QuickLinks -- Click here to rapidly navigate through this document

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, 2004

Commission File Number 000-50856

NEUROMETRIX, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-3308180**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

62 Fourth Avenue
Waltham, Massachusetts 02451
(Address, 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 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 an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes ☐ No ☒

There was no established public trading market for the registrant's common stock as of the last business day of the registrant's most recently completed second fiscal quarter.

As of February 28, 2005, there were 12,056,395 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the registrant's 2005 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, 2004, 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, 2004

TABLE OF CONTENTS

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 "Management's Discussion and Analysis of Financial Condition and Results of Operations-Important Factors that May Affect Future Operating Results." 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 two 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 as great as approximately 9.5 million annual patient tests, or over $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 FDA. The NC-stat System has been on the market since May 1999 and is presently used in over 2,200 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 2004, we increased our revenues from the prior year by 95%, generating $17.9 million in revenues, compared with $9.2 million in 2003. Our gross margin percentage in 2004 was 72.9%, and 87.6% of our revenues were attributable to sales of the disposable biosensors that physicians use to perform tests with our NC-stat System. We incurred net losses of approximately $4.3 million in 2004 and $3.7 million in 2003. Since our inception, more than 300,000 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 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.

- *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 two million traditional NCS/nEMG procedures currently performed each year in the United States. Although the largest 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 as great as approximately 9.5 million annual patient tests, or over $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

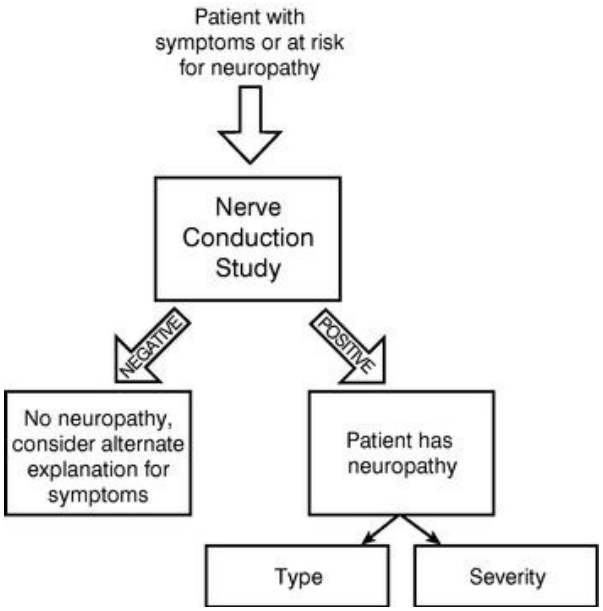
Neuropathies traditionally have been evaluated using clinical and diagnostic methods. The clinical examination of a patient with a potential neuropathy focuses on the nature, location and duration of the symptoms. The physician will also perform a physical examination of the patient to corroborate and 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 to a neurologist. This process may lead to loss of control of the patient's care by the primary care 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 complex and 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. 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.

Company Name	Drug Name	Status
Eli Lilly and Company	ruboxistaurin mesylate	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 II clinical trial
Johnson & Johnson	Topiramate	Approved in the United States as anticonvulsant; studies 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, which is less than one third of 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 10 to 20 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. The non-invasive nature and convenient

features of the NC-stat System also facilitate repeat testing in patients to demonstrate response to treatment interventions.

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 but may not be experiencing symptoms, 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 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 CMS and physician associations.

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

Clinical Indication	Specific Biosensors Utilized	Total Number of Biosensors Utilized	Aggregate Price of Biosensors Utilized
Diabetic peripheral neuropathy	Peroneal Motor (2) Median Motor/Sensory (1) Sural (1)	4	$ 134
Low back pain with bilateral sciatica	Peroneal Motor (2) Tibial Motor (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. An improved point-of-service nerve conduction testing system is currently in development.

- *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 processed and analyzed by the onCall Information System and stored in a central database, and a detailed report is generated 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 alternative. 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 550,000 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 28 regional managers and two district sales managers 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 50 independent regional sales agencies employing a total of more than 300 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 expand the number of independent sales agencies and representatives selling 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 and endocrinologists. 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 and our third generation NC-stat monitor and docking station. We also 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. 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 two 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 diabetic peripheral neuropathy, or DPN, market for a point-of-service product offering such as the NC-stat System could be as great as six million annual patient tests.* The number of individuals with diabetes in the United States was estimated to be 18.2 million, or 6.3% of the population, in 2002. Among this group, 5.2 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 exams 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 become increasingly available in the marketplace over the next few years, 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 years. 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 the 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 further 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. We thus anticipate 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 as great as approximately 9.5 million annual patient tests in the United States. We estimate that the potential market for NC-stat System could be over $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.

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.

Products Under Development

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 NC-stat monitor and docking station 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.

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, 2004, we had over 2,200 active customers. No single customer accounted for more than 10% of our revenues in 2004, 2003 or 2002.

Geographic Information

All of our assets, revenues and expenses for the years ended December 31, 2004, 2003 and 2002 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 28 regional sales managers and two district sales managers who lead more than 50 independent regional sales agencies employing a total of more than 300 independent sales representatives. 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 sell 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 invoice products directly to physician offices and other customers, typically at list prices. The independent regional sales agencies and their sales representatives are compensated by commissions that we pay directly to them. Our regional managers are compensated by a combination of base salary, commission 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 independent sales agencies and representatives. The establishment and development of a broader 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 ("Lilly"), 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. Under the agreement, each program will focus on educating physicians regarding diabetic microvascular complications, DPN, screening and diagnosis of DPN, nerve conduction studies, our NC-stat System and its application in DPN and the benefits to physicians and patients of using the NC-stat System. The agreement also provides for specific marketing rights for Lilly in relation to any attendee of a program that, within six months of attending a program, purchases an NC-stat System from us. After the completion of 30 programs, either party may elect to cancel its respective participation in the remaining programs.

Lilly will be responsible for costs and expenses associated with the programs arising from speaker training, Lilly-executed physician recruitment vehicles and related materials. We will be solely responsible for costs and expenses associated with the programs related to our specific recruiting costs.

The direct costs and expenses arising from the conduct of the programs will be shared equally by us and Lilly and may not exceed $15,000 per program unless mutually agreed to by the parties. The initial term of the agreement will be for 18 months and may be renewed for five one-year successive terms upon agreement by the parties. The agreement provides for early termination (i) by Lilly or us in the event of a change of control of our company, (ii) by either party if a material breach by the other party has occurred and such breach is not cured within ninety days of written notification of the breach to the breaching party and (iii) by Lilly in the event its development of ruboxistaurin for, among other things, DPN and/or its symptoms, is ended or delayed beyond the initial term of the agreement or otherwise, in Lilly's judgment, rendered impractical due to product development issues. Depending on how the agreement expires or is terminated, the parties' specific marketing rights and obligations for any attendee of a program that, within six months of attending a program, purchases an NC-stat System from us may continue in force until December 31, 2010.

Lilly currently has a therapeutic agent in Phase III clinical trials for the treatment of DPN. We hope to increase our installed base of customers using the NC-stat System and hope to establish the NC-stat System as a leading diagnostic for DPN.

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 2004. 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.

Polyflex Circuits, Inc., a wholly owned subsidiary of the Parlex Corporation, has been manufacturing NC-stat biosensors under general purchase orders since early 1999. While our relationship with Polyflex Circuits is good, we have no supply agreement in place with Polyflex, and it could cease manufacturing NC-stat biosensors at any time. We have identified alternative suppliers capable of manufacturing NC-stat biosensors 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. The Company is currently negotiating a supply agreement with Polyflex Circuits, but there is no assurance that an agreement will be successfully negotiated, or if negotiated, it will be on reasonable terms.

Advanced Electronics, Inc., or AEI, has been manufacturing our NC-stat monitors and docking stations since November 2002. In October 2003, we entered into a one-year contract manufacturing agreement with AEI that automatically renews each year unless either party elects not to renew the agreement upon 90 days' prior written notice. The current term of the agreement expires in November 2005. Both AEI and NEUROMetrix have been performing to the terms of the agreement; however, AEI could cease manufacturing NC-stat monitors and docking stations for us when the current term of the agreement expires. We have identified alternative suppliers capable of manufacturing the NC-stat monitor and docking station 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 action 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. onCall's 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.

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 NC-stat monitor and docking station 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 19 people, including four 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.

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 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 the Nicolet Biomedical division of Viasys Healthcare Inc., the Functional Diagnostics division of Medtronic, Inc., Oxford Instruments, Plc., and Cadwell Laboratories, Inc. Viasys Healthcare, Medtronic and Oxford Instruments have 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 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, 2004, we had 11 issued U.S. patents, two issued foreign patents (one in Australia and one in Canada) and 18 pending patent applications, including 12 U.S. applications 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. We also use onCall as a trademark but have not sought its registration in the United States or any foreign countries.

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. Third-party payers include governmental programs such as Medicare and Medicaid, private insurance plans, and workers' compensation plans. These third-party payers may deny reimbursement for a diagnostic procedure if they determine that the diagnostic test 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 price ceilings on specific product lines and procedures. There can be no assurance 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' 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 Board 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. There can be no assurance 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.

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;
- advertising and promotion;
- production; 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 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. These trials generally require submission to the FDA of an application for an investigational device exemption, or IDE, if a medical device presents a "significant risk" as defined by the FDA. 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. The results of our clinical testing may not support or may not be sufficient to obtain approval of 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.

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 2003.

U.S. Anti-Kickback and False Claims Laws

In the United States, there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services. Violations of these laws can lead to 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 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. Although we plan to structure our future business relationships with purchasers of our products to comply with these and other applicable laws, it is possible that some of our business practices in the future could be subject to scrutiny and challenge by federal or state enforcement officials 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. 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, with all patient specific information de-identified, we nevertheless seek to comply with a number of these 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, 2004, we had a total of 68 employees. Of the total employees, 19 were in research and development, 31 in sales and marketing and 18 in general and administrative services. Two employees hold both M.D. and Ph.D. degrees, four 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 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, 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 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, 2004, 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.

	High	Low
Year ended December 31, 2004:		
First quarter	N/A	N/A
Second quarter	N/A	N/A
Third quarter	$ 11.05	$ 7.39
Fourth quarter	$ 11.75	$ 8.20

On March 16, 2005, there were approximately 54 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 16, 2005, the last reported sale price per share of our common stock on the NASDAQ National Market was $9.47.

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, 2004 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 $1,133,000 of the net proceeds to fund cash spending of our research and development activities, (iii) an estimated $383,000 of the net proceeds to fund the expansion of our sales and marketing efforts and (iv) an estimated $42,000 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

You should read the data set forth below 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. The selected statement of operations data set forth below for the years ended December 31, 2004, December 31, 2003, December 31, 2002 and the consolidated balance sheet data as of December 31, 2004 and December 31, 2003 are derived from our audited financial statements that are included elsewhere in this Annual Report on Form 10-K. The selected statement of operations data for the years ended December 31, 2001 and December 31, 2000 and the balance sheet data as of December 31, 2002, December 31, 2001 and December 31, 2000 are derived from our financial statements that are not included in this Annual Report on Form 10-K.

	Year Ended December 31,				
	2004	2003	2002	2001	2000
	(In thousands, except share and per share data)				
					(Unaudited)
Statement of Operations Data:					
Revenues	$ 17,920	$ 9,168	$ 4,225	$ 3,464	$ 979
Cost of revenues	4,853	2,707	1,370	1,424	634
Gross margin Operating expenses:	13,067	6,461	2,855	2,040	345
Research and development(1)	3,268	2,397	2,146	2,561	1,984
Sales and marketing(1)	8,488	4,768	2,870	5,304	3,477
General and administrative(1)	4,845	2,850	2,673	3,228	2,325
Total operating expenses	16,601	10,015	7,689	11,093	7,786
Loss from operations	(3,534)	(3,554)	(4,834)	(9,053)	(7,441)
Interest income (expense), net	(750)	(113)	41	336	459
Net loss	(4,284)	(3,667)	(4,793)	(8,717)	(6,982)
Accretion of dividend on redeemable convertible preferred stock	(1,386)	(2,009)	(1,893)	(1,757)	(1,104)
Deemed dividend on redeemable convertible preferred stock	(788)	—	(6,873)	—	—
Beneficial conversion feature associated with redeemable convertible preferred stock	(7,051)	—	—	—	—
Net loss attributable to common stockholders	$ (13,509)	$ (5,676)	$ (13,559)	$ (10,474)	$ (8,086)
Net loss per common share:					
Basic and diluted	$ (2.35)	$ (5.46)	$ (13.17)	$ (10.47)	$ (8.36)
Weighted average basic and diluted common shares outstanding	5,747,579	1,038,817	1,029,210	1,000,323	967,435

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

Research and development	$ 249	$ 35	$ 7	$ 8	$ 5
Sales and marketing	357	37	6	15	10
General and administrative	423	24	37	33	37
Total non-cash stock-based compensation	$ 1,029	$ 96	$ 50	$ 56	$ 52

	As of December 31,				
	2004	2003	2002	2001	2000
	(In thousands, except share and per share data)				
				(Unaudited)	(Unaudited)
Balance Sheet Data:					
Cash and cash equivalents	$ 1,936	$ 1,623	$ 2,701	$ 5,396	$ 5,389
Short-term investments	18,575	—	—	—	—
Working capital	22,500	2,754	3,724	6,380	4,996
Long-term investments	9,497	—	—	—	—
Total assets	37,953	7,218	7,053	9,899	7,158
Long-term debt and other long-term liabilities	189	2,232	124	331	964
Warrants for redeemable convertible preferred stock	—	450	—	—	—
Redeemable convertible preferred stock	—	47,694	45,684	34,995	20,816
Accumulated deficit	(57,478)	(44,901)	(39,860)	(26,321)	(15,851)
Total stockholders' equity/(deficit)	34,056	(45,502)	(39,928)	(26,431)	(16,014)

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 entitled "Important Factors That May Affect Future Operating Results" 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. The NC-stat System is comprised of: (1) disposable 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 2004, our revenues grew over 95% from the prior year, generating $17.9 million in revenues, of which 87.6% was attributable to sales of NC-stat biosensors. Our gross margin percentage in 2004 was 72.9%.

We derive our revenues from the sale of NC-stat biosensors, monitors and docking stations directly to end users, which are generally physicians. 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 probable 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. To date, we believe nearly all of the nerve conduction studies performed by our customers with the NC-stat System have been satisfactorily covered by third-party payers. However, widespread adoption of the NC-stat System by the medical community is unlikely to occur if physicians do not continue to 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 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 plan to continue to increase our sales force and our total headcount and participate in various industry conferences in order to accelerate the market awareness and adoption of our products. In addition, in March 2005, we entered into an education and development program agreement with Eli Lilly and Company. Through this agreement, our Company and Eli Lilly and Company will conduct a broad series of up to 84 educational and development programs across the country over the next 18 months. Each program will focus on educating physicians regarding diabetic microvascular complications, DPN, screening and diagnosis of DPN, nerve conduction studies, our NC-stat System and its application in DPN and the benefits to physicians and patients of using the NC-stat System. 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 are focused on monitoring our business as it grows and appropriately acquiring and allocating resources to address these issues, with a goal of achieving and sustaining profitability.

Since our inception in 1996, we have incurred losses every quarter. 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. We do not know whether or when we will become profitable. At December 31, 2004, we had an accumulated deficit of approximately $57.5 million. We have financed our operations through the public and private placement of equity securities and through debt facilities including a line of credit. As of December 31, 2004, 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").

Our financial objective is to achieve and sustain profitable growth. Our efforts in 2005 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, including the introduction of new biosensors. 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. Executing these objectives is expected to require the hiring of additional sales and administrative personnel, additional investments in research and development and the introduction of new and enhanced product offerings, with the goal of increasing our market penetration. We believe that the accomplishment of these combined efforts will have a positive impact on our progress toward the objective of achieving profitability.

Results of Operations

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

	Year Ended December 31,		
	2004	2003	2002
Revenues:			
Diagnostic device	12.4%	14.2%	17.1%
Biosensor	87.6	85.8	82.9
Total revenues	100.0	100.0	100.0
Cost of revenues	27.1	29.5	32.4
Gross margin	72.9	70.5	67.6
Operating expenses:			
Research and development	18.2	26.1	50.8
Sales and marketing	47.4	52.0	67.9
General and administrative	27.0	31.1	63.3
Total operating expenses	92.6	109.2	182.0
Loss from operations	(19.7)	(38.8)	(114.4)
Interest income (expense), net	(4.2)	(1.2)	1.0
Net loss	(23.9)%	(40.0)%	(113.5)%

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

Revenues

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

	12-Month Period Ended December 31,			
	2004	2003	Change	% Change
Customers	2,207	1,736	471	27.1%

	12-Months Ended December 31,			
	2004	2003	Change	% Change
Biosensor units	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	$ 17,920.1	$ 9,167.6	$ 8,752.5	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.

We expect revenues in 2005 to continue to increase as we expand our sales and marketing efforts and our customer base and make enhancements and improvements to our NC-stat System, including the introduction of new biosensors, but we expect revenues to increase at a slower rate than in 2004. 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,			
	2004	2003	Change	% Change
	(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 costs 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 of dividend on preferred stock	(1,386.3)	(2,009.5)	623.2	-31.0
Deemed dividend and beneficial conversion feature on redeemable convertible preferred stock	(7,838.7)	—	(7,838.7)	—
Net loss available to common stockholders	$ (13,509.0)	$ (5,676.2)	$ (7,832.8)	138.0

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

Research and development	$ 249.2	$ 35.1
Sales and marketing	356.4	36.8
General and administrative	423.0	24.5
Total non-cash stock-based compensation	$ 1,028.6	$ 96.4

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 monitor and docking station, 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.

At the end of 2004, we raised the list price of our diagnostic devices. The list price increase should result in a higher diagnostic device gross margin percentage in 2005 when compared to 2004. We anticipate our overall gross margin percentage will remain relatively consistent for 2005. However, if sales volumes do not increase, if biosensor revenues as a percent of total revenues do not increase, if there is a change in the mix of biosensors sold, or if pricing pressures increase, then gross margin may be negatively impacted in future quarters.

Research and Development

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

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.

For 2005, we expect our spending on R&D will increase due to the hiring of additional employees and increased spending on development projects. We expect R&D expenses, as a percentage of total revenues, to decrease slightly. This percentage may vary, however, depending primarily on our revenues for the year of 2005.

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.

We expect to hire additional sales and marketing personnel during the year of 2005. For 2005, we expect sales and marketing expenses, as a percentage of total revenues, to increase over the level of the total year of 2004. This percentage may vary, however, depending primarily on our revenues for the year of 2005.

General and Administrative

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

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-off's during the year of 2004. Also contributing to the increase in G&A expense 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 G&A expense was a decrease in recruiting costs of $31,900 resulting from an executive search in 2003 that did not recur in 2004.

We expect our general and administrative expenses to increase during the year of 2005 as a result of our expected growth and the additional requirements that we will need to fulfill as a publicly traded company, although these expenses, as a percentage of total revenues, are likely to continue to decrease as revenues increase. This percentage may vary, however, depending primarily on our revenues during 2005.

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 our net proceeds from our recent IPO and the net proceeds from our sale of Series E-1 redeemable convertible preferred stock in March 2004. Based on this higher available balance of funds for investment, we expect interest income to increase in 2005 as compared to 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 borrowing under a credit line entered into in May 2003 with Lighthouse Capital Partners. We expect little or no interest expense in 2005.

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 and none expected in 2005.

Comparison of Years Ended December 31, 2003 and December 31, 2002

Revenues

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

	Year Ended December 31,			
	2003	2002	Change	% Change
Customers	1,736	1,390	346	24.9%
Biosensor units	203,000	116,200	86,800	74.7
		(in thousands)		
Revenues:				
Diagnostic device	$ 1,302.3	$ 722.6	$ 579.7	80.2
Biosensor	7,865.3	3,502.4	4,362.9	124.6
Total revenues	$ 9,167.6	$ 4,225.0	$ 4,942.6	117.0

Diagnostic device revenues were $1.3 million and $722,600 in 2003 and 2002, respectively, representing a year-over-year increase of $579,700, or 80.2%. Of this increase, approximately $240,000 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 $285,000 is attributable to an increase in the list price of our NC-stat monitors and docking stations. Diagnostic device revenues accounted for 14.2% and 17.1% of our total revenues in 2003 and 2002, respectively.

Biosensor revenues were $7.9 million and $3.5 million in 2003 and 2002, respectively, representing a year-over-year increase of $4.4 million, or 124.6%. 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 biosensors have an average selling price that is 60-80% higher than our comparable motor-only biosensors. Biosensor revenues accounted for 85.8% and 82.9% of our total revenues in 2003 and 2002, respectively.

Our customers used 203,000 biosensor units in 2003, compared to 116,200 units in 2002, an increase of 86,800 units, or 74.7%.

Our total revenues were $9.2 million and $4.2 million in 2003 and 2002, respectively, representing a year-over-year increase of $4.9 million, or 117.0%. During 2003, a total of 1,736 customers used our NC-stat System, compared to 1,390 customers during 2002. This represents a 24.9% 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:

	Year Ended December 31,			
	2003	2002	Change	% Change
	(in thousands)			
Cost of revenues:				
Diagnostic device	$ 658.1	$ 420.1	$ 238.0	56.7%
Biosensor	2,048.4	950.0	1,098.4	115.6
Total cost of revenues	2,706.5	1,370.1	1,336.4	97.5
Gross margin:				
Diagnostic device	644.2	302.5	341.7	113.0
Biosensor	5,816.9	2,552.4	3,264.5	127.9
Total gross margin	6,461.1	2,854.9	3,606.2	126.3
Gross margin %:				
Diagnostic device	49.5%	41.9%		
Biosensor	74.0	72.9		
Total gross margin %	70.5	67.6		
Operating expenses:				
Research and development(1)	$ 2,396.8	$ 2,146.1	$ 250.7	11.7
Sales and marketing(1)	4,767.6	2,869.7	1,897.9	66.1
General and administrative(1)	2,850.5	2,672.7	177.8	6.7
Total operating expenses	10,014.9	7,688.5	2,326.4	30.3
Loss from operations	(3,553.8)	(4,833.6)	1,279.8	-26.5
Interest income	23.4	80.3	(56.9)	-70.9
Interest expense	(136.3)	(40.2)	(96.1)	239.1
Net loss	(3,666.7)	(4,793.5)	1,126.8	-23.5
Accretion on redeemable convertible preferred stock	(2,009.5)	(1,892.7)	(116.8)	6.2
Deemed dividend on redeemable convertible preferred stock	—	(6,872.9)	6,872.9	—
Net loss available to common stockholders	$ (5,676.2)	$ (13,559.1)	$ 7,882.9	-58.1

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

Research and development	$ 35.1	$ 7.7
Sales and marketing	36.8	5.8
General and administrative	24.5	36.7
Total non-cash stock-based compensation	$ 96.4	$ 50.2

Gross Margin

Diagnostic device gross margin percentage was 49.5% and 41.9% in 2003 and 2002, respectively. The increase in the gross margin percentage in 2003 compared to 2002 is attributed partially to an increase in the list price of our NC-stat monitor and docking station, and partially to a decrease in the price we paid for our diagnostic devices resulting from a change in our third-party manufacturer.

Biosensor gross margin percentage increased to 74.0% in 2003 from 72.9% in 2002. Our motor/sensory biosensors, introduced in 2003, provide improved performance, resulting in lower overall warranty costs and higher gross margin.

Our overall gross margin percentage was 70.5% in 2003 compared to 67.6% in 2002. A favorable mix towards higher gross margin biosensor revenues in 2003 contributed to this increase in overall gross margin percentage, along with those factors discussed above.

Research and Development

R&D expenses increased $250,700, or 11.7%, to $2.4 million in 2003 from $2.1 million in 2002. As a percentage of revenues, R&D expenses were 26.1% and 50.8% in 2003 and 2002, respectively. The increase in expenses was primarily due to increases of $21,600 and $33,800 in compensation expense and recruiting expense, respectively, which resulted from the hiring of two additional employees in our R&D department, an increase of $58,800 in outside consulting expense, and an increase of $56,800 in prototype costs related to new product development, including the development of two biosensors introduced in 2003 and one biosensor introduced in the first half of 2004.

Sales and Marketing

Sales and marketing expenses increased $1.9 million, or 66.1%, to $4.8 million in 2003 from $2.9 million in 2002. As a percentage of revenues, sales and marketing expenses were 52.0% and 67.9% in 2003 and 2002, respectively. The increase in expenses was primarily due to an increase of $610,600 in sales commissions paid to our regional sales managers and an increase of $469,500 in sales commissions to our independent regional sales agencies, both of which were directly related to our higher revenues in 2003, and an increase of $479,700 in compensation and bonus expense, which resulted from the hiring of two additional employees in our sales and marketing department, including our chief operating officer in July 2002. Because our independent regional sales agencies are compensated exclusively on a commission basis, their compensation is linked directly to our revenues. The compensation of our internal sales force is predominately based upon meeting internal performance goals and, therefore, also linked to our revenues. Also contributing to the increase in sales and marketing expenses was an increase of $149,700 in advertising and product promotion expense and an increase of $127,500 in travel and lodging expense.

General and Administrative

General and administrative expenses increased $177,800, or 6.7%, to $2.9 million in 2003 from $2.7 million in 2002. As a percentage of revenues, general and administrative expenses were 31.1% and 63.3% in 2003 and 2002, respectively. The increase in expenses was primarily due to an increase of $115,500 in general recruiting costs and an increase of $33,800 in insurance costs. General and administrative staffing levels remained consistent during 2003 and 2002.

Interest Income

Interest income was $23,400 and $80,300 in 2003 and 2002, respectively. Interest income was earned from investments in cash equivalents and short-term investments (with maturities of 90 to 180 days). Interest income decreased in 2003 compared to 2002 because of lower average cash balances available for investment and lower yields on outstanding investment balances.

Interest Expense

Interest expense was $136,300 and $40,200 in 2003 and 2002, respectively, representing an increase of $96,100 or 239.1%. The increase in interest expense was primarily due to increased borrowing under a new credit line obtained in May 2003.

Deemed Dividend on Redeemable Convertible Preferred Stock

In 2002, we recorded a $6.9 million deemed dividend as a result of the December 2002 Series E-1 redeemable convertible preferred stock financing and the anti-dilution provisions associated with the Series D and Series E redeemable convertible preferred stock. The $6.9 million deemed dividend resulted from an adjustment to the conversion ratios as a result of anti-dilution protection associated with the Series D and Series E redeemable convertible preferred stock. There was no deemed dividend in 2003.

Liquidity and Capital Resources

Our principal source of liquidity is our current cash and cash equivalents, and short-term and long-term investments. As of December 31, 2004, weighted average maturity of our short and long term investments was 281 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:

	Year Ended December 31,			
	2004	2003	Change	% Change
Cash and cash equivalents	1,936	1,623	313	19.3%
Short-term investments	18,575	—	18,575	N/A
Working capital	22,500	2,754	19,746	717.0%
Long-term investments	9,497	—	9,497	N/A

During 2004, our cash and cash equivalents, short-term investments and long-term investments increased primarily due to the receipt of approximately $24.0 million of net proceeds from our IPO in July 2004 and approximately $10.6 million of net proceeds from the sale of our Series E-1 redeemable convertible preferred stock in March 2004.

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 3.0 million 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 using a portion of the proceeds of 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, 2004 and December 31, 2003:

	Years Ended December 31,	
	2004	2003
Days' sales outstanding (days)	50	53
Inventory turnover rate (times per year)	4.1	2.8

Our customer payment terms are generally 30 days from invoice date. At December 31, 2004, our DSO was at 50 days, a decrease of three days as compared to December 31, 2003. This decrease in DSO resulted from a corresponding decrease in accounts receivable balances aging greater than 60 days from invoice. This decrease was primarily due to adding resources to more aggressively manage collections in 2004 and the significant revenue growth in the fourth quarter of 2004 relative to the small increase in our accounts receivable balance during the fourth quarter. We continue to focus our efforts on reducing our accounts receivable balances over 60 days past due. Accounts payable are normally paid within 30 days from receipt of a vendor's invoice.

Our inventory turnover for the year ended December 31, 2004 was 4.1 times compared to 2.8 times during the year of 2003. The increase in the inventory turnover rate in 2004 as compared to 2003 was primarily due to the 95% growth in revenue during 2004 while managing our inventory growth to 19%.

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

	Years Ended December 31,		
	2004	2003	2002
	(in thousands)		
Net cash used in operating activities	$ (2,652)	$ (3,873)	$ (4,560)
Net cash used in investing activities	$ (28,706)	$ (204)	$ (30)
Net cash provided by financing activities	$ 31,671	$ 2,999	$ 1,895

Cash used in operating activities was $2.7 million in 2004 and $3.9 million in 2003. The major use of cash was to fund operating losses of $4.3 million in 2004 and $3.7 million in 2003. In 2004, cash was also used to fund an increase of $1.3 million in accounts receivable resulting from the significant growth in revenues, an increase in prepaid expenses of $249,400 resulting from increases in prepaid insurance, and an increase of $205,900 in inventories to support our anticipated sales volume increase and new products introduced during the year. These uses of cash in 2004 were partially offset by increases in accrued expenses, accounts payable, and deferred revenue and costs of $998,300, $464,900 and $341,200 respectively.

Cash used in investing activities was $28.7 million and $203,600 in 2004 and 2003, respectively. In 2004, $31.0 million of proceeds from equity financings was invested in short-term and long-term investments. In 2004 and 2003 cash was used for the purchase of fixed assets, in the amount of $545,200 and $203,600, respectively, primarily representing additional computer equipment for our expanded operations in 2004 and tooling costs for the new manufacturer of our NC-stat monitor and docking station in 2003.

Cash provided by financing activities was $31.7 million and $3.0 million in 2004 and 2003, respectively. The cash from financing activities in 2004 was primarily generated from the issuance of common stock through our initial public offering of 3.4 million shares at $8.00 per share and issuance of preferred stock in a private placement prior to the initial public offering. The cash generated from these financing activities was partially offset by the repayment of $3.0 million in long-term debt to

Lighthouse Capital Partners in 2004. The cash from financing activities in 2003 primarily represented proceeds from the issuance of long-term debt provided by Lighthouse Capital Partners, as described below.

In May 2003, we entered into a loan and security agreement with Lighthouse Capital Partners that provided us with a secured line of credit of up to $3.0 million. This line of credit was secured by all of our tangible and intangible assets. On December 31, 2003, we had a total outstanding balance of $3.0 million under this secured line of credit as a result of several advances made between August 2003 and December 2003. This line of credit was repaid in full in 2004.

In connection with our property lease that we entered into with a term beginning January 1, 2001, we are required to maintain, for the benefit of the lessor, an irrevocable standby letter of credit stating the lessor as the beneficiary in the amount of $1,860,000 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. The lease expires in March 2009. The certificate of deposit is renewable in 30-day increments. The amount is classified as restricted cash in the balance sheet.

During 2005, we will be expending funds in connection with our efforts to expand our sales and marketing for the NC-stat System and continue our ongoing program of making enhancements and improvements to the NC-stat System, including the introduction of new biosensors. We also expect to expend funds on the design of a drug delivery system, which is in its early stages of development, for the minimally invasive treatment of neuropathies by both primary care and specialist physicians. We believe that the combination of funds available from cash and cash equivalents and funds available from our short and long-term investments will be adequate to finance our ongoing operations for at least two years, including the expenditures anticipated for 2005 described above.

As of December 31, 2004, we have federal and state net operating loss carryforwards available to offset future taxable income of $32.0 million and $31.3 million, respectively, and federal and state research and development credits of $377,000 and $237,000, respectively, available to offset future taxes. The net operating loss and research and development credit carryforwards expire at various dates beginning in 2011 for federal and 2003 for state. Ownership changes in our company, as defined in the Internal Revenue Code, may limit the amount of net operating loss and research and development credit carryforwards that can be utilized annually to offset future taxable income and taxes. 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 Obligation and Contingent Liabilities and Commitments

As of December 31, 2004, we did not have any off-balance sheet financing arrangements.

The following table summarizes our principal contractual obligations as of December 31, 2004 and the effects such obligations are expected to have on our liquidity and cash flows in future periods.

	Payments due in				
Contractual Obligations	**Total**	**2005**	**2006 and 2007**	**2008 and 2009**	**After 2009**
Operating lease obligations	$ 3,952,500	$ 930,000	$ 1,860,000	$ 1,162,500	$ —
Purchase order obligations	$ 723,900	$ 723,900	$ —	$ —	$ —
Total contractual obligations	$ 4,676,400	$ 1,653,900	$ 1,860,000	$ 1,162,500	$ —

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 2004, 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, 2004, 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, 2004. 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 probable 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.

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 item is considered a separate unit of accounting if it has value to the customer on a stand-alone basis and there is objective and reliable evidence of the fair value of the undelivered items. 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, 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.

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.

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. In the event that actual results differ from these estimates, our provision for income taxes could be materially impacted.

New Accounting Pronouncements

In January 2003, the Financial Accounting Standards Board issued FIN No. 46, Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51 (FIN No. 46). The primary objectives of FIN No. 46 are to provide guidance on the identification of entities for which control is achieved through means other than through voting rights (variable interest entities) and to determine when and which business enterprise should consolidate the variable interest entities. The new model for consolidation applies to an entity which either (1) the equity investors (if any) do not have a controlling financial interest or (2) the equity investment at risk is insufficient to finance the entity's activities without receiving additional subordinated financial support from the other parties. FIN No. 46 also requires enhanced disclosures for variable interest entities. FIN No. 46 applies immediately to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. The standard as amended by FIN 46R, applies to the first fiscal year or interim period beginning after March 15, 2004 to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. The adoption of FIN No. 46 did not have a material impact on our financial position, results of operations, or cash flows.

In November 2004, the FASB issued FASB Statement No. 151, "Inventory Costs—an Amendment of ARB No. 43, Chapter 4" ("FAS 151"). FAS 151 amends ARB 43, Chapter 4, to clarify that abnormal amounts of idle facility expense, freight, handling costs, and wasted materials (spoilage) should be recognized as current-period charges. In addition, this Statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provisions of this Statement are effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of the provisions of FAS 151 is not expected to have a material impact on our financial position or results of operations.

In December 2004, the FASB issued FASB Statement No. 123 (revised 2004), "Share-Based Payment" ("FAS 123(R)"). FAS 123(R) replaces FASB Statement No. 123, "Accounting for Stock-Based Compensation", and supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees". FAS 123(R) requires that the compensation cost relating to share-based payment transactions be recognized in financial statements. That cost will be measured based on the fair value of the equity or liability instruments issued. The provisions of this Statement are effective for the first interim or annual reporting period that begins after June 15, 2005. We are currently evaluating the method of adoption and the impact of FAS 123(R) on our financial position and results of operations. We are also evaluating the form of any stock based incentive compensation we may offer in the future.

In December 2004, the FASB issued FASB Statement No. 153, "Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29, Accounting for Nonmonetary Transactions" ("FAS 153"). FAS 153 requires that exchanges of nonmonetary assets be measured based on the fair value of the assets exchanged. Further, it expands the exception for nonmonetary exchanges of similar productive assets to nonmonetary assets that do not have commercial substance. The provisions of this Statement are effective for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. The adoption of the provisions of FAS 153 is not expected to have a material impact on our financial position or results of operations.

Important Factors That May Affect Future Operating Results

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 achieve profitability.

Since our inception in 1996, we have incurred losses every quarter. We began commercial sales of our products in May 1999 and we have yet to demonstrate that we can generate sufficient sales of our products to become profitable. The extent of our future operating losses and the timing of profitability are highly uncertain, and we may never achieve or 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 in 2004. At December 31, 2004, we had an accumulated deficit of approximately $57.5 million. It is possible that we will never generate sufficient revenues from product sales to achieve profitability.

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. 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. The Center for Medicare and Medicaid Services, or 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.

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 diabetic peripheral neuropathy, or 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 two 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 as great as 9.5 million annual patient tests. This represents a more than four-fold 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, including the industry data on which we base 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, Polyflex Circuits, Inc., a wholly owned subsidiary of Parlex Corporation, for the manufacture of the NC-stat biosensors, and a single manufacturer, Advanced Electronics, Inc., or AEI, for the manufacture of our NC-stat monitors and docking stations. We order all of our products from Polyflex on a purchase order basis. Because we do not have a supply agreement in place with Polyflex, Polyflex may cease manufacturing our products or increase the price it charges us for our products at any time. We do have a one-year, automatically renewable contract manufacturing agreement with AEI. However, under the agreement, either party may elect not to renew the agreement upon 90 days' written notice prior to the end of the current term. Accordingly, AEI could cease manufacturing NC-stat monitors and docking stations for us when the current term of the agreement expires in November 2005. We have not experienced any significant problems in the past with the quality or quantity of products delivered by either AEI or Polyflex. 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 higher- margin disposable biosensors, sales of which accounted for approximately 87.6% and 85.8% of our total revenues in 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 Food and Drug Administration, or 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, 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 68 employees as of December 31, 2004, 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 expect to increase our sales force and our total headcount significantly during the next year. 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, our revenues may decline, our future revenue growth may be limited and our expenses may increase.

We presently employ 28 regional sales managers who lead more than 50 independent regional sales agencies employing a total of more than 300 sales representatives. We are highly dependent on our regional sales managers to generate our revenues. We currently intend to increase our existing sales

force significantly using part of the net proceeds from this offering. 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 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 the Nicolet Biomedical division of Viasys Healthcare Inc., the Functional Diagnostics division of Medtronic, Inc., Oxford Instruments, Plc., and Cadwell Laboratories, 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, Medtronic and Oxford Instruments, 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.

Other than Neumed, we do not know if these companies or others are engaged in research and development efforts to develop products to perform point-of-service nerve conduction studies that would be directly competitive with the NC-stat System. 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 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;
- 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.

Our principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

Based on most recent information, our officers, directors and principal stockholders together controlled a significant portion of our outstanding common stock. If some or all of these stockholders act together, they will be able to control our management and affairs in all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock. In addition, this significant concentration of share ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages to owning stock in companies with controlling stockholders.

The sale or expected sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

Sales or the expectation of sales of a substantial number of shares of our common stock in the public market could harm the market price of our common stock. As additional shares of our common stock become available for resale in the public market, the supply of our common stock will increase, which could decrease the price. Moreover, the holders of 7,488,758 shares of our common stock, comprised of shares issued upon conversion of our preferred stock, and the holder of a warrant to purchase 100,000 shares of common stock, have rights, subject to various conditions and limitations, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Also, shares of common stock that we may issue under our existing Amended and Restated 1998 Equity Incentive Plan, our 2004 Stock Option and Incentive Plan and 2004 Employee Stock Purchase Plan may be freely sold. If any of these holders cause a large number of securities to be sold in the public market, the sales could reduce the trading price of our common stock. These sales also could impede our ability to raise future capital.

We will incur increased expenses as a result of recently enacted laws and regulations affecting public companies.

Recently enacted laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted by the Securities and Exchange Commission and by the National Association of Securities Dealers, Inc., will result in increased expenses to us. The new rules could make it more difficult or more costly for us to obtain some types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events also could make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board committees or as executive officers. We will incur increased expenses in order to comply with these new rules, and we may not be able to accurately predict the timing or amount of these expenses.

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 acquirors 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.

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 "Management's Discussion and Analysis of Financial Condition and Results of Operations-Important Factors that May Affect Future Operating Results." 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, accrued expenses and long-term investments. 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-23 of this Form 10-K with the exception of quarterly financial information which is presented below:

	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

	Year Ended December 31, 2003				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Revenues	$ 1,621,005	$ 2,089,527	$ 2,586,694	$ 2,870,331	$ 9,167,557
Gross margin	$ 1,144,359	$ 1,451,185	$ 1,827,605	$ 2,037,869	$ 6,461,018
Net loss attributable to common shareholders	$ (1,542,722)	$ (1,395,362)	$ (1,283,619)	$ (1,454,455)	$ (5,676,158)
Net loss per common share (basic and diluted)	$ (1.49)	$ (1.34)	$ (1.24)	$ (1.40)	$ (5.46)
Weighted average shares used to compute basic and diluted net loss per common share	1,037,007	1,038,181	1,038,615	1,041,421	1,038,817

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, 2004. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that they believe that our disclosure controls and procedures are reasonably 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 and procedures for 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 identified in connection with our evaluation of our disclosure controls and procedures that occurred during the fiscal quarter ended December 31, 2004 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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 2005 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 Schedules

(a) 1. *Financial Statements*

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

2. *Financial Statement Schedules*

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

3. *Exhibit Index:*

Exhibit Number	Description
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	Series E-1 Convertible Preferred Stock Purchase Agreement by and among NeuroMetrix, Inc. and the purchasers thereto, dated as of December 20, 2002, with amendments dated as of May 21, 2003 and March 12, 2004 (1)
10.8	Form of Indemnification Agreement between NeuroMetrix, Inc. and each of its directors (1)
10.9	Employment Agreement, dated June 21, 2004, by and between NeuroMetrix, Inc. and Shai N. Gozani, M.D., Ph.D. (1)
10.10	Letter Agreement, dated June 19, 2002, by and between NeuroMetrix, Inc. and Gary L. Gregory (1)
10.11	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)
10.12	NeuroMetrix, Inc. Confidentiality and Non-Compete Agreement, dated as of June 28, 2002, by and between Gary L. Gregory and NeuroMetrix, Inc. (1)
10.13	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)
10.14	Preferred Stock Purchase Warrant, dated May 21, 2003, issued to Lighthouse Capital Partners IV, L.P. (1)
†10.15	Contract Manufacturing Agreement, dated as of November 20, 2002, by and between Advanced Electronics, Inc. and NeuroMetrix, Inc. (1)
10.16	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)
10.17	Second Amendment to Amended and Restated 1998 Equity Incentive Plan (1)
10.18	NeuroMetrix, Inc. Non-Statutory Stock Option Agreement (1998 Plan) dated as of June 21, 2004 by and between Gary Gregory and NeuroMetrix, Inc. (1)
10.19	Indemnification Agreement dated June 21, 2004, by and between Shai N. Gozani, M.D., Ph.D., and NeuroMetrix, Inc. (1)
10.20	Consent, Waiver and Amendment dated as of June 18, 2004 by and among NeuroMetrix, Inc. and the parties listed on the signature pages thereto (1)
10.21	NeuroMetrix, Inc. Confidentiality & Non-Compete Agreement, dated as of May 1, 2000, by and between Michael Williams and NeuroMetrix, Inc. (1)
10.22	NeuroMetrix, Inc. Confidentiality & Non-Compete Agreement, dated as of October 13, 1998, by and between Guy Daniello and NeuroMetrix Inc. (1)
10.23	Form of Incentive Stock Option Agreement, under the NeuroMetrix, Inc. 2004 Stock Option And Incentive Plan (2)
10.24	Form of Non-Qualified Stock Option Agreement For Company Employees, under the NeuroMetrix, Inc. 2004 Stock Option And Incentive Plan (2)
10.25	Form of Non-Qualified Stock Option Agreement For Non-Employee Directors, under the NeuroMetrix, Inc. 2004 Stock Option And Incentive Plan (2)
10.26	Letter Agreement, dated February 7, 2005, by and between NeuroMetrix, Inc. and W. Bradford Smith (3)
10.27	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)
10.28	NeuroMetrix, Inc. Confidentiality & Non-Compete Agreement, dated as of February 7, 2005, by and between W. Bradford Smith and NeuroMetrix, Inc.(3)
*23.1	Consent of PricewaterhouseCoopers LLP

*31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
*31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
*32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith.

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

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

(2) Incorporated herein by reference to NeuroMetrix, Inc.'s Quarterly Report on Form 10-Q filed on November 15, 2004.

(3) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on February 11, 2005.

SIGNATURES

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

NEUROMETRIX, INC.

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

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

Date: March 22, 2005

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant on March 22, 2005 in the capacities indicated below.

Name	Title
/s/ SHAI N. GOZANI, M.D., PH.D. Shai N. Gozani, M.D., Ph. D.	Chairman, President and Chief Executive Officer (Principal Executive Officer)
/s/ W. BRADFORD SMITH W. Bradford Smith	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)
/s/ DAVID E. GOODMAN, M.D. David E. Goodman, M.D.	Director
/s/ CHARLES E. HARRIS Charles E. Harris	Director
/s/ CHARLES R. LAMANTIA Charles R. LaMantia	Director
/s/ WILLIAM LAVERACK, JR. William Laverack, Jr.	Director
/s/ W. MARK LORTZ W. Mark Lortz	Director

INDEX TO FINANCIAL STATEMENTS

NeuroMetrix, Inc.

Years ended December 31, 2004, 2003 and 2002

Report of Independent Registered Public Accounting Firm

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

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, 2004 and 2003, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing 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 includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
January 25, 2005

NeuroMetrix, Inc.

Balance Sheets

	December 31, 2004	December 31, 2003
Assets		
Current assets:		
Cash and cash equivalents	$ 1,936,241	$ 1,622,516
Short-term investments	18,574,593	—
Accounts receivable, net of allowance for doubtful accounts of $300,000 at December 31, 2004 and 2003, respectively	3,126,565	1,851,983
Inventory	1,284,261	1,078,390
Prepaid expenses and other current assets	672,970	217,165
Current portion of deferred costs	140,719	115,978
Total current assets	25,735,349	4,886,032
Restricted cash	1,897,200	1,897,200
Long-term investments	9,497,158	—
Fixed assets, net	679,359	339,224
Deferred costs	143,462	95,325
Total assets	$ 37,952,528	$ 7,217,781
Liabilities, Warrants for Redeemable Convertible Preferred Stock, Redeemable Convertible Preferred Stock and Stockholders' Equity/(Deficit)		
Current liabilities:		
Accounts payable	$ 899,291	$ 434,385
Accrued expenses	593,420	444,594
Accrued compensation	1,343,206	492,481
Current portion of long-term debt	—	515,236
Current portion of deferred revenue	399,468	245,447
Total current liabilities	3,235,385	2,132,143
Long-term debt	—	2,046,986
Deferred revenue	471,734	211,676
Other long-term liabilities	189,091	185,454
Total liabilities	3,896,210	4,576,259
Commitments and contingencies (Note 11)		
Warrants for redeemable convertible preferred stock	—	450,100
Redeemable convertible preferred stock (liquidation preference $55,657,459 at December 31, 2003)	—	47,693,742
Stockholders' equity (deficit)		
Common stock, $0.0001 par value; 50,000,000 and 30,000,000 authorized at December 31, 2004 and 2003, respectively; 12,034,650 and 1,042,990 shares issued and outstanding at December 31, 2004 and 2003, respectively	1,203	104
Additional paid-in capital	92,278,379	—
Subscriptions receivable	—	(2,143)
Deferred compensation	(745,086)	(598,933)
Accumulated deficit	(57,478,178)	(44,901,348)
Total stockholders' equity/(deficit)	34,056,318	(45,502,320)
Total liabilities, warrants for redeemable convertible preferred stock, redeemable convertible preferred stock and stockholders' equity/(deficit)	$ 37,952,528	$ 7,217,781

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

NeuroMetrix, Inc.

Statements of Operations

	Year Ended December 31,		
	2004	2003	2002
Revenues:			
Diagnostic device	$ 2,219,489	$ 1,302,306	$ 722,645
Biosensor	15,700,600	7,865,251	3,502,362
Total revenues	17,920,089	9,167,557	4,225,007
Cost of revenues	4,853,326	2,706,539	1,370,159
Gross margin	13,066,763	6,461,018	2,854,848
Operating expenses:			
Research and development(1)	3,268,363	2,396,772	2,146,060
Sales and marketing(1)	8,488,047	4,767,640	2,869,737
General and administrative(1)	4,844,378	2,850,455	2,672,661
Total operating expenses	16,600,788	10,014,867	7,688,458
Loss from operations	(3,534,025)	(3,553,849)	(4,833,610)
Interest income	214,092	23,481	80,322
Interest expense	(964,056)	(136,340)	(40,175)
Net loss	(4,283,989)	(3,666,708)	(4,793,463)
Accretion of redeemable convertible preferred stock	(1,386,301)	(2,009,450)	(1,892,747)
Deemed dividend on redeemable convertible preferred stock	(787,885)	—	(6,872,920)
Beneficial conversion feature associated with redeemable convertible preferred stock	(7,050,771)	—	—
Net loss attributable to common stockholders	$ (13,508,946)	$ (5,676,158)	$ (13,559,130)
Net loss per common share (basic and diluted)	$ (2.35)	$ (5.46)	$ (13.17)
Weighted average shares used to compute basic and diluted net loss per common share	5,747,579	1,038,817	1,029,210

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

Research and development	$ 249,131	$ 35,125	$ 7,733
Sales and marketing	356,422	36,790	5,759
General and administrative	423,042	24,535	36,754
Total non-cash stock-based compensation	$ 1,028,595	$ 96,450	$ 50,246

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						
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Subscriptions Receivable	Deferred Compensation	Accumulated Deficit	Total
Balance at December 31, 2001	16,164,765	$ 34,994,937	1,027,428	$ 103	$ —	$ (2,143)	$ (108,527)	$ (26,320,815)	$ (26,431,382)
Issuance of common stock upon exercise of stock options	—	—	9,964	1	11,784	—	—	—	11,785
Purchase of treasury stock	—	—	(1,250)	—	(10)	—	—	—	(10)
Issuance of Series E-1 redeemable preferred stock, net of issuance costs of $76,312	1,333,334	1,923,688	—	—	—	—	—	—	—
Deemed dividend on Series D and E redeemable convertible preferred stock	—	6,872,920	—	—	—	—	—	(6,872,920)	(6,872,920)
Compensation expense associated with stock options	—	—	—	—	21,445	—	—	—	21,445
Accretion of redeemable convertible preferred stock to redemption	—	1,892,747	—	—	(20,027)	—	—	(1,872,720)	(1,892,747)
Adjustment to deferred compensation	—	—	—	—	(13,192)	—	13,192	—	—
Amortization of deferred compensation	—	—	—	—	—	—	28,801	—	28,801
Net loss	—	—	—	—	—	—	—	(4,793,463)	(4,793,463)
Balance at December 31, 2002	17,498,099	45,684,292	1,036,142	104	—	—	(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)

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

	Redeemable Convertible Preferred Stock		Common Stock						
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Subscriptions Receivable	Deferred Compensation	Accumulated Deficit	Total
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
Conversion of warrant to purchase common stock	—	—	—	—	450,100	—	—	—	450,100
Deferred compensation associated with stock options	—	—	—	—	1,187,177	—	(750,566)	—	436,611
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

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

NeuroMetrix, Inc.

Statements of Cash Flows

	Year Ended December 31,		
	2004	2003	2002
Cash flows for operating activities:			
Net loss	$ (4,283,989)	$ (3,666,708)	$ (4,793,463)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	205,023	214,589	261,222
Compensation expense associated with stock options	1,028,595	96,450	50,246
Accrued payments on long-term debt	—	12,222	—
Allowance (recoveries) for doubtful accounts	—	100,000	(100,000)
Accrued interest on investments	(206,433)	—	—
Loss on disposal of fixed assets	—	—	2,773
Accretion of debt issuance discount	437,778	—	—
Changes in operating assets and liabilities:			
Accounts receivable	(1,274,582)	(1,121,584)	(166,253)
Inventory	(205,871)	(216,078)	186,470
Prepaid expenses and other current assets	(160,197)	(33,974)	(32,767)
Accounts payable	464,906	329,401	(237,352)
Accrued expenses and compensation	998,301	334,275	222,244
Other long-term liabilities	3,637	61,818	61,818
Deferred revenue and costs	341,201	16,217	(14,918)
Net cash used in operating activities	(2,651,631)	(3,873,372)	(4,559,980)
Cash flows for investing activities:			
Purchases of fixed assets	(545,158)	(203,611)	(29,922)
Purchases of investments	(30,954,418)	—	—
Maturities of investments	2,793,492	—	—
Net cash used in investing activities	(28,706,084)	(203,611)	(29,922)
Cash flows from financing activities:			
Proceeds from exercise of stock options	47,074	5,879	11,776
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	10,553,484	—	1,923,688
Proceeds from initial public offering, net of offering costs of $3,572,908	24,006,064	—	—
Issuance of common stock under employee stock purchase plan	64,818	—	—
Proceeds from long-term debt and related warrants	—	3,000,100	—
Payments on long-term debt	(3,000,000)	(7,139)	(40,420)
Net cash provided by financing activities	31,671,440	2,998,840	1,895,044
Net increase (decrease) in cash and cash equivalents	313,725	(1,078,143)	(2,694,858)
Cash and cash equivalents, beginning of year	1,622,516	2,700,659	5,395,517
Cash and cash equivalents, end of year	$ 1,936,241	$ 1,622,516	$ 2,700,659
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 497,404	$ 152,992	$ 40,175
Fair value of warrant issued in connection with note payable	$ —	$ 450,100	$ —
Accretion of redeemable convertible preferred stock	$ 1,386,301	$ 2,009,450	$ 1,892,747
Deemed dividend on redeemable convertible preferred stock	$ 787,885	$ —	$ 6,872,970
Beneficial conversion feature associated with redeemable convertible preferred stock	$ 7,050,771	$ —	$ —
Conversion of redeemable convertible preferred stock	$ 67,472,183	$ —	$ —

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

1. Nature of the Business

NeuroMetrix, Inc. (the "Company"), a Massachusetts corporation, was formed in June 1996 to utilize proprietary or licensed biomedical engineering and neurophysiology technology developed in the Harvard-M.I.T. Division of Health Sciences and Technology. In May 2001, the Company reincorporated in Delaware.

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 are associated with diabetes, low back pain and carpal tunnel syndrome, as well as other clinical disorders.

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 proceeds of $24 million. All of the shares were sold by the Company. The Company granted the underwriters a 30-day option to purchase up to an additional 450,000 shares of common stock from the Company, which the underwriters exercised in full on August 17, 2004. The total net proceeds to the Company of approximately $24.0 million, after expenses, will be used for the expansion of sales and marketing activities, research and development activities relating to potential new products, capital expenditures, repayment of outstanding debt obligations and other general corporate purposes. The Company's shares trade on The Nasdaq National Market System 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 common stock.

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 share and common share-equivalents have been restated to reflect this reverse split for all periods presented.

2. 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 three months or less to be cash equivalents. Cash equivalents are recorded at cost, plus accrued interest, which approximates fair value. The Company invests cash primarily in a money market investment which management believes is subject to minimal credit and market risk.

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 in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income.

Restricted Cash

At December 31, 2004 and 2003, the Company maintained restricted cash in the amount of $1,897,200 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 and trade receivables. 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, 2004 and 2003 and for the years ended December 31, 2004, 2003 and 2002, no single customer accounted for more than 10% of accounts receivable or revenue.

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 due to 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 which approximate their fair value at December 31, 2004 and 2003.

Revenue Recognition

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

When multiple elements are contained in a single arrangement, the Company allocates revenue between the elements based on their relative fair value, provided that each element meets the criteria for treatment as a separate unit of accounting. An element is considered a separate unit of accounting if it has value to the customer on a stand-alone basis and there is objective and reliable evidence of the fair value of the undelivered elements. 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 probable, 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 3 years. The deferred revenue and 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.

Software upgrades are delivered through automated processes over data lines and are sold separately. Revenue is recognized upon delivery since no post-delivery obligations exist.

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 Financial Accounting Standards Board Statement No. 48, *Revenue Recognition When Right of Return Exists*.

Proceeds received in advance of product shipment are recorded as deferred revenues. Shipping and handling costs are included in cost of revenues net of amounts invoiced to the customer since the amounts are immaterial for all periods presented.

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 monthly 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 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

Cost 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 liability is reviewed for reasonableness at least quarterly.

The following is a rollforward of the Company's accrued warranty liability for the years ended December 31, 2004, 2003 and 2002:

	Year Ended December 31,		
	2004	2003	2002
Balance at beginning of period	$ 22,151	$ 2,711	$ —
Accrual for warranties	187,176	117,695	78,341
Settlements made	(149,451)	(98,255)	(75,630)
Balance at end of period	$ 59,876	$ 22,151	$ 2,711

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 income. Leasehold improvements are amortized over the shorter of the 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 of Disposal of Long-Lived Assets* ("SFAS No. 144"). 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, 2004, 2003 and 2002.

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 25"), and related interpretations. The Company has not adopted the fair value method of accounting for stock-based compensation prescribed by SFAS 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 in accordance with SFAS No. 123, as amended, and Emerging Issues Task Force ("EITF") Issue No. 96-18, *Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, under which compensation expense is generally recognized over the period of service.

The Company provides the disclosure requirements of SFAS No. 148, *Accounting for Stock Based Compensation—Transition and Disclosure—an amendment of FASB Statement No. 123* ("SFAS 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 loss attributable to common stockholders and net loss per common share would approximate the pro forma amounts below:

	Year Ended December 31,		
	2004	2003	2002
Net loss attributable to common stockholders, as reported	$ (13,508,946)	$ (5,676,158)	$ (13,559,130)
Add employee stock based compensation expense included in reported net loss	1,028,595	96,450	50,246
Less stock-based compensation expense determined under fair value method	(1,503,188)	(209,329)	(81,087)
Net loss—pro forma	$ (13,983,539)	$ (5,789,037)	$ (13,589,971)
Net loss per common share (basic and diluted)			
As reported	$ (2.35)	$ (5.46)	$ (13.17)
Pro forma	$ (2.43)	$ (5.57)	$ (13.20)

Prior to the July 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:

	Year Ended December 31,		
	2004	2003	2002
Risk-free interest rate	3.5%	3.0%	3.9%
Expected dividend yield	0	0	0
Expected option term	5 years	5 years	5 years
Volatility	65.0%	0.0%	0.0%
Weighted average fair value of options granted	$ 5.25	$ 5.60	$ 0.40

The weighted average fair value of options granted prior to and subsequent to the IPO was $5.15 and $5.74, respectively

Since options vest over several years and additional option grants are expected to be made in future years, the pro forma effects of applying the fair value method may be material to reported net income or loss in future years.

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* ("SFAS No. 128"). 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).

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

	Year Ended December 31,		
	2004	2003	2002
Options	1,132,571	450,412	381,651
Warrants	100,000	100,000	—
Convertible preferred stock	—	5,647,289	5,647,289

Advertising

Advertising costs are expensed as incurred. Advertising expense was approximately $215,300, $329,200 and $230,000 in the years ended December 31, 2004, 2003 and 2002, respectively.

Other Comprehensive Income (Loss)

SFAS 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, 2004, 2003 and 2002, the Company had no components of comprehensive income or loss other than net 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, 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 January 2003, the FASB issued FIN No. 46, Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51 ("FIN No. 46"). The primary objectives of FIN No. 46 are to provide guidance on the identification of entities for which control is achieved through means other than through voting rights (variable interest entities) and to determine when and which business enterprise should consolidate the variable interest entities. The new model for consolidation applies to an entity which either (1) the equity investors (if any) do not have a controlling financial interest or (2) the equity investment at risk is insufficient to finance the entity's activities without receiving additional subordinated financial support from the other parties. FIN No. 46 also requires enhanced disclosures for variable interest entities. FIN No. 46 applies immediately to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. The standard as amended by FIN 46R, applies to the first fiscal year or interim period beginning after March 15, 2004 to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. The adoption of FIN No. 46 did not have a material impact on the Company's financial position, results of operations, or cash flows.

In November 2004, the FASB issued FASB Statement No. 151, "Inventory Costs—an Amendment of ARB No. 43, Chapter 4" ("FAS 151"). FAS 151 amends ARB 43, Chapter 4, to clarify that abnormal amounts of idle facility expense, freight, handling costs, and wasted materials (spoilage) should be recognized as current-period charges. In addition, this Statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provisions of this Statement are effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of the provisions of FAS 151 is not expected to have a material impact on our financial position or results of operations.

In December 2004, the FASB issued FASB Statement No. 123 (revised 2004), "Share-Based Payment" ("FAS 123(R)"). FAS 123(R) replaces FASB Statement No. 123, "Accounting for Stock-Based Compensation", and supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees".

FAS 123(R) requires that the compensation cost relating to share-based payment transactions be recognized in financial statements. That cost will be measured based on the fair value of the equity or liability instruments issued. The provisions of this Statement are effective for the first interim or annual reporting period that begins after June 15, 2005. We are currently evaluating the method of adoption and the impact of FAS 123(R) on our financial position and results of operations. We are also evaluating the form of any stock based incentive compensation we may offer in the future.

In December 2004, the FASB issued FASB Statement No. 153, "Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29, Accounting for Nonmonetary Transactions" ("FAS 153"). FAS 153 requires that exchanges of nonmonetary assets be measured based on the fair value of the assets exchanged. Further, it expands the exception for nonmonetary exchanges of similar productive assets to nonmonetary assets that do not have commercial substance. The provisions of this Statement are effective for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. The adoption of the provisions of FAS 153 is not expected to have a material impact on our financial position or results of operations.

3. Inventories

At December 31, 2004 and 2003, inventory consists of the following:

	December 31,	
	2004	2003
Purchased components	$ 293,263	$ 238,757
Finished goods	990,998	839,633
	$ 1,284,261	$ 1,078,390

4. Held-to-Maturity Securities

Held-to-Maturity securities as of December 31, 2004 are as follows:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
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
	$ 28,071,751	$ 43,888	$ (196,281)	$ 27,919,358

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

	December 31, 2004	
	Amortized Cost	Fair Value
Due in one year or less	$ 18,574,593	$ 18,529,593
Due after one year through five years	9,497,158	9,389,765
	$ 28,071,751	$ 27,919,358

5. Fixed Assets

Fixed assets consist of the following:

	Estimated Useful Life (Years)	December 31, 2004	December 31, 2003
Computer and laboratory equipment	3	$ 1,195,816	$ 847,027
Furniture and equipment	3	188,859	186,664
Production equipment	7	620,511	352,814
Construction in progress	—	7,546	81,069
Leasehold improvements	*	19,443	19,443
		2,032,175	1,487,017
Less—accumulated depreciation		(1,352,816)	(1,147,793)
		$ 679,359	$ 339,224

*—Lesser of life of lease or useful life

Depreciation expense was $205,023, $214,589 and $261,222 for the years ended December 31, 2004, 2003 and 2002, respectively.

6. Accrued Expenses

Accrued expenses consist of the following for the fiscal years ended December 31, 2004 and 2003:

	December 31, 2004	December 31, 2003
Licenses	$ —	$ 100,000
Professional services	164,701	79,866
Other	428,719	264,728
	$ 593,420	$ 444,594

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 $3.0 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 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 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 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, 2003 and 2002 was $1,386,301, $2,009,450 and $1,892,747, respectively.

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 convertible preferred stock and 2,333,333 shares of Series E-1 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 December 2002, the Company sold 1,333,334 shares of Series E-1 preferred stock at a price of $1.50 per share, resulting in gross proceeds of approximately $2,000,000. As a result of the anti-dilution provisions associated with the Series D and Series E preferred stock, the Company recorded a charge in the form of a deemed dividend of $6,872,920 in the year ended December 31, 2002. This charge

resulted from an adjustment to the conversion prices as a result of anti-dilution protection associated with the Series D and Series E preferred stock, described above.

In March 2004, the Company sold 7,050,771 shares of Series E-1 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 preferred stock resulted in a 1-for-4 exchange or a conversion price of $6.00 per share. The Series E-1 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 preferred stock financing and the anti-dilution provisions associated with the Series D 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 preferred stock.

9. Common Stock and Stock Option Plans

As of December 31, 2004, the Company had 50,000,000 shares of common stock authorized and 12,034,650 shares issued and outstanding. As of December 31, 2004, the Company has reserved 100,000 shares of common stock in the event that the warrant to purchase 100,000 shares of common stock is exercised. In addition, the Company has reserved 1,132,571 shares of common stock for future issuance upon exercise of common stock options. There were no treasury shares outstanding at December 31, 2004 and 2003, 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.

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. 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. As of December 31, 2004, 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.

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, 2004, 1,250,000 shares of common stock were authorized for issuance under the 1998 equity plan, of which 177,282 shares had been issued and 1,006,121 shares were subject to outstanding options at a weighted average price of $5.24 per share. The 1998 equity plan was closed to any future grants at the time of our initial public offering and therefore we will not make any additional grants under our 1998 equity 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. As of December 31, 2004, 894,928 shares of common stock were authorized for issuance under the 2004 stock plan, of which no

shares had been issued, 120,200 shares were subject to outstanding options at a weighted average price of $9.18 per share and 704,800 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 our 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.

A summary of activity under the Company's 1996, 1998 and 2004 Stock Plans for the years ended December 31, 2004, 2003 and 2002 is presented below:

	Number of Shares	Exercise Price Range	Weighted Average Exercise Price
Stock Option Awards			
Outstanding at December 31, 2001	306,586	$ 0.008 – 2.250	1.1725
Granted at fair value	143,250	2.250	2.2500
Exercised	(9,964)	0.008 – 1.350	1.1817
Forfeited	(58,221)	0.900 – 2.250	1.5020
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	2.660
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

The following table summarizes information about stock options outstanding at December 31, 2004:

Exercise Price	Number of Options Outstanding	Weighted average remaining contractual life (years)	Number of Options Exercisable
$0.20 – 0.40	37,500	3.4	37,500
$0.90 – 1.35	85,616	5.8	85,329
$1.69 – 2.25	335,368	8.0	146,770
$4.48	18,750	9.3	10,000
$8.00 – 9.00	592,300	9.5	—
$9.40 – 10.42	63,037	9.8	4,500
	1,132,571		284,099

The Company recorded deferred compensation of $738,137, $630,900 and $0, in the years ended December 31, 2004, 2003 and 2002, 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 operations over the vesting period of the related stock options. The Company recorded compensation expense for the years ended December 31, 2004, 2003 and 2002 of $1,028,595, $96,450 and $50,246, respectively. Included in the compensation expense recorded by the Company is $436,612 and $21,445 of compensation expense associated with the modification of stock options in the years ended December 31, 2004 and 2002, respectively.

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

10. Income Taxes

The Company's effective income tax rate differs from the statutory federal income tax rate as follows for the years ended December 31, 2004, 2003 and 2002.

	Year Ended December 31,		
	2004	2003	2002
Federal tax benefit rate	(34.0)%	(34.0)%	(34.0)%
State tax benefit, net of federal benefits	(3.5)	(5.5)	(6.3)
Permanent items	4.2	1.3	0.5
Federal research and development credits	(1.8)	(1.5)	(1.2)
Valuation allowance	35.1	39.7	41.0
Effective income tax rate	0.0%	0.0%	0.0%

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

	December 31,	
	2004	2003
Deferred tax asset:		
Net operating loss carryforwards	$ 12,853,450	$ 11,485,743
Research and development credit carryforwards	533,820	455,640
Accrued expenses	606,063	477,756
Other	(41,793)	30,339
Total gross deferred tax asset	13,951,540	12,449,478
Valuation allowance	(13,951,540	(12,449,478)
Net deferred tax asset	$ —	$ —

As of December 31, 2004, the Company had federal and state net operating loss carryforwards ("NOL") of approximately $32,025,000 and $31,339,000, respectively, as well as federal and state research and experimentation credits of approximately $377,000 and $237,000, respectively, which may be available to reduce future taxable income and begin to expire in 2011. 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 losses. Management has determined that it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets and, as a result, a valuation allowance of approximately $13,951,540 and $12,449,478 has been established at December 31, 2004 and 2003, respectively.

Ownership changes, as defined in the Internal Revenue Code, may have limited the amount of net operating loss carryforwards that can be utilized annually to offset future taxable income. 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 new office and laboratory space. The lease expires on March 31, 2009.

Future minimum lease payments under noncancelable operating leases as of December 31, 2004 are as follows:

2005	$ 930,000
2006	930,000
2007	930,000
2008	930,000
2009	232,500
Total minimum lease payments	$ 3,952,500

Total recorded rent expense was $871,819 for each the years ended December 31, 2004, 2003 and 2002. 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, 2004 and 2003 of $247,273 and $185,454, 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 in the amount of $1,860,000 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, 2004 and 2003, the Company has $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, 2004, 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 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, 2004 and 2003 and $25,000 for the year ended December 31, 2002 relating to these fees. At December 31, 2004, 2003 and 2002, M.I.T. owned approximately 4.6%, 9.3% and 9.3%, respectively, of the Company's common stock outstanding and 0.0%, 5.6% 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 is 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, 2004, 2003 and 2002, $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, 2004, 2003 and 2002 the Company made no contributions to the plan.

NeuroMetrix, Inc.

Schedule II—Valuation and Qualifying Accounts

For the three years ended December 31, 2004, 2003 and 2002:

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Allowance for Doubtful Accounts:				
2004	$ 300,000	$ 235,464	$ 235,464	$ 300,000
2003	200,000	200,326	100,326	300,000
2002	300,000	35,320	135,320	200,000
Deferred Tax Asset Valuation Allowance:				
2004	$ 12,449,478	1,502,062	—	13,951,540
2003	10,996,007	1,453,471	—	12,449,478
2002	9,029,508	1,966,499	—	10,996,007

QuickLinks

Exhibit 23.1

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 January 25, 2005 relating to the financial statements and financial statement schedule, which appears in this Form 10-K.

PricewaterhouseCoopers LLP

Boston, Massachusetts
March 23, 2005

QuickLinks

QuickLinks -- Click here to rapidly navigate through this document

Exhibit 31.1

CERTIFICATION

I, Shai N. Gozani, certify that:

1. I have reviewed this Annual Report on Form 10-K of NeuroMetrix, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers 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)) 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) [Paragraph omitted in accordance with SEC transition instructions contained in SEC Release 34-47986 dated June 5, 2003]

   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 officers 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 22, 2005

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

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

QuickLinks

QuickLinks -- Click here to rapidly navigate through this document

Exhibit 31.2

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 officers 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)) for the registrant and have:

   e) 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;

   f) [Paragraph omitted in accordance with SEC transition instructions contained in SEC Release 34-47986 dated June 5, 2003]

   g) 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

   h) 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 officers 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):

   c) 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

   d) 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 22, 2005

/s/ W. BRADFORD SMITH

W. Bradford Smith
Chief Financial Officer

QuickLinks

QuickLinks -- Click here to rapidly navigate through this document

Exhibit 32

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 22, 2005

/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.

QuickLinks