expenses:				
Research and development(1)	\$ 3,268.4	\$ 2,396.8	\$ 871.6	36.4
Sales and marketing(1)	8,488.0	4,767.6	3,720.4	78.0
General and administrative(1)	4,844.4	2,850.5	1,993.9	70.0
Total operating expenses	16,600.8	10,014.9	6,585.9	65.8
Loss from operations	(3,534.0)	(3,553.8)	19.8	-0.6
Interest income	214.1	23.5	190.6	811.1
Interest expense	(964.1)	(136.3)	(827.8)	607.3
Net loss	(4,284.0)	(3,666.7)	(617.3)	16.8
Accretion on redeemable convertible preferred stock	(1,386.3)	(2,009.5)	623.2	-31.0
Deemed dividend on redeemable convertible preferred stock	(7,838.7)	—	(7,838.7)	—
Net loss available to common stockholders	<u>\$ (13,509.0)</u>	<u>\$ (5,676.2)</u>	<u>\$ (7,832.8)</u>	-138.0

(1) Includes non-cash stock-based compensation of:

Research and development	\$ 249.1	\$ 35.1
Sales and marketing	356.4	36.8
General and administrative	423.0	24.5
Total non-cash stock-based compensation	<u>\$ 1,028.6</u>	<u>\$ 96.4</u>

Gross Margin

Diagnostic device gross margin percentage was 67.2% and 49.5% for the years ended December 31, 2004 and December 31, 2003, respectively. The increase in the gross margin percentage for the year of 2004 compared to 2003 is attributable partially to an increase in the list price of our NC-stat neurodiagnostic system, and partially to a decrease in the cost of our diagnostic devices commencing in mid-2003 resulting from a change in our third-party manufacturer.

Biosensor gross margin percentage decreased to 73.7% for the year ended December 31, 2004 from 74.0% for the same period in 2003. The small decrease in biosensor gross margin percentage is primarily due to a less favorable mix towards higher sales volume of lower margin biosensors during the year of 2004 when compared to 2003.

Our overall gross margin percentage was 72.9% for the year ended December 31, 2004 compared to 70.5% for 2003.

Research and Development

R&D expenses increased \$871,600, or 36.4%, to \$3.3 million for the year ended December 31, 2004 from \$2.4 million for the same period in 2003. As a percentage of revenues, R&D expenses were 18.2% and 26.1% for the years ended December 31, 2004 and December 31, 2003, respectively. The increase in expenses was due to an increase of \$564,400 in employee compensation and benefit costs primarily from the hiring of additional employees in our R&D department, an increase in stock-based compensation of \$214,000 and an increase of \$87,400 in outside consulting costs.

Sales and Marketing

Sales and marketing expenses increased \$3.7 million, or 78.0%, to \$8.5 million for the year ended December 31, 2004 from \$4.8 million for the year ended 2003. As a percentage of revenues, sales and marketing expenses were 47.4% and 52.0% for the years ended December 31, 2004 and December 31, 2003, respectively. The increase in expenses was primarily due to an increase of \$1.1 million in sales commissions paid to our independent regional sales agencies and an increase of \$792,900 in sales commissions paid to our direct sales force, which were directly related to our higher revenues in 2004, and increases of \$741,900, \$440,700 and \$133,000 in employee compensation and benefit costs, travel expenses and recruiting costs, respectively, which resulted from the addition of seventeen employees in our sales and marketing department. The increase was also partially due to an increase of \$189,000 in outside consulting service expense. Sales and marketing expense also increased due to an increase in non-cash stock based compensation of \$319,600 in 2004 compared to 2003. These increases were partially offset by a reduction of \$113,900 in costs for advertising, promotional materials and trade shows. This reduction was due to the fact that we performed a significant portion of advertising design work in-house during 2004, which resulted in lower costs as compared to the previous year when this design work was contracted to vendors. Also, during 2003 we incurred advertising and promotion costs related to the introduction of our new motor/sensory biosensors.

General and Administrative

General and administrative expenses increased \$2.0 million, or 70.0%, to \$4.8 million for the year ended December 31, 2004 from \$2.8 million for the year ended December 31, 2003. As a percentage of revenues, general and administrative expenses were 27.0% and 31.1% for the years ended December 31, 2004 and December 31, 2003, respectively. The increase in expenses was primarily due to an increase of \$349,000 in employee compensation and benefit costs resulting partially from the hiring of four additional employees, an increase of \$397,000 in non-cash stock-based compensation related to employee stock options, an increase of \$325,400 in outside consulting services expense partially used to assist in the preparation for and the IPO process, an increase of credit card and bank transaction fees of \$97,400 and an increase of \$68,100 to bad debt write-offs during the year of 2004. Also contributing to the increase in general and administrative expenses were increases of \$362,300 in our insurance costs, \$327,300 increase in our legal and accounting costs and an increase of \$25,200 in financial printing costs and filing fees, all related to fulfilling the requirements of a publicly traded company. Partially offsetting these increases in general and administrative expenses was a decrease in recruiting costs of \$31,900 resulting from an executive search in 2003 that did not recur in 2004.

Interest Income

Interest income was \$214,100 and \$23,500 during the years ended December 31, 2004 and December 31, 2003, respectively. Interest income was earned from investments in cash equivalents, short-

term investments and long-term investments. All cash invested is designated as held to maturity, however, the investments held are liquid and marketable. Interest income increased during the year ended December 31, 2004 compared to the same period in 2003 due primarily to the investment of the net proceeds from our IPO in the third quarter of 2004 and the net proceeds from our sale of Series E-1 redeemable convertible preferred stock in March 2004.

Interest Expense

Interest expense was \$964,100 and \$136,300 during the years ended December 31, 2004 and 2003, respectively, representing an increase of \$827,700. The increase in interest expense was primarily due to full repayment of our borrowings under a credit line entered into in May 2003 with Lighthouse Capital Partners which triggered an additional payment equal to 11% of the original principal amount of the line of credit.

Deemed Dividend and Beneficial Conversion Feature on Redeemable Convertible Preferred Stock

In the first quarter of 2004, we recorded a \$787,900 deemed dividend as a result of the March 2004 Series E-1 redeemable convertible preferred stock financing. The deemed dividend resulted from an adjustment to the conversion ratios as a result of anti-dilution protection associated with the Series D redeemable convertible preferred stock. We also recorded a charge of \$7.1 million for a beneficial conversion feature embedded within the Series E-1 redeemable convertible preferred stock issued in March 2004. There was no deemed dividend or beneficial conversion charge in 2003.

Liquidity and Capital Resources

Our principal source of liquidity is our current cash and cash equivalents, and short-term and long-term held-to-maturity investments. As of December 31, 2005, weighted average maturity of our cash equivalents and short-term held-to-maturity investments was 107 days. Our ability to generate cash from operations is dependent upon our ability to generate revenue from sales of our diagnostic devices and consumable biosensors, 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
	2005	2004		
	(in thousands)			
Cash and cash equivalents	\$ 8,170	\$ 1,936	\$ 6,234	322.0%
Short-term held-to-maturity investments	24,082	18,575	5,507	29.6
Long-term held-to-maturity investments	—	9,497	(9,497)	-100.0
Total cash, cash equivalents, short-term and long-term held-to-maturity investments	<u>\$ 32,252</u>	<u>\$ 30,008</u>	<u>\$ 2,244</u>	7.5%

During 2005, our cash and cash equivalents and short-term and long-term held-to-maturity investments increased \$2.2 million, primarily due to positive cash flow from operations of \$1.9 million and \$812,200 of proceeds from the exercise of stock options and the issuance of common stock through our employee stock purchase plan, offset in part by capital expenditures of \$475,100.

In March 2004, we sold 7,050,771 shares of our Series E-1 redeemable convertible preferred stock to existing preferred stockholders for net proceeds of \$10.6 million. These shares converted into 1.8 million shares of common stock upon the closing of our initial public offering. These shares contained a beneficial conversion feature, as the estimated fair value of our common stock at the date of the sale was in excess of the conversion price associated with Series E-1 redeemable convertible preferred stock share price. The

total value of the beneficial conversion feature of approximately \$7.1 million was recognized in the form of a preferred stock dividend in the first quarter of 2004. In addition, we recognized a deemed dividend of approximately \$787,900 in the first quarter of 2004 as a result of an adjustment in the conversion rate of the Series D redeemable convertible preferred stock associated with anti-dilution provisions in connection with the March 2004 Series E-1 redeemable convertible preferred stock sale.

On July 27, 2004, we closed the initial public offering of our common stock selling 3,000,000 shares at \$8.00 per share. On August 19, 2004 we sold a 450,000 common share over-allotment to our underwriters at \$8.00 per share. Our initial public offering, including the over-allotment shares, provided net proceeds of approximately \$24.0 million. We repaid approximately \$2.9 million of secured debt which was outstanding at the beginning of the quarter in July 2004 by using a portion of the proceeds received from our initial public offering.

In managing our working capital, two of the financial measurements that we monitor are days' sales outstanding, or DSO, and inventory turnover rate, which are presented in the table below for the years ended December 31, 2005 and December 31, 2004:

	<u>Years Ended</u> <u>December 31,</u>	
	<u>2005</u>	<u>2004</u>
Days' sales outstanding (days)	40	50
Inventory turnover rate (times per year)	4.5	4.1

Our payment terms extended to our customers generally require payment within 30 days from invoice date. At December 31, 2005, our DSO was 40 days, a decrease of 10 days as compared to December 31, 2004. This decrease in DSO resulted from increasing revenues and a decrease in the percentage of accounts receivable balances more than 60 days past due. This decrease in the percentage of accounts receivable balances more than 60 days past due was primarily due to more aggressive management of collections and the significant revenue growth in the year ended December 31, 2005 relative to the more modest increase in our accounts receivable balances during the year ended December 31, 2004. We continue to focus our efforts on reducing our accounts receivable balances over 60 days past due. Accounts payable are normally paid within 30 to 40 days from receipt of a vendor's invoice.

Our inventory turnover for the year ended December 31, 2005 was 4.5 times, compared with 4.1 times for the year ended December 31, 2004. The increase in the inventory turnover rate for the year ended December 31, 2005 as compared to the year ended December 31, 2004 was primarily due to the effective management of inventory levels of biosensors. We monitor our inventories closely, especially as it pertains to the mix of different biosensors sold, and the sales volumes of new biosensors launched in 2004. We expect to increase our inventory levels through the first quarter of 2006 with a target of maintaining at least three months worth of inventory in our facility in Waltham, MA. This may have the effect of decreasing our inventory turnover rate.

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

	<u>Years Ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
	(in thousands)		
Net cash provided by (used in) operating activities	\$ 1,908	\$ (2,652)	\$ (3,873)
Net cash provided by (used in) investing activities	\$ 3,514	\$ (28,706)	\$ (204)
Net cash provided by financing activities	\$ 812	\$ 31,671	\$ 2,999

Cash provided by operating activities was approximately \$1.9 million in the 2005, compared with cash used in operating activities of \$2.7 million in 2004. In 2005, we recorded \$938,000 in net income. In addition, we had \$1.5 million in depreciation, amortization and other non-cash items. We had a net use of cash totaling approximately \$550,000 for our investment in working capital. The primary drivers of our investment in working capital were as follows: Our accounts receivable increased \$1.8 million, excluding the change in the allowance for doubtful accounts, due to growth in revenues offset by the more rapid collection of amounts due from our customers as evidenced by the decrease in DSO from 50 in 2004 to 40 in 2005. Our inventories increased \$1.4 million due to the growth in our business and due to a strategic decision to increase inventory levels from two months to three months of purchases. Accounts payable, representing amounts due to our vendors, increased approximately \$800,000, principally due to increases in amounts due to our third-party manufacturers as a result of the growth in our business and the increase in our inventory levels. Accrued expenses increased \$1.2 million, primarily due to increases in commissions and bonuses owed to sales representatives and third party distributors as a result of the increase in our revenues. Deferred revenue, net of deferred costs, increased \$589,000 due to the increase in the number of new NC-stat docking stations sold to customers.

Cash used in operations in 2004 was driven by the net loss of \$4.3 million and a net investment of \$363,700 in working capital, offset in part by \$2.0 million of non-cash items.

Cash provided by investing activities was \$3.5 million in 2005, compared with cash used in investing activities of \$28.7 million in 2004. In 2005, there were net maturities of investments in the amount of approximately \$3.6 million, which was primarily reinvested in cash equivalents. In 2004, \$31.0 million of proceeds from equity financings was invested in short-term and long-term held-to-maturity investments. In 2005 and 2004 cash was used for the purchase of fixed assets in the amount of \$475,100 and \$545,200, respectively, primarily representing production tooling equipment for new products, especially the third generation neurodiagnostic systems in development, computer equipment and leasehold improvements in 2005 and production tooling and computer equipment in 2004.

In connection with our property lease entered into at the beginning of January, 2001, we are required to maintain, for the benefit of the lessor, an irrevocable standby letter of credit stating the lessor as the beneficiary. The original amount of the letter of credit was \$1,860,000. During September 2005, in accordance with the terms of the lease agreement, the amount required under the letter of credit was reduced to \$1,430,000. The letter of credit is secured by a certificate of deposit in an amount equal to 102% of the letter of credit. The lease expires in March 2009. The certificate of deposit is renewable in 30-day increments. This amount is classified as restricted cash in the balance sheet. The restricted cash balance as of December 31, 2005 has been reduced by approximately \$438,600 from the balance as of December 31, 2004 to approximately \$1,458,600.

Cash provided by financing activities was \$812,200 and \$31.7 million in 2005 and 2004, respectively. Cash provided by financing activities in 2005 represents the proceeds from the exercise of stock options and the issuance of shares under our employee stock purchase plan. The cash from financing activities in 2004 primarily represented the net proceeds of \$24.0 million realized from our initial public offering, including the net proceeds from the over-allotment shares, as well as net proceeds of \$10.6 million received from the issuance of preferred stock in a private placement, offset by payments on long-term debt of \$3.0 million.

During 2006, we will be continuing to expend funds in connection with our efforts to expand our sales and marketing for the NC-stat System, although more modestly than the expansion in the last several quarters, and continue our ongoing program of making enhancements and improvements to the NC-stat System, including the development of new and/or improved biosensors, products for the diagnosis of additional neuropathies, and the development of a third generation neurodiagnostic system. In connection with the development efforts on a third generation neurodiagnostic system, we expect to continue to incur

additional capital expenditures in the first quarter of 2006 for production tooling costs. We also plan to expend funds on the design of a drug delivery system, which is in its early stages of development, for the minimally invasive delivery of therapeutic agents to treat neuropathies by both primary care and specialist physicians. We also expect to incur capital expenditures for computer hardware and software to support the growth in our business and the additional requirements of our customer base. We believe that the combination of funds available from cash and cash equivalents and funds available from our short-term investments will be adequate to finance our ongoing operations for at least 24 months, including the expenditures described above.

As of December 31, 2005, we have federal and state net operating loss carryforwards available to offset future taxable income of \$35.5 million and \$28.8 million, respectively, and federal and state research and development credits of \$563,000 and \$126,000, 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 2011 for federal and 2006 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.

To date, inflation has not had a material impact on our financial operations.

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

As of December 31, 2005, we did not have any off-balance sheet financing arrangements.

The following table summarizes our principal contractual obligations as of December 31, 2005 and the effects such obligations are expected to have on our liquidity and cash flows in future periods.

Contractual Obligations	Payments due in				
	Total	2006	2007 and 2008	2009 and 2010	After 2010
Operating lease obligations	\$ 3,022,500	\$ 930,000	\$ 1,860,000	\$ 232,500	\$ —
Purchase order obligations	2,656,900	2,656,900	—	—	—
License agreement obligations	85,000	85,000	—	—	—
Total contractual obligations	<u>\$ 5,764,400</u>	<u>\$ 3,671,900</u>	<u>\$ 1,860,000</u>	<u>\$ 232,500</u>	<u>\$ —</u>

In addition to the above-listed items, we entered into two separate license agreements. The first license agreement is with the Massachusetts Institute of Technology, or M.I.T. We have obtained a right to use certain technology through the term of the M.I.T.'s patent rights on such technology, which is exclusive for a period of 15 years from the date of the license agreement. In exchange, we issued shares of common stock to M.I.T. and are required to pay royalties of 2.15% of net sales of products incorporating the licensed technology. In addition, we are required to pay royalties ranging from 25% to 50% of payments received from sublicensees, depending on the degree to which the licensor's technology was incorporated into the products sublicensed by us. In addition, we are obligated to pay M.I.T. annual license maintenance fees. On or before December 31, 2002, we have paid M.I.T. annual license maintenance fees totaling \$50,000 in the aggregate. For each year after 2003, we are obligated to pay M.I.T. annual license maintenance fees of \$75,000 if minimum sales requirements are not met. All annual license maintenance fees that we pay can be used to offset future royalties payable under the agreement. We have the right to terminate this license agreement at any time upon six months' notice. Through the year ended December 31, 2005, we have not incorporated this licensed technology into our products.

The second license agreement is with an unrelated third party. We obtained the right to use certain proprietary technology of this third party. This technology is used in the manufacture of our NC-stat

biosensors. The term of this agreement is perpetual, subject to rights of termination. In exchange, we were required to pay the licensor \$50,000 every year for the first three years of the agreement. In subsequent years, we are required to pay \$10,000 per year as long as we continue to use the licensed technology. We paid \$10,000 during the year ended December 31, 2005. We have the right to terminate this license agreement upon written notice not later than 30 days prior to any anniversary date.

Critical Accounting Policies

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 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 monitor and biosensors upon shipment if the fee is fixed and determinable, persuasive evidence of an arrangement exists, 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, 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.

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 thirty-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."

Warranty Costs

We accrue for device and biosensor 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 and based on the replacement cost of biosensors.

Asset Valuation

Asset valuation includes assessing the recorded value of certain assets, including accounts receivable, inventories and fixed assets. We use a variety of factors to assess valuation, depending upon the asset. Accounts receivable are evaluated based upon our historical experience, the age of the receivable and current market and economic conditions. Should current market and economic conditions deteriorate, our actual bad debt experience could exceed our estimate. The realizable value of inventories is based upon the types and levels of inventory held, forecasted demand, pricing, competition and changes in technology. Should current market and economic conditions deteriorate, our actual recovery could be less than our estimate.

Accounting for Income Taxes

As part of the process of preparing our financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves estimating our actual current tax exposure, including assessing the risks associated with tax audits, together with assessing temporary differences resulting from the different treatment of items for tax and accounting purposes. These differences, together with cumulative net operating losses, result in deferred tax assets and liabilities, which are included within our balance sheet. We assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe that recovery is not more likely than not, establish a valuation allowance. The primary factor used in the determination of the valuation allowance is our historical profitability. In the event that actual results differ from these estimates, our provision for income taxes could be materially impacted.

New Accounting Pronouncements

In November 2005, the Financial Accounting Standards Board ("FASB") issued FASB Staff Position ("FSP") FAS 115-1/124-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments." The guidance in this FSP addresses the determination of when an investment is considered impaired, whether that impairment is other-than-temporary and the measurement of an impairment loss. The FSP also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. The guidance in this FSP applies to reporting periods beginning after December 15, 2005. The adoption of this FSP did not have a material impact on the Company's financial position or results of operations.

In May 2005, the FASB issued SFAS No 154, "Accounting Changes and Error Corrections—a replacement of APB Opinion No. 20 and FASB Statement No. 3" ("SFAS No. 154"). SFAS No. 154 changes the requirements for the accounting and reporting of a change in accounting principle. SFAS No. 154 applies to all voluntary changes in accounting principles. It also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not contain specific transition provisions. When a pronouncement includes specific transition provisions, those provisions will

continue to be followed. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. Earlier application is permitted for accounting changes and corrections of errors occurring in fiscal years beginning after June 1, 2005. The adoption of SFAS No. 154 is not expected to have a material impact on our financial position or results of operations.

In December 2004, the FASB issued SFAS No. 123(R), which is a revision of SFAS No. 123, "Accounting for Stock-Based Compensation," and supersedes Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees" and SFAS No. 148 "Accounting for Stock-Based Compensation—Transition and Disclosure." This statement requires that the cost resulting from all share-based payment transactions be recognized in the financial statements. This statement establishes fair value as the measurement objective in accounting for share-based payment arrangements and requires all entities to apply a fair value based measurement method in accounting for share-based payment transactions with employees except for equity instruments held by employee share ownership plans. As a result, beginning January 1, 2006, we adopted SFAS No. 123(R) using the modified prospective method and have begun reflecting the stock-based compensation expense determined under fair value based methods in the income statement rather than as pro forma disclosure in the notes to the financial statements. 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 adoption of SFAS No. 123(R) will have a material impact on our results of operations.

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, short-term investments and long-term investments with a maturity of 18 months or less and maintain an average maturity of twelve months or less. We do not believe that a 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-26 of this Form 10-K with the exception of quarterly financial information which is presented below:

	Year Ended December 31, 2005				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Revenues	\$ 6,789,764	\$ 8,067,506	\$ 9,109,436	\$ 10,331,427	\$ 34,298,133
Gross margin	\$ 4,972,039	\$ 5,977,442	\$ 6,791,595	\$ 7,698,963	\$ 25,440,039
Net income (loss) attributable to common shareholders	\$ (596,314)	\$ (40,144)	\$ 769,265	\$ 805,451	\$ 938,258
Net income (loss) per common share					
Basic	\$ (0.05)	\$ (0.00)	\$ 0.06	\$ 0.07	\$ 0.08
Diluted	\$ (0.05)	\$ (0.00)	\$ 0.06	\$ 0.06	\$ 0.07
Weighted average shares used to compute net income (loss) per common share					
Basic	12,043,103	12,085,448	12,187,835	12,289,075	12,152,139
Diluted	12,043,103	12,085,448	13,103,158	13,181,140	12,986,365

	Year Ended December 31, 2004				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Revenues	\$ 3,030,267	\$ 4,296,015	\$ 4,819,318	\$ 5,774,489	\$ 17,920,089
Gross margin	\$ 2,203,060	\$ 3,125,592	\$ 3,529,075	\$ 4,209,036	\$ 13,066,763
Net loss attributable to common shareholders	\$ (9,153,072)	\$ (1,956,932)	\$ (1,563,769)	\$ (835,173)	\$ (13,508,946)
Net loss per common share (basic and diluted)	\$ (8.78)	\$ (1.85)	\$ (0.18)	\$ (0.07)	\$ (2.35)
Weighted average shares used to compute basic and diluted net loss per common share	1,042,990	1,055,993	8,819,558	12,025,223	5,747,579

Item 9. Disagreements with Accountants on Accounting and Financial Disclosure

There have been no changes or disagreements with accountants on accounting of 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 Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of December 31, 2005. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that they believe that our disclosure controls and procedures are effective to ensure 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 Securities and Exchange Commission's rules and forms. In designing and evaluating our disclosure controls and procedures, we and our management recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives,

and our management necessarily was required to apply its judgment in evaluating and implementing possible controls and procedures. 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) Changes in internal control over financial reporting.

There was no change in our internal control over financial reporting that occurred during the fiscal quarter ended December 31, 2005 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

(c) Management's Annual 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), for our company. Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework 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, 2005.

Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included on page F-2 of this Form 10-K.

Item 9B. Other Information

None.

PART III

Item 10. Directors and Executive Officers of the Registrant

The response to this item is contained in our Proxy Statement relating to our 2006 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 Shareholder 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

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 Schedule

(a) 1. *Financial Statements*

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

2. *Financial Statement Schedule*

The Schedule on page S-1 is filed as part of this report.

3. *Exhibit Index:*

<u>Exhibit Number</u>	<u>Description</u>
3.1	Form of Second Amended and Restated By-laws of NeuroMetrix, Inc.(1)
3.2	Form of Third Amended and Restated Certificate of Incorporation of NeuroMetrix, Inc.(1)
4.1	Specimen certificate for shares of common stock(1)
10.1	Lease Agreement dated October 18, 2000 between Fourth Avenue LLC and NeuroMetrix, Inc.(1)
10.2	Amended and Restated 1996 Stock Option/Restricted Stock Plan(1)
10.3	Amended and Restated 1998 Equity Incentive Plan(1)
10.4	First Amendment to Amended and Restated 1998 Equity Incentive Plan(1)
10.5	2004 Stock Option and Incentive Plan(1)
10.6	2004 Employee Stock Purchase Plan(1)

- 10.7 Form of Indemnification Agreement between NeuroMetrix, Inc. and each of its directors(1)
- 10.8 Employment Agreement, dated June 21, 2004, by and between NeuroMetrix, Inc. and Shai N. Gozani, M.D., Ph.D.(1)
- 10.9 Letter Agreement, dated June 19, 2002, by and between NeuroMetrix, Inc. and Gary L. Gregory (1)
- 10.10 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)
- 10.11 NeuroMetrix, Inc. Confidentiality and Non-Compete Agreement, dated as of June 28, 2002, by and between Gary L. Gregory and NeuroMetrix, Inc.(1)
- 10.12 NeuroMetrix, Inc. Confidentiality & 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 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)
- 10.14 Second Amendment to Amended and Restated 1998 Equity Incentive Plan(1)
- 10.15 NeuroMetrix, Inc. Non-Statutory Stock Option Agreement (1998 Plan) dated as of June 21, 2004 by and between Gary Gregory and NeuroMetrix, Inc.(1)
- 10.16 Indemnification Agreement dated June 21, 2004, by and between Shai N. Gozani, M.D., Ph.D., and NeuroMetrix, Inc.(1)
- 10.17 NeuroMetrix, Inc. Confidentiality & Non-Compete Agreement, dated as of May 1, 2000, by and between Michael Williams and NeuroMetrix, Inc.(1)
- 10.18 NeuroMetrix, Inc. Confidentiality & Non-Compete Agreement, dated as of October 13, 1998, by and between Guy Daniello and NeuroMetrix Inc.(1)
- 10.19 Form of Incentive Stock Option Agreement, under the NeuroMetrix, Inc. 2004 Stock Option And Incentive Plan(2)
- 10.20 Form of Non-Qualified Stock Option Agreement For Company Employees, under the NeuroMetrix, Inc. 2004 Stock Option And Incentive Plan(2)
- 10.21 Form of Non-Qualified Stock Option Agreement For Non-Employee Directors, under the NeuroMetrix, Inc. 2004 Stock Option And Incentive Plan(2)
- 10.22 Letter Agreement, dated February 7, 2005, by and between NeuroMetrix, Inc. and W. Bradford Smith(3)
- 10.23 Form of Incentive Stock Option Agreement, under the NeuroMetrix, Inc. 2004 Stock Option and Incentive Plan, by and between NeuroMetrix, Inc. and W. Bradford Smith(3)
- 10.24 NeuroMetrix, Inc. Confidentiality & Non-Compete Agreement, dated as of February 7, 2005, by and between W. Bradford Smith and NeuroMetrix, Inc.(3)
- 10.25 Executive Officer Compensation Arrangements (2004 Bonuses and 2005 Salaries and Bonus Targets)(5)
- *10.26 Director Compensation Arrangements
- *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.

- (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 Quarterly Report on Form 10-Q filed on November 15, 2004 (File No. 000-50856).
- (3) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on February 11, 2005 (File No. 000-50856).
- (4) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on March 16, 2005 (File No. 000-50856).
- (5) Incorporated herein by reference to NeuroMetrix, Inc.'s Quarterly Report on Form 10-Q filed on May 11, 2005 (File No. 000-50856).

INDEX TO FINANCIAL STATEMENTS
NeuroMetrix, Inc.
Years ended December 31, 2005, 2004 and 2003

	<u>Page</u>
Report of Independent Registered Public Accounting Firm	F-2
Financial Statements	
Balance Sheets	F-4
Statements of Operations	F-5
Statements of Changes in Redeemable Convertible Preferred Stock and Changes in Stockholders' (Deficit)/Equity	F-6
Statements of Cash Flows	F-8
Notes to Financial Statements	F-9
Schedule II—Valuation and Qualifying Accounts	S-1

Report of Independent Registered Public Accounting Firm

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

We have completed an integrated audit of NeuroMetrix, Inc.'s 2005 financial statements and of its internal control over financial reporting as of December 31, 2005 and audits of its 2004 and 2003 financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

Financial statements and financial statement schedule

In our opinion, the financial statements listed in the index appearing under Item 15 (a) (1) present fairly, in all material respects, the financial position of NeuroMetrix, Inc. at December 31, 2005 and 2004, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2005 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed under Item 15 (a) (2) 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 of financial statements 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.

Internal control over financial reporting

Also, in our opinion, management's assessment, included in "Management's Annual Report on Internal Control Over Financial Reporting" appearing under Item 9A, that the Company maintained effective internal control over financial reporting as of December 31, 2005 based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on criteria established in *Internal Control—Integrated Framework* issued by the COSO. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management's assessment and on the effectiveness of the Company's internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting 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 effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts

March 16, 2006

NeuroMetrix, Inc.

Balance Sheets

	December 31,	
	2005	2004
Assets		
Current assets:		
Cash and cash equivalents	\$ 8,170,037	\$ 1,936,241
Short-term held-to-maturity investments	24,081,946	18,574,593
Accounts receivable, net of allowance for doubtful accounts of \$400,000 and \$300,000 at December 31, 2005 and 2004, respectively	4,543,339	3,126,565
Inventories, net	2,683,409	1,284,261
Prepaid expenses and other current assets	614,169	672,970
Current portion of deferred costs	223,009	140,719
Total current assets	40,315,909	25,735,349
Restricted cash	1,458,598	1,897,200
Long-term held-to-maturity investments	—	9,497,158
Fixed assets, net	875,551	679,359
Deferred costs	247,013	143,462
Total assets	\$ 42,897,071	\$ 37,952,528
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,698,583	\$ 899,291
Accrued compensation	1,959,621	1,343,206
Accrued expenses	1,213,928	593,420
Current portion of deferred revenue	760,613	399,468
Total current liabilities	5,632,745	3,235,385
Deferred revenue	885,354	471,734
Other long-term liabilities	130,909	189,091
Total liabilities	6,649,008	3,896,210
Commitments and contingencies (Note 11)		
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; 12,375,276 and 12,034,650 shares issued and outstanding at December 31, 2005 and 2004, respectively	1,238	1,203
Additional paid-in capital	93,212,368	92,278,379
Deferred compensation	(425,623)	(745,086)
Accumulated deficit	(56,539,920)	(57,478,178)
Total stockholders' equity	36,248,063	34,056,318
Total liabilities and stockholders' equity	\$ 42,897,071	\$ 37,952,528

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

NeuroMetrix, Inc.
Statements of Operations

	Years Ended December 31,		
	2005	2004	2003
Revenues:			
Diagnostic device	\$ 4,221,311	\$ 2,219,489	\$ 1,302,306
Biosensor	30,076,822	15,700,600	7,865,251
Total revenues	34,298,133	17,920,089	9,167,557
Cost of revenues	8,858,094	4,853,326	2,706,539
Gross margin	25,440,039	13,066,763	6,461,018
Operating expenses:			
Research and development(1)	3,820,624	3,268,363	2,396,772
Sales and marketing(1)	14,150,157	8,488,047	4,767,640
General and administrative(1)	7,332,783	4,844,378	2,850,455
Total operating expenses	25,303,564	16,600,788	10,014,867
Income (loss) from operations	136,475	(3,534,025)	(3,553,849)
Interest income	838,825	214,092	23,481
Interest expense	(2,042)	(964,056)	(136,340)
Income (loss) before income taxes	973,258	(4,283,989)	(3,666,708)
Income tax provision	35,000	—	—
Net income (loss)	938,258	(4,283,989)	(3,666,708)
Accretion of redeemable convertible preferred stock	—	(1,386,301)	(2,009,450)
Deemed dividend on redeemable convertible preferred stock	—	(787,885)	—
Beneficial conversion feature associated with redeemable convertible preferred stock	—	(7,050,771)	—
Net income (loss) attributable to common stockholders	<u>\$ 938,258</u>	<u>\$ (13,508,946)</u>	<u>\$ (5,676,158)</u>
Net income (loss) per common share			
Basic	\$ 0.08	\$ (2.35)	\$ (5.46)
Diluted	\$ 0.07	\$ (2.35)	\$ (5.46)
Weighted average shares used to compute net income (loss) per common share			
Basic	12,152,139	5,747,579	1,038,817
Diluted	12,986,365	5,747,579	1,038,817

(1) Non-cash stock-based compensation expense included in these amounts are as follows:

Research and development	\$ 77,365	\$ 249,131	\$ 35,125
Sales and marketing	167,699	356,422	36,790
General and administrative	161,266	423,042	24,535
Total non-cash stock-based compensation	<u>\$ 406,330</u>	<u>\$ 1,028,595</u>	<u>\$ 96,450</u>

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

NeuroMetrix, Inc.

Statements of Changes in Redeemable Convertible Preferred Stock and Changes in Stockholders' (Deficit)/Equity

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Subscriptions Receivable	Deferred Compensation	Accumulated Deficit	Total
	Number of Shares	Amount	Number of Shares	Amount					
Balance at December 31, 2002	17,498,099	\$ 45,684,292	1,036,142	\$ 104	\$ —	\$ (2,143)	\$ (66,534)	\$ (39,859,918)	\$ (39,928,491)
Issuance of common stock upon exercise of stock options	—	—	8,723	—	5,894	—	—	—	5,894
Purchase of treasury stock	—	—	(1,875)	—	(15)	—	—	—	(15)
Accretion of redeemable convertible preferred stock to redemption	—	2,009,450	—	—	(634,728)	—	—	(1,374,722)	(2,009,450)
Adjustment to deferred compensation associated with terminated employees	—	—	—	—	(2,051)	—	2,051	—	—
Deferred compensation associated with stock options	—	—	—	—	630,900	—	(630,900)	—	—
Amortization of deferred compensation	—	—	—	—	—	—	96,450	—	96,450
Net loss	—	—	—	—	—	—	—	(3,666,708)	(3,666,708)
Balance at December 31, 2003	17,498,099	47,693,742	1,042,990	104	—	(2,143)	(598,933)	(44,901,348)	(45,502,320)
Issuance of Series E-1 redeemable preferred stock, net of issuance costs of \$22,672	7,050,771	10,553,484	—	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	49,621	5	44,926	—	—	—	44,931
Purchase of treasury stock	—	—	(6,251)	(1)	(1,249)	—	—	—	(1,250)
Cash received from subscriptions receivable	—	—	—	—	—	2,143	—	—	2,143
Beneficial conversion feature associated with redeemable convertible preferred stock	—	7,050,771	—	—	—	—	—	(7,050,771)	(7,050,771)
Deemed dividend on Series D redeemable convertible preferred stock	—	787,885	—	—	—	—	—	(787,885)	(787,885)
Accretion of redeemable convertible preferred stock to redemption	—	1,386,301	—	—	(932,116)	—	—	(454,185)	(1,386,301)
Initial public offering of common stock	—	—	3,450,000	345	24,005,719	—	—	—	24,006,064
Conversion of redeemable convertible preferred stock	(24,548,870)	(67,472,183)	7,488,758	749	67,471,434	—	—	—	67,472,183

NeuroMetrix, Inc.

Statements of Changes in Redeemable Convertible Preferred Stock and Changes in Stockholders' (Deficit)/Equity (Continued)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Subscriptions Receivable	Deferred Compensation	Accumulated Deficit	Total
	Number of Shares	Amount	Number of Shares	Amount					
Conversion of warrant to purchase common stock	—	—	—	—	450,100	—	—	—	450,100
Compensation expense associated with stock options	—	—	—	—	436,611	—	—	—	436,611
Deferred compensation associated with stock options	—	—	—	—	750,566	—	(750,566)	—	—
Adjustment to deferred compensation associated with terminated employees	—	—	—	—	(12,429)	—	12,429	—	—
Amortization of deferred compensation	—	—	—	—	—	—	591,984	—	591,984
Issuance of common stock under employee stock purchase plan	—	—	9,532	1	64,817	—	—	—	64,818
Net loss	—	—	—	—	—	—	—	(4,283,989)	(4,283,989)
Balance at December 31, 2004	—	—	12,034,650	1,203	92,278,379	—	(745,086)	(57,478,178)	34,056,318
Issuance of stock upon exercise of stock options and warrants	—	—	317,361	32	512,825	—	—	—	512,857
Compensation expense associated with stock options	—	—	—	—	120,272	—	—	—	120,272
Adjustment to deferred compensation associated with terminated employees	—	—	—	—	(33,405)	—	33,405	—	—
Amortization of deferred compensation	—	—	—	—	—	—	286,058	—	286,058
Issuance of common stock under employee stock purchase plan	—	—	23,265	3	299,297	—	—	—	299,300
Income tax effect of the exercise of stock options	—	—	—	—	35,000	—	—	—	35,000
Net income	—	—	—	—	—	—	—	938,258	938,258
Balance at December 31, 2005	—	\$ —	12,375,276	\$ 1,238	\$ 93,212,368	\$ —	\$ (425,623)	\$ (56,539,920)	\$ 36,248,063

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

NeuroMetrix, Inc.
Statements of Cash Flows

	Years Ended December 31,		
	2005	2004	2003
Cash flows for operating activities:			
Net income (loss)	\$ 938,258	\$ (4,283,989)	\$ (3,666,708)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	278,932	205,023	214,589
Compensation expense associated with stock options	406,330	1,028,595	96,450
Provision for doubtful accounts	359,827	235,464	200,326
Amortization of premium on investments	439,734	89,175	—
Income tax effect of the exercise of stock options	35,000	—	—
Accretion of debt issuance discount	—	437,778	—
Accrued payments on long-term debt	—	—	12,222
Changes in operating assets and liabilities:			
Accounts receivable	(1,776,601)	(1,510,046)	(1,221,910)
Inventories	(1,399,148)	(205,871)	(216,078)
Prepaid expenses and other current assets	58,801	(455,805)	(33,974)
Accounts payable	799,292	464,906	329,401
Accrued expenses and compensation	1,236,923	998,301	334,275
Other long-term liabilities	(58,182)	3,637	61,818
Deferred revenue and deferred costs	588,924	341,201	16,217
Net cash provided by (used in) operating activities	<u>1,908,090</u>	<u>(2,651,631)</u>	<u>(3,873,372)</u>
Cash flows for investing activities:			
Purchases of fixed assets	(475,124)	(545,158)	(203,611)
Purchases of investments	(15,290,120)	(30,954,418)	—
Maturities of investments	18,840,191	2,793,492	—
Release of restricted cash	438,602	—	—
Net cash provided by (used in) investing activities	<u>3,513,549</u>	<u>(28,706,084)</u>	<u>(203,611)</u>
Cash flows from financing activities:			
Proceeds from exercise of stock options	512,857	47,074	5,879
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	10,553,484	—
Proceeds from initial public offering, net of offering costs of \$3,572,908	—	24,006,064	—
Proceeds from issuance of common stock under employee stock purchase plan	299,300	64,818	—
Proceeds from long-term debt and related warrants	—	—	3,000,100
Payments on long-term debt	—	(3,000,000)	(7,139)
Net cash provided by financing activities	<u>812,157</u>	<u>31,671,440</u>	<u>2,998,840</u>
Net increase (decrease) in cash and cash equivalents	6,233,796	313,725	(1,078,143)
Cash and cash equivalents, beginning of year	1,936,241	1,622,516	2,700,659
Cash and cash equivalents, end of year	<u>\$ 8,170,037</u>	<u>\$ 1,936,241</u>	<u>\$ 1,622,516</u>
Supplemental disclosure of cash flow information:			
Cash paid for interest	\$ 2,042	\$ 497,404	\$ 152,992

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

NeuroMetrix, Inc.
Notes to Financial Statements

1. Nature of the Business

NeuroMetrix, Inc. (the "Company"), a Delaware corporation, was formed in June 1996. The Company designs, develops and sells proprietary medical devices used to diagnose neuropathies. Neuropathies are diseases of the peripheral nerves and parts of the spine that frequently are caused by or associated with diabetes, low back pain and carpal tunnel syndrome, as well as other clinical disorders. The Company operates in one business segment.

On July 27, 2004, the Company completed an initial public offering ("IPO") of 3,000,000 shares of its common stock at \$8.00 per share, for gross consideration of \$24,000,000. All of the shares were sold by the Company. In connection with the IPO, the Company granted the underwriters a 30-day over-allotment option to purchase up to an additional 450,000 shares of common stock from the Company at \$8.00 per share, which the underwriters exercised in full on August 17, 2004 for gross consideration of \$3,600,000. The Company's shares trade on The Nasdaq National Market under the symbol "NURO."

On July 27, 2004, upon completion of the Company's IPO, all shares of the Company's redeemable convertible preferred stock outstanding on that date converted into 7,488,758 shares of common stock and the outstanding warrant to purchase redeemable convertible preferred stock converted into a warrant to purchase 100,000 shares of common stock. This warrant was exercised in full on June 13, 2005.

Reverse Stock Split

On June 2, 2004, the Company's Board of Directors approved a 1-for-4 reverse stock split of the Company's issued common stock, subject to stockholder approval, to be effected prior to the Company's proposed initial public offering. On June 18, 2004, the Company's stockholders approved this reverse stock split. This reverse stock split became effective on July 15, 2004 upon the filing by the Company of an amended and restated certificate of incorporation with the Delaware Secretary of State. Common shares and other potential common shares have been restated to reflect this reverse split for all periods presented.

2. Basis of Presentation and Summary of Significant Accounting Policies

Significant accounting policies applied by the Company in the preparation of its financial statements are as follows:

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.

NeuroMetrix, Inc.
Notes to Financial Statements (Continued)

2. Basis of Presentation and Summary of Significant Accounting Policies (Continued)

Restricted Cash

At December 31, 2005 and 2004, the Company maintained restricted cash in the amount of \$1,458,598 and \$1,897,200, respectively, associated with a facility lease. See Note 11.

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 deposits accounts, short-term and long-term investments and trade receivables. The Company invests its funds in highly rated institutions and limits its investment in any individual debtor. The Company has not experienced significant losses related to cash and cash equivalents and does not believe it is exposed to any significant credit risks relating to its cash and cash equivalents.

The Company distributes its products through its own regional sales managers who lead independent sales agencies. At December 31, 2005 and 2004 and for the years ended December 31, 2005, 2004 and 2003, 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 and cash equivalents, short-term and long-term investments, accounts receivable, accounts payable and accrued expenses, approximate their fair value at December 31, 2005 and 2004.

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 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, 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

2. Basis of Presentation and Summary of Significant Accounting Policies (Continued)

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.

Diagnostic device revenues consist of sales of NC-stat monitors and NC-stat docking stations. Revenues associated with the sale of the NC-stat monitors are recognized upon shipment provided that the fee is fixed and 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 and 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 deferred revenue and deferred costs are presented as separate line items on the accompanying balance sheet.

Biosensor revenues consist of sales of disposable NC-stat biosensors and are recognized upon shipment provided that the fee is fixed and determinable, evidence of a persuasive arrangement exists, collection of receivables is reasonably assured and product returns are reasonably estimable.

The Company recognizes revenues associated with installation and training upon completion of the service. The Company determines the fair value of installation and training based on hourly service billing rates.

Certain product sales are made with a thirty-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 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 uses the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities reflect the impact of temporary differences between amounts of assets and liabilities for financial reporting purposes and such amounts as measured under enacted tax laws, operating losses and

NeuroMetrix, Inc.
Notes to Financial Statements (Continued)

2. Basis of Presentation and Summary of Significant Accounting Policies (Continued)

tax credit carryforwards. A valuation allowance is required to offset any net deferred tax assets if, based upon the available evidence, there is reasonable uncertainty as to the realization of the deferred tax assets.

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 and other operating costs such as facilities, supplies and overhead directly related to the Company's research and development efforts.

Product Warranty Costs

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

The following is a rollforward of the Company's accrued warranty liability for the years ended December 31, 2005, 2004 and 2003:

	<u>Years Ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Balance at beginning of period	\$ 59,876	\$ 22,151	\$ 2,711
Accrual for warranties	310,290	187,176	117,695
Settlements made	(306,044)	(149,451)	(98,255)
Balance at end of period	<u>\$ 64,122</u>	<u>\$ 59,876</u>	<u>\$ 22,151</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 property and equipment and other long-lived assets 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 an asset impairment. When indicators of impairment are present, the carrying values of the asset are evaluated in relation to their operating performance and future undiscounted cash flows of the underlining business. If the future undiscounted cash flows are less than their book value, an impairment exists. 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. No impairment was identified in the years ended December 31, 2005, 2004 and 2003.

Notes to Financial Statements (Continued)

2. Basis of Presentation and Summary of Significant Accounting Policies (Continued)

Accounting for Stock-Based Compensation

Employee stock awards granted under the Company's compensation plans are accounted for in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB No. 25"), and related interpretations. The Company has not adopted the fair value method of accounting for stock-based compensation prescribed by SFAS No. 123, "Accounting for Stock-Based Compensation" ("SFAS No. 123"). Accordingly, compensation expense is recorded for options issued to employees to the extent that the fair market value of the Company's common stock exceeds the exercise price of the option at the date granted and all other criteria for fixed accounting have been met. All stock-based awards granted to non-employees are accounted for at their fair value and the resulting compensation expense is generally recognized over the period of service. Effective January 1, 2006, the Company adopted SFAS No. 123(R) using the modified prospective method, and amortizing its stock-based compensation expense, as calculated using the Black-Scholes option pricing model, using the straight-line method.

The Company provides the disclosure requirements of SFAS No. 148, "Accounting for Stock Based Compensation—Transition and Disclosure—an amendment of Financial Accounting Standards Board Statement No. 123" ("SFAS No. 148"). If compensation expense for the Company's stock-based compensation plan had been determined based on the fair value at the grant dates as calculated in accordance with SFAS No. 123, the Company's net income (loss) attributable to common stockholders and net income (loss) per common share would approximate the pro forma amounts below:

	Years Ended December 31,		
	2005	2004	2003
Net income (loss) attributable to common stockholders, as reported	\$ 938,258	\$ (13,508,946)	\$ (5,676,158)
Add employee stock based compensation expense included in reported net income (loss)	406,330	1,028,595	96,450
Less stock-based compensation expense determined under fair value method	(1,432,031)	(1,503,188)	(209,329)
Net loss—pro forma	\$ (87,443)	\$ (13,983,539)	\$ (5,789,037)
Net income (loss) per common share:			
As reported			
Basic	\$ 0.08	\$ (2.35)	\$ (5.46)
Diluted	\$ 0.07	\$ (2.35)	\$ (5.46)
Pro forma (basic and diluted)	\$ (0.01)	\$ (2.43)	\$ (5.57)

NeuroMetrix, Inc.

Notes to Financial Statements (Continued)

2. Basis of Presentation and Summary of Significant Accounting Policies (Continued)

Prior to the July 2004 IPO, the Company established the fair value of common stock by reference to the previously issued redeemable convertible preferred stock and by reference to an expected IPO price. Prior to the IPO, assumed volatility was zero percent. The Company has estimated the fair value of its granted stock options by applying the following weighted average assumptions:

	Years Ended December 31,		
	2005	2004	2003
Risk-free interest rate	3.5%-4.6 %	3.5 %	3.0 %
Expected dividend yield	0	0	0
Expected option term	5 years	5 years	5 years
Volatility	52.6 %	65.0 %	0.0 %
Weighted average fair value of options granted at fair value	\$ 7.23	\$ 4.92	\$ 5.60
Weighted average fair value of options granted below fair value	\$ —	\$ 8.34	\$ —

For 2004, the weighted average fair value of options granted prior to and subsequent to the IPO was \$5.15 and \$5.74, respectively.

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) attributable to common stockholders by the weighted average number of common shares outstanding. Diluted net income (loss) per common share is computed by dividing net income (loss) attributable to common stockholders by the weighted average number of common shares and dilutive potential common share equivalents then outstanding. Potential common shares consist of shares issuable upon the exercise of stock options and warrants (using the treasury stock method), unvested restricted stock awards and the weighted average conversion of the preferred stock into shares of common stock (using the if-converted method).

	Years Ended December 31,		
	2005	2004	2003
Basic:			
Net income (loss) available to common stockholders	\$ 938,258	\$ (13,508,946)	\$ (5,676,158)
Weighted average shares	12,152,139	5,747,579	1,038,817
Basic income (loss) per common share	\$ 0.08	\$ (2.35)	\$ (5.46)
Diluted:			
Net income (loss) available to common stockholders	\$ 938,258	\$ (13,508,946)	\$ (5,676,158)
Weighted average shares	12,152,139	5,747,579	1,038,817
Effect of stock options	821,254	—	—
Effect of warrant	12,972	—	—
Weighted average shares, as adjusted	12,986,365	5,747,579	1,038,817
Diluted income (loss) per common share	\$ 0.07	\$ (2.35)	\$ (5.46)

NeuroMetrix, Inc.
Notes to Financial Statements (Continued)

2. Basis of Presentation and Summary of Significant Accounting Policies (Continued)

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

	Years Ended December 31,		
	2005	2004	2003
Options	45,400	1,132,571	450,412
Warrants	—	100,000	100,000
Convertible preferred stock	—	—	5,647,289

Advertising

Advertising costs are expensed as incurred. Advertising expense was approximately \$280,000, \$215,300 and \$329,200 in the years ended December 31, 2005, 2004 and 2003, respectively.

Other Comprehensive Income (Loss)

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. For the years ended December 31, 2005, 2004 and 2003, the Company had no components of comprehensive income or loss other than net income (loss).

Segments

The Company is in the business of designing, developing and selling proprietary medical devices. The Company evaluates its business activities that are regularly reviewed by the Chief Executive Officer for which discrete financial information is available. As a result of this evaluation, the Company determined that it has one operating segment with operations in one geographical location which is the United States.

Use of Estimates

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

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 U.S. Food and Drug Administration.

Reclassification

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

Recent Accounting Pronouncements

In November 2005, the Financial Accounting Standards Board ("FASB") issued FASB Staff Position ("FSP") FAS 115-1/124-1 "The Meaning of Other-Than-Temporary Impairment and Its Application to

Notes to Financial Statements (Continued)

2. Basis of Presentation and Summary of Significant Accounting Policies (Continued)

Certain Investments.” The guidance in this FSP addresses the determination of when an investment is considered impaired, whether that impairment is other-than-temporary and the measurement of an impairment loss. The FSP also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. The guidance in this FSP applies to reporting periods beginning after December 15, 2005. The adoption of this FSP did not have a material impact on the Company’s financial position or results of operations.

In May 2005, the FASB issued SFAS No 154, “Accounting Changes and Error Corrections—a replacement of APB Opinion No. 20 and FASB Statement No. 3” (“SFAS No. 154”). SFAS No. 154 changes the requirements for the accounting and reporting of a change in accounting principle. SFAS No. 154 applies to all voluntary changes in accounting principles. It also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not contain specific transition provisions. When a pronouncement includes specific transition provisions, those provisions will continue to be followed. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. Earlier application is permitted for accounting changes and corrections of errors occurring in fiscal years beginning after June 1, 2005. The adoption of SFAS No. 154 is not expected to have a material impact on the Company’s financial position or results of operations.

In December 2004, the FASB issued SFAS No. 123(R), “Share-Based Payment” (“SFAS No. 123(R)”), which is a revision of SFAS No. 123 and supersedes APB No. 25 and SFAS No. 148. This statement requires that the cost resulting from all share-based payment transactions be recognized in the financial statements. This statement establishes fair value as the measurement objective in accounting for share-based payment arrangements and requires all entities to apply a fair value based measurement method in accounting for share-based payment transactions with employees except for equity instruments held by employee share ownership plans. As a result, 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 income statement rather than as pro forma disclosure in the notes to the financial statements. 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 adoption of SFAS No. 123(R) will have a material impact on the Company’s results of operations.

3. Inventories

At December 31, 2005 and 2004, inventories consist of the following:

	December 31,	
	2005	2004
Purchased components	\$ 276,167	\$ 293,263
Finished goods	2,407,242	990,998
	<u>\$ 2,683,409</u>	<u>\$ 1,284,261</u>

NeuroMetrix, Inc.
Notes to Financial Statements (Continued)

4. Held-to-Maturity Investments

Held-to-maturity investments as of December 31, 2005 and 2004 are as follows:

	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
2005				
Commercial paper and bank notes	\$ 4,440,724	\$ 59,276	\$ —	\$ 4,500,000
U.S. agency obligations	2,990,521	—	(4,524)	2,985,997
Corporate bonds	10,061,701	1,429	(364,495)	9,698,635
Certificates of deposit	6,589,000	—	(13,545)	6,575,455
	<u>\$ 24,081,946</u>	<u>\$ 60,705</u>	<u>\$ (382,564)</u>	<u>\$ 23,760,087</u>
2004				
Commercial paper and bank notes	\$ 1,476,825	\$ 23,175	\$ —	\$ 1,500,000
U.S. agency obligations	9,625,229	20,713	(12,601)	9,633,341
Corporate bonds	13,477,697	—	(180,924)	13,296,773
Certificates of deposit	3,492,000	—	(2,756)	3,489,244
	<u>\$ 28,071,751</u>	<u>\$ 43,888</u>	<u>\$ (196,281)</u>	<u>\$ 27,919,358</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, 2005:

<u>Description of Securities</u>	<u>Less Than 12 Months</u>		<u>12 Months or Greater</u>		<u>Total</u>	
	<u>Fair Value</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>	<u>Gross Unrealized Losses</u>
U.S. agency obligations	\$ 2,587,943	\$ (2,489)	\$ 398,054	\$ (2,035)	\$ 2,985,997	\$ (4,524)
Corporate bonds	1,479,864	(39,075)	6,521,599	(325,420)	8,001,463	(364,495)
Certificates of deposit	1,290,058	(9,942)	496,397	(3,603)	1,786,455	(13,545)
Total	<u>\$ 5,357,865</u>	<u>\$ (51,506)</u>	<u>\$ 7,416,050</u>	<u>\$ (331,058)</u>	<u>\$ 12,773,915</u>	<u>\$ (382,564)</u>

U.S. agency obligations—The unrealized losses on the Company's investments in three U.S. agency obligations were caused by interest rate increases since the date of purchase. The contractual terms of these investments do not permit the issuer to settle the securities at a price less than the face value of the investment. Because the Company has the ability and intent to hold these investments until maturity, the Company does not consider these investments to be other-than-temporarily impaired at December 31, 2005.

Corporate bonds—The unrealized losses on the Company's investments in seven corporate bonds were caused by interest rate increases since the date of purchase. 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. Each of the bonds maintains a Standard & Poor's rating of A or higher and has made each of their scheduled interest payments. Therefore, it is not expected that the bonds would be settled at a price less than the amortized cost of the investment. Because the Company has the ability and intent to hold

NeuroMetrix, Inc.

Notes to Financial Statements (Continued)

4. Held-to-Maturity Investments (Continued)

these investments until maturity, the Company does not consider these investments to be other-than-temporarily impaired at December 31, 2005.

Certificates of deposit—The unrealized losses on the Company's investments in 18 certificates of deposit were caused by interest rate increases since the date of purchase. 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. Because the Company has the ability and intent to hold these investments until maturity, the Company does not consider these investments to be other-than-temporarily impaired at December 31, 2005.

The amortized cost and fair value of fixed maturity securities at December 31, 2005 and 2004, by contractual maturity, are shown below:

	December 31,			
	2005		2004	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Due in one year or less	\$ 24,081,946	\$ 23,760,087	\$ 18,574,593	\$ 18,529,593
Due after one year through five years	—	—	9,497,158	9,389,765
	<u>\$ 24,081,946</u>	<u>\$ 23,760,087</u>	<u>\$ 28,071,751</u>	<u>\$ 27,919,358</u>

5. Fixed Assets

Fixed assets consist of the following:

	Estimated Useful Life (Years)	December 31,	
		2005	2004
Computer and laboratory equipment	3	\$ 1,366,553	\$ 1,195,816
Furniture and equipment	3	198,330	188,859
Production equipment	7	636,406	620,511
Construction in progress	—	173,103	7,546
Leasehold improvements	*	132,907	19,443
		<u>2,507,299</u>	<u>2,032,175</u>
Less—accumulated depreciation		<u>(1,631,748)</u>	<u>(1,352,816)</u>
		<u>\$ 875,551</u>	<u>\$ 679,359</u>

*—Lesser of life of lease or estimated useful life

Depreciation expense was \$278,932, \$205,023 and \$214,589 for the years ended December 31, 2005, 2004 and 2003, respectively.

NeuroMetrix, Inc.
Notes to Financial Statements (Continued)

6. Accrued Expenses

Accrued expenses consist of the following for the fiscal years ended December 31, 2005 and 2004:

	<u>December 31,</u>	
	<u>2005</u>	<u>2004</u>
Professional services	\$ 438,519	\$ 164,701
Other	775,409	428,719
	<u>\$ 1,213,928</u>	<u>\$ 593,420</u>

7. Long-Term Debt

In March 1999, the Company obtained a commitment from a bank for a \$300,000 equipment term loan facility (the "Equipment Line"). On February 28, 2000, the bank increased the Equipment Line to \$400,000 and extended the maturity date to February 27, 2003. Advances under the Equipment Line bore interest at the bank's prime rate, plus 0.75% and were repayable in 30 equal monthly installments. In February 2003, the equipment line was repaid in full and terminated.

On May 21, 2003, the Company entered into an agreement with Lighthouse Capital Partners IV, L.P. ("Lighthouse") to establish a line of credit for \$3,000,000 ("Line of Credit"). The Company drew down \$3,000,000 million through December 31, 2003. All borrowings under the line of credit were collateralized by substantially all the assets of the Company. Borrowings bore interest at nominal rate of 11% per annum. Upon the final maturity date or the earlier prepayment of each advance, the Company was required to pay, in addition to the principal and interest, an additional amount equal to 11% of the original principal, or \$330,000. This additional amount was being accreted over the applicable borrowing period as additional interest expense.

On July 29, 2004, the Company paid \$3,123,521 to Lighthouse. This amount represented payment in full of all outstanding obligations under the line of credit with Lighthouse.

In connection with the Line of Credit, the Company issued Lighthouse warrants to purchase up to 400,000 shares of Series E-1 redeemable convertible preferred stock at an exercise price of \$1.50 per share, for a term of seven years. The fair value of the warrants calculated using the Black-Scholes option pricing model was estimated to be \$450,100, and was recorded as a debt discount. This discount was being accreted over the repayment term of 36 months as additional interest expense. Upon completion of the Company's IPO, this warrant converted into a warrant to purchase 100,000 shares of common stock. This warrant was exercised in full on a net basis on June 13, 2005, resulting in the issuance of 63,707 shares of common stock.

8. Redeemable Convertible Preferred Stock

The Company's redeemable convertible preferred stock was mandatorily redeemable by the holders based on facts and circumstances not in the Company's control. The carrying value of this preferred stock was being accreted to redemption value over the term to the redemption date. These adjustments were affected through charges first against retained earnings, then against additional paid-in capital until it was reduced to zero and then to accumulated deficit. Accretion for the years ended December 31, 2004 and 2003 was \$1,386,301 and \$2,009,450, respectively.

8. Redeemable Convertible Preferred Stock (Continued)

The Company's 875,000 shares of Series A redeemable convertible preferred stock, 625,000 shares of Series B redeemable convertible preferred stock, 3,998,100 shares of Series C convertible preferred stock, of which 2,850,000 shares were designated as Series C-1 redeemable convertible preferred stock and 1,148,100 shares were designated as Series C-2 nonvoting redeemable convertible preferred stock, 6,222,220 shares of Series D redeemable convertible preferred stock, 7,111,110 shares of Series E redeemable convertible preferred stock and 2,333,333 shares of Series E-1 redeemable convertible preferred stock automatically converted into 7,488,758 shares of common stock upon the completion of the Company's initial public offering in July 2004.

In March 2004, the Company sold 7,050,771 shares of Series E-1 redeemable convertible preferred stock at a price of \$1.50 per share, resulting in gross proceeds of \$10,576,157. The conversion rate associated with Series E-1 redeemable convertible preferred stock resulted in a 1-for-4 exchange or a conversion price of \$6.00 per share. The Series E-1 redeemable convertible preferred stock contained a beneficial conversion feature as the estimated fair value of the Company's common stock was in excess of the \$1.50 per share conversion price. Accordingly, the Company recorded a charge of \$7,050,771 as a beneficial conversion feature in March 2004. Also, as a result of this Series E-1 redeemable convertible preferred stock financing and the anti-dilution provisions associated with the Series D redeemable convertible preferred stock, the Company recorded a charge in the form of a deemed dividend of \$787,885 in March 2004. This charge resulted from an adjustment to the conversion price as a result of anti-dilution protection associated with the Series D redeemable convertible preferred stock.

9. Common Stock and Stock Option Plans

As of December 31, 2005, the Company had 50,000,000 shares of common stock authorized and 12,375,276 shares issued and outstanding. There were no treasury shares outstanding at December 31, 2005 and 2004, as all treasury shares have been issued upon employee stock option exercises.

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.

Stock Option Plans

During 1996, the Company's Board of Directors 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, 2005, 6,250 shares were subject to outstanding options at a weighted average exercise price of \$0.20 per share, 127,962 shares had been issued under the 1996 Stock Plan and no shares were available for future grant. If any options granted under the 1996 Stock Plan are forfeited, such shares are not available for future grant and revert back to the founder.

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, consultants and employees of the Company. As of December 31, 2005, 1,250,000 shares of

NeuroMetrix, Inc.
Notes to Financial Statements (Continued)

9. Common Stock and Stock Option Plans (Continued)

common stock were authorized for issuance under the 1998 Stock Plan, of which 430,061 shares had been issued and 747,294 shares were subject to outstanding options at a weighted average price of \$6.32 per share. 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. The 1998 Stock Plan was closed to any future grants at the time of the IPO and therefore we will not make any additional grants under the 1998 Stock Plan.

During 2004, the Company adopted the 2004 Stock Option and Incentive Plan (the "2004 Stock Plan"). The 2004 Stock Plan also provides for granting of incentive and nonqualified stock option and stock bonus awards to officers, consultants and employees of the Company. 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, 2005, 946,022 shares of common stock were authorized for issuance under the 2004 Stock Plan, of which 875 shares had been issued, 367,075 shares were subject to outstanding options at a weighted average price of \$12.56 per share and 578,072 shares were available for future grant. Also, on December 31 of each year an additional number of shares, equal to 15% of the annual net increase in the total number of outstanding shares of common stock during the year, will be added to the shares available for the issuance of awards under the 2004 Stock Plan.

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. However, incentive stock options may not be granted at less than the fair market value of the Company's common stock as determined by the Board of Directors at the date of grant or for a term in excess of 10 years. 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 in the case of incentive stock options and no less than 85% of the fair market value of the common stock on the date of the option grant in the case of non-qualified stock options. 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. All options granted under the 1996 and 1998 Stock Plans become exercisable at such time as the Board of Directors specifies and expire 10 years from the date of grant.

NeuroMetrix, Inc.

Notes to Financial Statements (Continued)

9. Common Stock and Stock Option Plans (Continued)

A summary of activity under the Company's 1996, 1998 and 2004 Stock Plans for the years ended December 31, 2005, 2004 and 2003 is presented below:

	Number of Shares	Exercise Price Range	Weighted Average Exercise Price
Stock Option Awards			
Outstanding at December 31, 2002	381,651	\$ 0.008 – 2.250	\$ 1.5264
Granted at fair value	120,215	2.250	2.2500
Exercised	(8,723)	0.008 – 1.350	0.6738
Forfeited	(42,731)	0.900 – 2.250	1.3952
Outstanding at December 31, 2003	450,412	0.200 – 2.250	1.7485
Granted at fair value	657,344	8.000 – 10.420	8.1615
Granted below fair value	90,900	0.900 – 4.480	2.6600
Exercised	(49,621)	0.200 – 2.250	0.9055
Forfeited	(16,464)	0.900 – 8.530	2.8206
Outstanding at December 31, 2004	1,132,571	0.200 – 10.420	5.6275
Granted at fair value	278,650	9.280 – 37.230	13.7797
Exercised	(253,654)	0.400 – 10.000	2.0219
Forfeited	(36,948)	2.250 – 29.020	9.8482
Outstanding at December 31, 2005	<u>1,120,619</u>	\$ 0.200 – 37.230	\$ 8.3316

The following table summarizes information about stock options outstanding at December 31, 2005:

Exercise Price	Number of Options Outstanding	Weighted Average Remaining Contractual Life (Years)	Number of Options Exercisable	Weighted Average Exercise Price
\$0.20 – 1.35	31,224	3.6	31,224	\$ 0.6581
\$2.25 – 2.25	180,178	7.3	79,093	2.2500
\$4.48 – 8.00	533,864	8.5	204,905	7.8094
\$8.25 – 9.92	262,525	9.0	11,754	9.2699
\$10.00 – 14.76	60,428	9.1	4,991	10.1601
\$17.34 – 37.23	52,400	9.7	—	N/A
	<u>1,120,619</u>	8.4	<u>331,967</u>	\$ 5.8993

The Company recorded deferred compensation of \$0, \$750,566 and \$630,900 in the years ended December 31, 2005, 2004 and 2003, respectively, related to stock option grants to employees and non-employees. The deferred compensation represents the difference between the estimated fair value of common stock on the date of grant and the exercise price associated with the stock options. The deferred compensation is amortized to expense over the vesting period of the related stock options. The Company recorded compensation expense for the years ended December 31, 2005, 2004 and 2003 of \$406,330, \$1,028,595 and \$96,450, respectively. Included in the compensation expense recorded by the Company is \$35,790, \$436,611 and \$0 of compensation expense associated with the modification of stock options in the years ended December 31, 2005, 2004 and 2003, respectively.

NeuroMetrix, Inc.
Notes to Financial Statements (Continued)

9. Common Stock and Stock Option Plans (Continued)

Unamortized deferred compensation on forfeited options is recorded as a reduction to additional paid-in capital.

Employee Stock Purchase Plan

In June 2004, the Company's stockholders approved our 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. Any employee who owns 5% or more of the voting power or value of our stock is not eligible to participate and 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 the period, participating employees can purchase shares at 85% of the lower of their fair market value at the beginning or end of the period. Under this plan, the Company issued 23,265 and 9,532 shares of its common stock during the years ended December 31, 2005 and 2004, respectively.

Common Stock Reserved for Future Issuance

At December 31, 2005, the Company has reserved authorized shares of common stock for future issuance as follows:

Outstanding stock options	1,120,619
Possible future issuance under stock option plans	578,072
Possible future issuance under employee stock purchase plan	342,203
Total	<u>2,040,894</u>

10. Income Taxes

The income tax provision consists of the following for the years ended December 31, 2005, 2004 and 2003:

	<u>Years Ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Federal tax expense	\$ 35,000	\$ —	\$ —
State tax expense	—	—	—
Total	<u>\$ 35,000</u>	<u>\$ —</u>	<u>\$ —</u>

NeuroMetrix, Inc.
Notes to Financial Statements (Continued)

10. Income Taxes (Continued)

The Company's effective income tax rate differs from the statutory federal income tax rate as follows for the years ended December 31, 2005, 2004 and 2003.

	<u>Years Ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Federal tax provision (benefit) rate	34.0%	(34.0)%	(34.0)%
State tax provision (benefit), net of federal provision (benefits)	7.7	(3.5)	(5.5)
Permanent items	16.3	4.2	1.3
Federal research and development credits	(15.8)	(1.8)	(1.5)
Alternative minimum tax	3.6	—	—
Valuation allowance	(42.2)	35.1	39.7
Effective income tax rate	<u>3.6%</u>	<u>0.0%</u>	<u>0.0%</u>

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

	<u>December 31,</u>	
	<u>2005</u>	<u>2004</u>
Deferred tax assets:		
Net operating loss carryforwards	\$ 13,870,554	\$ 12,853,450
Research and development credit carryforwards	645,809	533,820
Accrued expenses	983,958	645,807
Other	3,594	(81,537)
Total gross deferred tax assets	<u>15,503,915</u>	<u>13,951,540</u>
Valuation allowance	<u>(15,503,915)</u>	<u>(13,951,540)</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2005, the Company had federal and state net operating loss carryforwards ("NOL") of approximately \$35,491,000 and \$28,768,000, respectively, as well as federal and state research and experimentation credits of approximately \$563,000 and \$126,000, respectively, which may be available to reduce future taxable income and the related taxes thereon. The federal NOLs begin to expire in 2011 and the state NOLs begin to expire in 2006. 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 carryforwards. 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 \$15,503,915 and \$13,951,540 has been established at December 31, 2005 and 2004, respectively. Deferred tax assets and related valuation allowance of \$2,290,695 attributable to net operating loss carryforwards and \$49,000 attributable to federal and state research and experimentation credits result from the exercise of employee stock options, the tax benefit of which, when recognized, will be accounted for as a credit to additional paid-in capital rather than a reduction of income tax expense.

Ownership changes, as defined in the Internal Revenue Code, have limited the amount of net operating loss carryforwards that can be utilized annually to offset future taxable income. The Company anticipates that these limitations will have no material impact on their ability to utilize the affected loss

NeuroMetrix, Inc.
Notes to Financial Statements (Continued)

10. Income Taxes (Continued)

carryforwards in future years. Subsequent ownership changes could further affect the limitation in future years.

11. Commitments and Contingencies

Operating Leases

In September 2000, the Company entered into a noncancelable operating lease, commencing January 1, 2001, for office and laboratory space. The lease expires on March 31, 2009.

Future minimum lease payments under noncancelable operating leases as of December 31, 2005 are as follows:

2006	\$ 930,000
2007	930,000
2008	930,000
2009	232,500
Total minimum lease payments	<u>\$ 3,022,500</u>

Total recorded rent expense was \$871,819 for each the years ended December 31, 2005, 2004 and 2003. The Company records rent expense on its facility lease on a straight line basis over the term. Accordingly, the Company has recorded a liability for accrued rent expense at December 31, 2005 and 2004 of \$189,091 and \$247,273, respectively on the accompanying balance sheets.

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 2009. The certificate of deposit is renewable in 30-day increments. At December 31, 2005 and 2004, the Company has \$1,458,598 and \$1,897,200 recorded as restricted cash associated with this lease on the accompanying balance sheet.

Royalty Agreements

In June 1996, the Company entered into a license agreement with the Massachusetts Institute of Technology, ("M.I.T."), a related party, as amended on February 25, 1998, under which the Company obtained an exclusive right to use certain technology through the term of M.I.T.'s patent rights on such technology. In exchange, the Company is required to pay royalties of 2.15% of net sales of products incorporating the licensed technology. In addition, the Company is required to pay royalties ranging from 25% to 50% of payments received from sublicensees, depending on the degree to which M.I.T.'s technology was incorporated into the products sublicensed by the Company. Through the year ended December 31, 2005, the Company has not incorporated this licensed technology into its products and therefore, no amounts have been accrued as being owed.

In addition, the Company is obligated to pay M.I.T. annual license maintenance fees if certain minimum net sales requirements are not met. These payments can be used to offset future royalties

NeuroMetrix, Inc.
Notes to Financial Statements (Continued)

11. Commitments and Contingencies (Continued)

payable under the agreement. Under the amended agreement, the Company has a right to terminate this agreement at anytime upon a written notice and has recorded royalty expense totaling \$75,000 for each of the years ended December 31, 2005, 2004 and 2003 relating to these fees. At December 31, 2005, 2004 and 2003, M.I.T. owned approximately 0.0%, 4.6% and 9.3%, respectively, of the Company's common stock outstanding and 0.0%, 0.0% and 5.6%, respectively, of the Company's redeemable convertible preferred stock outstanding.

In February 1999 the Company entered into another license agreement with an unrelated third party under which the Company obtained the right to use certain technology through the term of the licensor's patent right on such technology. In exchange, the Company was required to pay the licensor \$50,000 annually for the first three years of the agreement. In subsequent years, the Company is required to pay \$10,000 annually as long as it continues to use the licensed technology. Under this agreement, the Company has a right to terminate this agreement at anytime upon a written notice. During each of the years ended December 31, 2005, 2004 and 2003, \$10,000 was paid and recorded as cost of goods sold.

12. 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, 2005, 2004 and 2003 the Company made no contributions to the plan.

NeuroMetrix, Inc.

Schedule II—Valuation and Qualifying Accounts

For the three years ended December 31, 2005, 2004 and 2003:

	<u>Balance at Beginning of Period</u>	<u>Additions</u>	<u>Deductions</u>	<u>Balance at End of Period</u>
Allowance for Doubtful Accounts:				
2005	\$ 300,000	\$ 359,827	\$ 259,827	\$ 400,000
2004	300,000	235,464	235,464	300,000
2003	200,000	200,326	100,326	300,000
Deferred Tax Asset Valuation Allowance:				
2005	\$ 13,951,540	\$ 1,552,375	\$ —	\$ 15,503,915
2004	12,449,478	1,502,062	—	13,951,540
2003	10,996,007	1,453,471	—	12,449,478

Director Compensation Arrangements

The following summarizes the compensation arrangements established between NeuroMetrix, Inc. (the "Company") and its directors through verbal agreements effective for the period from May 18, 2005 through December 31, 2005:

The non-employee members of the Board of Directors of the Company (the "Board"), other than those affiliated with venture capital firms that were stockholders of the Company as of the effective date of the initial public offering of the Company (*i.e.* William Laverack, Jr.), will receive annual cash compensation in the amount of \$5,000 for service as a member of the Board, which will be paid following each annual meeting of the stockholders of the Company. In addition, these non-employee directors will receive the sum of \$1,000 for each board or committee meeting that they attend, provided that they will not be entitled to additional compensation for attending committee meetings that occur on the same day as a board meeting at which they attend. This cash compensation will be in addition to any stock options or other equity compensation that the Company determines to grant to the directors on a case by case basis. The non-employee members of the Board that are affiliated with venture capital firms that were stockholders of the Company as of the effective date of the initial public offering of the Company will not be compensated for serving as directors, although the Company will reimburse these directors for all reasonable out-of-pocket expenses incurred by them in attending board or committee meetings. Dr. Gozani, the only employee member of the Board, will not be separately compensated for his service on the Board.

The following summarizes the compensation arrangements established between the Company and its directors through verbal agreements effective from and after January 1, 2006:

Each of the non-employee members of the Board, other than those affiliated with venture capital firms that were stockholders of the Company as of the effective date of the initial public offering of the Company (*i.e.*, William Laverack, Jr.), will receive annual cash compensation in the amount of \$10,000 for service as a member of the Board, which will be paid following each annual meeting of the stockholders of the Company. On January 1, 2006, each of these non-employee directors will be paid this annual cash compensation, on a pro rata basis, for the period from January 1, 2006 to the anticipated date of the 2006 annual meeting of the stockholders of the Company, less a pro rata portion of any annual cash compensation previously paid to such director attributable to this period. In addition, each of these non-employee directors will receive the sum of \$1,500 for each Board or Committee meeting that he attends, provided that such director will not be entitled to additional compensation for attending committee meetings that occur on the same day as a board meeting he attends. This cash compensation will be in addition to any stock options or other equity compensation that the Company determines to grant to the directors on a case by case basis.

The non-employee members of the Board that are affiliated with venture capital firms that were stockholders of the Company as of the effective date of the initial public offering of the Company will not be compensated for serving as directors, although the Company will reimburse these directors for all reasonable out-of-pocket expenses incurred by them in attending board or committee meetings. Dr. Gozani, the only employee member of the Board, will not be separately compensated for his service on the Board.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-118059) of NeuroMetrix, Inc. of our report dated March 16, 2006 relating to the financial statements, financial statement schedule, management's assessment of the effectiveness of internal control over financial reporting and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

PricewaterhouseCoopers LLP

Boston, Massachusetts

March 16, 2006

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 16, 2006

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

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

Chief Executive Officer and President

CERTIFICATION

I, W. Bradford Smith, 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 16, 2006

/s/ W. BRADFORD SMITH

W. Bradford Smith
Chief Financial Officer

CERTIFICATION

The undersigned officers of NeuroMetrix, Inc. (the "Company") hereby certify that 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 16, 2006

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

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

Chief Executive Officer and President

/s/ W. BRADFORD SMITH

W. Bradford Smith

Chief 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.
